FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS CORPORATION; NOVARTIS PHARMACEUTICALS CORPORATION; and NOVARTIS INTERNATIONAL AG, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civ. No. 04-4473 (HAA) (ES)
NOVARTIS CORPORATION; NOVARTIS PHARMACEUTICALS CORPORATION; and NOVARTIS INTERNATIONAL AG, Plaintiffs, v. WATSON LABORATORIES, INC. and WATSON PHARMACEUTICALS, INC., Defendants.	Civ. No. 06-1130 (HAA) (ES) **OPINION and ORDER**

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Ackerman, Senior District Judge:

This suit relates to Teva's[1] marketing of generic versions of Novartis's[2] product Lotrel®, a prescription drug medication for the treatment of hypertension[3] that is covered by Novartis's U.S. Patent

[1] Teva Pharmaceuticals USA, Inc.

[2] Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG. Novartis, as referenced in this Opinion, also includes one of Novartis's predecessor companies, Ciba-Geigy Corporation.

[3] The patent is also intended to cover other ailments including: congestive heart failure, angina, myocardial infarction, artherosclerosis, diabetic nephropathy, diabetic cardiac myopathy,

No. 6,162,802 ("the '802 patent").[4] With discovery completed, the Court must now determine the meanings of various disputed claims contained in the contested patent in accordance with the instruction of *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976-79 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The Court held a hearing for this purpose on June 26, 2008, and has carefully considered all of the parties' written and oral arguments. In the Opinion that follows, the Court sets forth its construction of the patent claims in dispute.

I. INTRODUCTION

A. Factual Background and Procedural History

The '802 patent, entitled "Synergistic Combination Therapy Using Benazepril and Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor," was filed on March 10, 1992. On December 19, 2000, after more than eight years of prosecution, the United States Patent and Trademark Office ("PTO") issued the '802 patent to Ciba-Geigy Corp., a predecessor of Novartis, as assignee of inventors Joseph Papa and Marc M.J. Henis. Generally, the '802 patent claims methods for the treatment of cardiovascular disorders, including hypertension, and pharmaceutical compositions combining two different anti-hypertensive agents, amlodipine and benazepril.

On March 3, 1995, Novartis received approval from the FDA to market Lotrel in six dosage

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renal insufficiency, peripheral vascular disease, left ventricular hypertrophy, cognitive dysfunction, stroke, and headache. (*See* '802 patent, col. 5, l. 6.)

[4] Several cases involving Novartis and its '802 patent are pending before this Court: *Novartis Corp. v. Par Pharma Companies, Inc.*, Civ. No. 04-4688 (HAA); *Novartis Corp. v. Lupin, Ltd.*, Civ. No. 06-5954 (HAA); *Novartis Corp. v. Dr. Reddy's Lab., Inc.*, Civ. No. 07-3221 (HAA); *Novartis Corp. v. Mylan Lab., Inc.*, Civ. No. 07-4918 (HAA); *Novartis Corp. v. Teva*, Civ. No. 08-686 (HAA).

strengths: 2.5/10 mg (amlodipine besylate/benazepril hydrochloride), 5/10 mg, 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg. Lotrel is approved for the treatment of hypertension and has been marketed in the United States since its approval. In accordance with 21 U.S.C. § 355(b)(1), Novartis filed with the FDA the patent numbers and expiration dates for each patent covering Lotrel. The FDA publishes this information in a list of innovator drug products and their related patent information called *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." 21 U.S.C. § 355(j)(7)(A). The Orange Book listed four patents for Lotrel; however, the '802 patent represents the only remaining unexpired patent, and the only patent-at-issue in this matter.[5]

On June 8, 2004, Teva filed an Abbreviated New Drug Application ("ANDA"), No. 77-179, pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j), to market generic equivalents of four of Novartis's Lotrel drug products before the expiration of the '802 patent.[6] (Pl. Br. at 2.) Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e., in a "Paragraph IV Certification," Teva certified in its ANDA that "to the best of its knowledge" its drug formulations would not infringe the '802 patent or that the '802 patent is invalid and unenforceable.[7] As required by statute, Teva served

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[5] In addition to the '802 patent, the Orange Book listed the following U.S. Patent Numbers for Lotrel: 4,410,510 ("the '510 patent") covering benazepril hydrochloride; 4,572,909 ("the '909 patent"); and 4,879,303 ("the '303 patent"). The '909 and '303 patents, directed to the amlodipine component of Lotrel, are owned by Pfizer Inc. ("Pfizer"). Novartis owned the '510 patent, and licensed the right to use the '909 and '303 patents from Pfizer.

[6] Teva sought approval to market generic versions of the 2.5/10 mg, 5/10 mg, 5/20 mg, and 10/20 mg dosage strengths.

[7] Teva's ANDA could not be approved until the '909 and '303 patents expired because its ANDA did not challenge either of these patents via a Paragraph IV certification. The '909 patent expired on July 31, 2006. On March 22, 2007, only a few days before the '303 patent's March 25, 2007 expiration date, the Federal Circuit held that the '303 patent was invalid for obviousness and unenforceable. *Pfizer v. Apotex*, 480 F.3d 1348, 1372 (Fed. Cir. 2007), *reh'g and reh'g en banc denied*, 488 F.3d 1377, No. 2006-1216 (Fed. Cir. 2007).

Novartis on or about August 6, 2004 with a notice of its position and intent to seek approval from the FDA. 35 U.S.C. § 355(j)(5)(B)(i); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001). Novartis timely filed the instant lawsuit on September 16, 2004, pursuant to 35 U.S.C. § 217(e)(2), which gave rise to an automatic 30-month stay under the Hatch-Waxman Act,[8] during which time the FDA could not grant Teva final approval to market its proposed products. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA granted tentative approval to Teva's ANDA on July 11, 2006. On or about February 6, 2007, the statutory 30-month stay expired. *Id.*

In May 2007, the FDA granted final approval to Teva's ANDA, and subsequently District Judge Dennis M. Cavanaugh granted Novartis's proposed TRO (Doc. No. 56), temporarily restraining Teva "from making, using, selling, or offering to sell products under its [ANDA No. 77-179]." (J. Cavanaugh's March 19, 2007 Order, at *2.) On June 11, 2007, this Court vacated the existing temporary restraining orders, and denied Novartis's motion for a preliminary injunction.

The Court conducted a *Markman* hearing on June 26, 2008, during which each side was granted the opportunity to present testimony by one expert. Novartis's expert testified regarding the meaning of "physically separated." After cross-examining Novartis's expert, Teva declined to call its expert to the stand.

II. DISCUSSION

A. Claims of the '802 Patent

In this case, Novartis accuses Teva of infringing claims 1, 2 and 19 of the '802 patent under 35

[8] Commonly referred to as the "Hatch-Waxman Act," this legislation is formally known as The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at scattered sections of 21, 35, and 42 U.S.C.).

U.S.C. § 271(a).[9] However, all claims of the '802 patent are implicated as they are all either directly or indirectly dependent on claims 1 and 19, the patent's only independent claims. Novartis asserts that Teva infringes the '802 patent directly and indirectly.

By way of background, claims 1-17 of the '802 patent are directed to a method of treatment of various conditions. This method of treatment utilizes the administration of a combination of benazepril, an angiotensin converting enzyme inhibitor ("ACEI" or "ACE inhibitor"), and amlodipine, a calcium channel blocker ("CCB"). Claims 2-16 are all dependent on claim 1, which reads as follows:

> 1. A method of treating a condition selected from the group consisting of hypertension, congestive heart failure, angina, myocardial infarction, artherosclerosis, diabetic nephropathy, diabetic cardiac myopathy, renal insufficiency, peripheral vascular disease, left ventricular hypertrophy, cognitive dysfunction, stroke, and headache, in a human in need thereof, consisting of administering a daily dose of
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> (a) benazepril, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 2 mg to 80 mg of benazepril hydrochloride; and
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> (b) amlodipine, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 1 mg to 20 mg of amlodipine free base,
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> wherein the ratio of benazepril to amlodipine corresponds to a weight ratio of from 1:1 to 8:1 of benazepril hydrochloride to amlodipine free base.

('802 patent, col.5, ll. 6-21.) Dependent claims 2, 3, 17, and 18 are also of particular relevance to the instant dispute. *See Pods, Inc. v. Porta Stor, Inc. et al.*, 484 F.3d 1359, 1366 (Fed. Cir. 2007) (noting that a court is "not limited to considering just the language of" a particular claim in dispute "because '[o]ther claims of the patent in question, both asserted and unasserted, [are] valuable sources of

[9] Section 271(a) provides "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."

enlightenment as to the meaning of a claim term'") (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005)). These method claims provide:

> 2. The method of claim 1 wherein the benazepril and the amlodipine are administered in a single dosage form, such that the benazepril and amlodipine are **physically separated** from each other.
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> 3. The method of claim 2 wherein the single dosage form comprises a capsule comprising within it (a) a coated compressed tablet of benazepril and (b) amlodipine powder.
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> . . . .
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> 17. The method of claim 1 wherein the benazepril is administered in a first formulation which is free of the amlodipine and the amlodipine is administered in a second formulation which is free of the benazepril.
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> 18. The method of claim 17 wherein said first formulation and said second formulation are administered within about one hour of each other.

('802 patent, col. 5, ll. 22-28; col. 6, ll. 1-7 (emphasis added).)[10]

Claims 19-33 of the '802 patent are directed to a pharmaceutical composition consisting essentially of a combination of benazepril and amlodipine. Claims 20-33 are all dependent on claim 19, which reads as follows:

> 19. A pharmaceutical composition consisting essentially of a daily dose of
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> (a) benazepril, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 2 mg to 80 mg of benazepril hydrochloride; and

[10] Claims 4-16 of the '802 patent, not reproduced herein, provide additional limitations to the method of treatment claims cited above. For example, these dependent claims further limit the claimed method of treatment to specific "amounts" or daily "dosage ranges," (claims 5, 14-16), and to specific "ratios" or "weight ratios" of the two formulations, benazepril and amlodipine (claims 6-7, 11-13). Other claims limit the method of treatment to a benazepril *hydrochloride* formulation or an amlodipine *besylate* formulation (claims 4, 8-10).

> (b) amlodipine, in free or pharmaceutically acceptable salt form, in an amount corresponding to from 1 mg to 20 mg to amlodipine free base,
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> wherein the ratio of benazepril to amlodipine corresponds to a weight ratio of from 1:1 to 8:1 of benazepril hydrochloride to amlodipine free base, such that the benazepril and the amlodipine are **physically separated** from one another.

('802 patent, col. 6, ll. 8-19 (emphasis added).)[11]

Novartis argues that the administration of Teva's products to patients with hypertension would infringe claim 1 of the '802 patent. It is undisputed, Novartis asserts, that Teva seeks to market and sell its products for the approved indication of treating hypertension to a human being in need thereof and in dosages meeting the required dose and ratio limitations for benazepril and amlodipine set forth in claim 1. The parties do, however, dispute three primary issues requiring construction by this Court: (1) the meaning of the claim limitation "physically separated"; (2) whether the limitation "physically separated" applies to the "daily dose" limitation in Claim 1; and (3) the meaning of the limitation "daily dose."

B. The *Markman* Hearing

There are two steps in a patent infringement analysis. First, the court must determine the proper construction, or meaning, of the disputed claim or claims.[12] Second, findings must be made as to

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[11] Claims 20-33 of the '802 patent, not reproduced herein, provide additional limitations to the composition claim cited above. For example, these dependent claims further limit the claimed pharmaceutical composition to specific "amounts," (claims 26-28), and to specific "ratios" or "weight ratios," between the two formulations, benazepril and amlodipine, (claims 23-25). Claim 29 limits the composition to a capsule form "comprising within it (a) a coated compressed tablet of benazepril, and (b) amlodipine powder." The remaining claims limit the pharmaceutical compositions to a benazepril *hydrochloride* formulation or an amlodipine *besylate* formulation (claims 20-22, 30-33).

[12] The Federal Circuit has recently suggested that a district court cannot decline to construe a limitation that has an ordinary *meaning* where that ordinary meaning does not

whether the accused product or method infringes the asserted claim as properly construed. *See Markman*, 517 U.S. at 377-90. Under *Markman*, claim construction is a matter of law to be decided only by the court, whereas the issue of infringement is a question left to the factfinder. *Id.*

A *Markman* hearing may be held before, during, or after discovery, and even, in theory, during the infringement trial or on post-trial motions. *See Elf Atochem N. Am., Inc. v. Libbey-Owens-Ford Co.*, 894 F. Supp. 844, 850 (D. Del. 1995). Although the Federal Circuit has not mandated a time for conducting *Markman* hearings, courts generally hold them before the infringement trial and after the parties have conducted discovery relating to their respective contentions as to claim construction. Within this Circuit, for instance, it is common practice for courts to conduct *Markman* hearings after discovery is completed. *See, e.g.*, *Conopco, Inc. v. Warner-Lambert Co. (In re Conopco, Inc.)*, No. Civ. A. 99-101, 2000 WL 342872, at *4 (D.N.J. Jan. 26, 2000) ("[C]ourts have held that *Markman* hearings to determine proper claim construction are inappropriate prior to completion of discovery."); *ADC Telecomm., Inc. v. Siecor Corp.*, 954 F. Supp. 820, 821, 826-31 (D. Del. 1997); *S.S. White Burs, Inc. v. Neo-Flo, Inc.*, No. Civ. A. 02-3656, 2003 WL 21250553, at *3 (E.D. Pa. May 2, 2003).

A fundamental principle of claim construction is that patent claims must have the same meaning to all persons at all times, and that the meanings of the claims are determined and fixed at the time the Patent and Trademark Office ("PTO") issued the patent. *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338 (Fed. Cir. 2005) (en banc) ("Claim interpretation requires the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of invention."). The

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resolve the parties' "fundamental dispute regarding the *scope* of a claim term." *O2 Micro Int'l, Ltd. v. Beyond Innovation Tech., Co., Ltd.* 521 F.3d 1351, 1361-63 (Fed Cir. 2008). While this Court is inclined to simply say that "physically separated" means physically separated because that term has an ordinary meaning, the Court will, in an abundance of caution, endeavor to put flesh on the bones of this seemingly straightforward term.

purpose of a *Markman* hearing is for the court and the parties to settle conclusively on the interpretation of disputed claims. *See Elf Atochem*, 894 F. Supp. at 850, 857-58. Indeed, the need for uniformity of claim construction and concerns about fairness to competitors inform the policy of reserving the claim construction function to the trial judge. *See Markman*, 52 F.3d at 987 ("The more appropriate analogy for interpreting patent claims is the statutory interpretation analogy. Statutory interpretation is a matter of law strictly for the court. There can be only one correct interpretation of a statute that applies to all persons.").

In some instances, claim construction may be dispositive of the entire case because the likelihood of success for one side is greater on the issue of infringement based on the court's construction. *See Nystrom v. Trex Co.*, 424 F.3d 1136, 1140-41 (Fed. Cir. 2005) ("Based on the district court's claim construction ruling, Nystrom conceded that he could not prove his infringement case against TREX."). In those cases, the court's and the litigants' resources may be saved by consenting to judgment. Even if the claim construction is not dispositive of the case, it will lay the groundwork for the ensuing infringement trial.

C. General Principles of Claim Construction

In interpreting a disputed claim, the court looks primarily to the intrinsic evidence in the record, "i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing *Markman*, 52 F.3d at 979). Intrinsic evidence is the "most significant source of the legally operative meaning of disputed claim language." *Id.* First, the court must look to the words of the claim itself to define the proper scope of the claimed invention. When interpreting the words of the claim, "a court must presume that the

terms in the claim mean what they say," *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999), and the court must give those words their ordinary and customary meaning, as viewed by a person of ordinary skill in the art in question at the time of the invention, *Phillips*, 415 F.3d at 1312-13; *id.* at 1313 ("It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed."). However, the court will not accord a claim term its ordinary meaning in two situations. "The first arises if the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term. The second is 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." *Johnson Worldwide*, 175 F.3d at 990 (internal citations omitted); *see also Phillips*, 415 F.3d at 1316. In either situation, the court must adopt the proffered definition of a term. *Id.*

Although an invention is defined by a patent's claims, they "do not stand alone." *Phillips*, 415 F.3d at 1315. Instead, claims "are part of 'a fully integrated written instrument,'" *id.* at 1315 (citing *Markman*, 52 F.3d at 978), consisting principally of a written description of the invention, 35 U.S.C. § 112 para. 1, often referred to as the specification,[13] and concluding with the claims, *id.* para. 2. "For that reason, claims 'must be read in view of the specification, of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313; *see also*

[13] As defined by 35 U.S.C. § 112, the specification of a patent is technically the written description of the disclosed invention plus the claims. 35 U.S.C. § 112 para. 2. However, as used widely by courts and practitioners, the term "specification" herein refers only to the written description of the invention, excluding the claims.

Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.") (citation omitted). Thus, the second step in claim construction is for the court "to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics*, 90 F.3d at 1582.

Next to the claim language itself, the specification is the most relevant evidence to any construction analysis. "Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *Id*. In addition to defining terms, the specification "teaches about the problems solved by the claimed invention, the way the claimed invention solves those problems, and the prior art that relates to the invention. These teachings provide valuable context for the meaning of the claim language." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1554 (Fed. Cir. 1997), *abrogated on other grounds, Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Pursuant to 35 U.S.C. § 112, paragraph 1, a patent's specification must describe the claimed invention in "full, clear, concise, and exact terms." This written description requirement, the Federal Circuit has recognized, maintains a "close kinship" with the meaning of a patent's claims. *Phillips*, 415 F.3d at 1316. "In light of the statutory directive that the inventor provide a 'full' and 'exact' description of the claimed invention, the specification necessarily informs the proper construction of the claims." *Id.*; 5A-18 Donald S. Chisum, Chisum on Patents § 18.03(2)(c) (2006).

The third step in claim construction entails consideration of a patent's prosecution history. The prosecution history of a patent, also known as the "file wrapper," "can often inform the meaning of the

claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be."[14] *Phillips*, 415 F.3d at 1317. When construing claims, one of the purposes of consulting the prosecution history is to "exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1580 (Fed. Cir. 1988) (citation omitted). Importantly, "where the patentee has *unequivocally disavowed* a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g., Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (emphasis added); *see also id.* ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution."). For example, during the application process, a patent examiner may require the applicant to limit the scope of his or her proposed claims so as not to include prior art within their ambit. An applicant may also limit the scope of his or her proposed claims in the process of distinguishing his or her invention over the prior art in order to obtain a patent. When an applicant surrenders or disclaims subject matter in this manner, the disclaimer becomes part of the prosecution history. If the application ultimately issues as a patent, the patent holder is bound by his or her prior disclaimers. *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed. Cir. 1998) ("[E]xplicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim.").

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[14] A patent's prosecution history "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. This record also includes "any express representations made by the applicant regarding the scope of the claims." *Vitronics*, 90 F.3d at 1582.

Thus, examination of a patent's prosecution history and the application of prosecution disclaimer is a helpful tool during claim construction as it "ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers." *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005).

The Federal Circuit, however, has warned that a court's reliance on prosecution history must be tempered with the recognition that a "prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." *Phillips*, 415 F.3d at 1317. As such, it is important to acknowledge that a prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* Accordingly, prosecution disclaimer is not appropriate in instances "where the alleged disavowal of claim scope is ambiguous," or where remarks made by an inventor to overcome a rejection may be viewed "as amenable to multiple reasonable interpretations." *Omega*, 334 F.3d at 1324 (citing *N. Telecom Ltd. v. Samsung Elec. Co.*, 215 F.3d 1281, 1293-95 (Fed. Cir. 2000)). Thus, "for prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Id.* at 1325-26; *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) (reiterating that "arguments made to distinguish prior art references" will be considered disavowals "only if they constitute clear and unmistakable surrenders of subject matter").

It is important to note, however, that there is a distinction between construing the claims in light of their prosecution history and applying the doctrine of prosecution history estoppel.[15] Courts consult

[15] The doctrine of prosecution history estoppel "precludes a patent owner in an infringement suit from obtaining a construction of a claim that would in effect resurrect subject matter surrendered during the course of proceedings in the Patent and Trademark Office." 5A-18 Chisum, *supra*, § 18.05; *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 564-65 (Fed. Cir. 2000) (en banc) ("The logic of prosecution history estoppel is that

the prosecution history of a patent during claim construction, while they *apply* the doctrine of prosecution history estoppel only during trial as a measure to prevent a patentee from improperly benefitting from the doctrine of equivalents.[16] *Altech Controls Corp. v. E.I.L. Instruments, Inc.*, 71 F. Supp. 2d 677, 680 (S.D. Tex. 1999) ("Prosecution history estoppel imposes a legal limitation on the application of the doctrine of equivalents in excluding from the range of equivalents any subject matter surrendered during the prosecution of the application for the patent."). The Federal Circuit has cautioned district courts not to confuse "following the statements in the prosecution history in defining a claim term, [with] the doctrine of prosecution history estoppel, which limits expansion of the protection under the doctrine of equivalents when a claim has been distinguished over relevant prior art." *Spectrum*, 164 F.3d at 1378 n. 2.

Lastly, although "[i]n most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term," a court may rely on extrinsic evidence, such as expert and inventor testimony, dictionaries, and learned treatises, if an analysis of the intrinsic evidence does not give clarity

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the patentee, during prosecution, has created a record that fairly notifies the public that the patentee has surrendered the right to claim particular matter as within the reach of the patent."), *vacated & remanded on other grounds*, 535 U.S. 722 (2002), *on remand*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc), *cert. denied*, 541 U.S. 988, 124 (2004); *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999).

[16] The doctrine of equivalents "allows a patent owner to hold as an infringement a product or process that does not [fall within] the literal terms of a patent's claim but performs substantially the same function in substantially the same way to obtain the same result as the claimed subject matter." 5A-18 Chisum, supra, § 18.04 (footnote omitted). The doctrine is a response to the difficulties in capturing an invention with words. For a court only to conduct literal infringement analysis and confine an invention strictly to its written application may, in some instances, be unfair to the inventor. The Supreme Court observed in *Festo* that "the nature of language makes it impossible to capture the essence of a thing in a patent application. . . . [It] may not capture every nuance of the invention or describe with complete precision the range of its novelty." *Festo*, 535 U.S. at 731.

to a disputed claim term. *Vitronics*, 90 F.3d at 1583. The sequence in which the various sources are consulted is not important; rather, the appropriate weight must be given to those sources "in light of the statutes and policies that inform patent law." *Phillips*, 415 F.3d at 1324. Nevertheless, a court should not rely on extrinsic evidence when the public record unambiguously defines the scope of the claimed invention. "The claims, specification, and file history, rather than extrinsic evidence, constitute the public record . . . on which the public is entitled to rely." *Vitronics*, 90 F.3d at 1583. Notwithstanding the disfavored treatment of extrinsic evidence, *Vitronics* instructs that judges may consult technical treatises and dictionaries to gain a better understanding of the underlying technology. *Id*. at 1584 n.6. Judges may even adopt the dictionary definition of terms as long as the definition does not contradict the intrinsic evidence associated with related patent documents. *Id.*

D. Claim Terms

Again, the Court will address three terms needing construction either in meaning or scope: (1) the meaning of "physically separated"; (2) whether "physically separated" applies to Claim 1's "daily dose" limitation; and (3) the meaning of "daily dose."

1. "Physically separated" means that the two ingredients are not in physical contact with each other.

The parties' proposed construction of the limitation "physically separated" can be categorized as a "functional" versus "structural" dispute. Novartis believes the claim language provides a functional solution so it proposes a functional construction: "[physically separated means] a single dosage form wherein contact between benazepril and amlodipine is not necessarily completely eliminated but minimized sufficiently to overcome the incompatibility between the two agents." (Novartis Br. at 6.)

This is a functional construction in the sense that it hinges infringement on whether the accused product (Teva's generic drug) *functions* so as to treat hypertension.[17] In other words, if the contact between the two ingredients is noticeable, but sufficiently minimized such that there is no adverse reaction between them, then the drug would *function* the way it is intended, and therefore, according to Novartis, the product would be infringing the '802 patent.

The logical application of Novartis's construction would effectively mandate that any version of the drug in which the two ingredients are in such contact as to be *ineffective* in a combined treatment would be a version that does *not* infringe the '802 patent. But any version in which the two ingredients are in some contact, but still *effective*, would be a version that *does* infringe the '802 patent. Such a functional construction would inevitably result in Novartis claiming the entire universe of useful applications of the drug, and disclaiming only those combinations that are effectively worthless. In other words, to avoid a finding of infringement, Teva–or any other generic manufacturer–would have to prove that its version of the drug does not work to treat hypertension effectively because the two ingredients are in sufficiently incompatible contact as to be ineffective for their purpose. In that regard, Novartis's construction forces Teva to navigate between the proverbial Scylla and Charybdis. In short, Novartis's functional supposition asks this Court to construe "physically separated" to mean that a product infringes the '802 patent if it works.

By contrast, Teva proposes a structural construction: "[physically separated means] kept apart by a barrier." This is a structural construction in the sense that it hinges infringement on whether the accused product contains a *structure* that keeps the two ingredients from interacting with each other. In

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[17] "In other words, 'physical separat[ion]' is discussed in the specification as a *functional* solution to the problem of incompatibility between benazepril and amlodipine." (Novartis Br. at 7 (emphasis added).)

other words, if there is no physical object–e.g., a barrier–separating the two ingredients, then, according to Teva, the product would not be infringing the '802 patent.

The Court begins with the claim language, reiterating that "a court must presume that the terms in the claim mean what they say." *Johnson Worldwide*, 175 F.3d at 989. Again, Claim 2 covers "[t]he method of claim 1 wherein the benazepril and the amlodipine are administered in a single dosage form, such that the benazepril and amlodipine are *physically separated* from each other." (emphasis added.) In the absence of an express definition of the term "physically separated" in the claim language, the Court looks to the term's ordinary and customary meaning. *See Johnson Worldwide*, 175 F.3d at 990 (holding that court will not accord a claim term its ordinary meaning "if the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term.). As Teva's counsel suggested at the hearing, "[i]t doesn't really matter whether [it] is egg yolks, fighting grandchildren, or pharmaceuticals . . . physically separated is a well understood term." (Tr. 17:22-23.) Yet, noticeably absent from *Novartis's* written and oral submissions to this Court is an analysis of the words "physical" and "separate," either in their ordinary lay meaning (as the above example of "fighting grandchildren" clearly refers), or in their ordinary meaning to a person of skill in the art. By contrast, Teva submits dictionary definitions of those two terms as support for its argument that "physically separated" means "kept apart by a barrier." Novartis does not dispute these dictionary definitions, nor does it contend that some other, perhaps more technical, dictionary definition should apply in this context.

Merriam-Webster's Dictionary defines "physical" as "having material existence, and defines "separate" as "to set or keep apart" or "to isolate from a mixture" or "to divide into constituent parts." With these definitions, one could reformulate Claim 2 in the following language: "[t]he method of claim

1 wherein the benazepril and the amlodipine are administered in a single dosage form, such that the benazepril and amlodipine are *kept apart* from each other *by something that has a material existence*." Alternatively, the language could read, in relevant part, as follows: ". . . the benazepril and amlodipine are *divided into constituent parts by something that has a material existence*." These reformulations of the claim language track remarkably close to Teva's proposed construction of "kept apart by a barrier."

Despite these seemingly straightforward definitions of the relevant terms, the Court is mindful that claims in a patent "are part of a fully integrated written instrument," *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted), that includes the specification. Indeed, as previously observed, the second step in claim construction is for the court "to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics*, 90 F.3d at 1582. There is no suggestion by either party that the specification expressly defines the term "physically separated." But Novartis does suggest that the specification defines the term by implication.

Novartis finds the implied definition in the first example of how to accomplish physical separation: the "bi-layered tablet." The relevant specification language is worth quoting in full:

> Benazepril and amlodipine are physically incompatible substances. Hence, if incorporated into a single dosage form they must be kept physically separated. This may be accomplished in any of the myriad ways known in the art, such as bi-layered tablets, coated pellets of one agent incorporated into a tablet of the other, separately coated pellets of one agent in capsule together with powder of the other agent, each agent microencapsulated separately and then blended together for use in a tablet or capsule, use of a dual or multiple compartment transdermal device, etc. Due to the incompatibility, combination products of the two agents in an injectable solution are not really acceptable. For convenience purposes, a coated compressed tablet of benazepril together with amlodipine powder in a capsule has been found to be the most desirable oral form.

('802 patent, col. 3, ll. 48-63.) Again, Novartis focuses on the first of the "myriad ways" in which physical separation may be accomplished, the bi-layered tablet, to support the theory that the requirement that the ingredients be "physically separated" does not go so far as to require a "barrier" as proposed by Teva. Indeed, Novartis asserts that the requirement of "physically separated" is a *functional* solution to the problem of incompatibility between the two agents, and that the bi-layered tablet is an example of a functional solution that does not include a barrier.

Novartis's argument thus proceeds from an understanding of "bi-layered tablet" in its ordinary sense. At the hearing, Novartis's counsel stressed that "[u]nless the patent inventors specifically define their phrase differently, . . . then the Court must, under the *Markman* standards, apply the common meaning of the term."[18] (Tr. 28:12-18.) Novartis's counsel further emphasized that "bi means two," (Tr. 28:12), and encouraged the Court to "reach[] for the Webster's dictionary to look up bi. It means two," (Tr. 28:5-6.).[19] But Teva does not quarrel with the unremarkable fact that "bi" means "two." Instead,

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[18] By this argument, Novartis implicitly contends that the ordinary meaning of "physically separated" does not apply because the ordinary meaning of "bi" in the specification teaches otherwise. While the Court observes that it is conceivable for a specification term's ordinary meaning to negate the ordinary meaning of a claim term, Novartis's attempt to do so here puts it at the short end of a fulcrum ill-designed to accomplish the required heavy analytical lifting.

[19] At the hearing, Novartis's counsel seized on a previous statement by Teva's counsel: "Now, [Teva's] counsel's response to why bi-layer in their view does not mean that there can be any physical touching is what he called, I wrote the word down, he said it is a stretch to define 'bi' as two." (Tr. 28:1-4.) But Novartis's counsel apparently neglected to write down the remainder of the statement, because Teva's counsel actually stated that "the point here is [that] there is no reason to stretch for a meaning of bi-layer that is inconsistent with everything else in the specification . . . when there are plenty of examples of the use of bi-layer that are utterly consistent with the claim language and the specification." (Tr. 23:18-23.) As will be discussed, Teva's counsel was simply arguing for a contextual analysis of bi-layered tablet, an analytical approach vigorously endorsed by Novartis's own expert. (*See* Tr. 62:9-10; 62:25 to 63:2.)

Teva asserts that "bi-layered tablet" is a term of art that is used differently in the art. In other words, Teva argues that "bi-layered tablet" has more than one ordinary meaning to a person of skill in the art.

The Court will now endeavor to analyze the various sources presented by both parties to ascertain the meaning of "bi-layered tablet." In isolation, if Novartis is correct, then it has a strong argument that "physically separated" does not require a barrier as Teva proposes. Again, Novartis begins with the dictionary that defines "bi" as "two." Thus, according to Novartis, a bi-layered tablet has two layers, with no identifiable physical barrier between the two layers. Novartis supports this assertion with testimony by Dr. Stephen Byrn, who was asked about a graphic of a "tri-layered tablet" that depicted one substance on one side of a tablet, and another substance on the other side of the tablet, with a clearly identifiable barrier, or layer, between the two active ingredients. Referring to this graphic, counsel for Novartis asked Dr. Byrn: "Would a person of ordinary skill consider the tablet on the right to be a bi-layered tablet?," to which he responded, "No, they would not." (Tr. 43:4-6.) Dr. Byrn's testimony in this regard supports Novartis's argument that any tablet that contains a physical barrier would be called a tri-layered tablet, not a bi-layered tablet, and therefore the specification's use of bi-layered tablet supports the interpretation of "physically separated" as one that does not require complete and total separation. Indeed, Dr. Byrn said as much in response to a question from the Court, which asked "Do you believe that physically, the term physically separated, means that two ingredients must be kept apart by some physical means?" Dr. Byrn replied: "No. . . . I just say that like that bi-layered tablet I showed, there is some, it is a bi-layered tablet but there is some contact so it is not total. I don't think the patent is saying total separation." (Tr. 86:25 to 87:8.) Dr. Byrn's statement that the patent is not saying "total separation" suggests a belief that if the patent did say "totally separated," then Teva's proposed construction of "kept apart by a barrier" would somehow be correct, despite the existence of

the bi-layered tablet in the specification's list of examples. In other words, Dr. Byrn's response to the Court raises questions about how he could believe that "physically separated" means "minimized touching" based on the specification listing "bi-layered tablet" as an example, but at the same time Dr. Byrn believes that the term "totally separated" would mean "no touching whatsoever," regardless of the "bi-layered tablet" example in the specification. Such testimony calls into question Dr. Byrns's credibility in this matter.

In any event, through Dr. Byrn's testimony, Novartis presented additional evidence, in the form of a treatise, to support its interpretation that "bi-layered tablet," as used in the specification, does not require complete separation of the active ingredients. Quoting from "The Theory and Practice of Industrial Pharmacy," Dr. Byrn read that "layered tablets . . . are usually prepared for one of two reasons: to separate physically or chemically incompatible ingredients, or to produce repeat-action or prolonged-action products. In some cases, a two-layer tablet may provide adequate surface separation of reactive ingredients; if complete physical separation is required for stability purposes, the three-layer tablet may be employed." (Tr. 50:22 to 51:4.) At first blush, this quotation provides strong support for Novartis's theory because it suggests that bi-layered tablets are utilized for the purpose of separating physically incompatible ingredients, even though it allows contact between the incompatible ingredients. But the treatise is simply giving a broad explanation of the uses of layered tablets, not necessarily bi-layered tablets exclusively, and Teva does not dispute that layered tablets, or even bi-layered tablets, can reduce the effects of incompatibility. Instead, Teva contends that "bi-layered tablet," as used in the specification, must necessarily refer to a type of bi-layered tablet that has a barrier between the two layers, which is what Novartis calls a tri-layered tablet.

Furthermore, the strength of Novartis's argument assumes in the first instance that "physically

separated" is a functional limitation, not a structural one. Indeed, if the patent declared that the two ingredients "should be as separated as possible," then Novartis's functional argument would be much stronger, and the above treatise's explanation that a two-layer tablet may provide adequate separation would fit perfectly with that argument. But that is not what the patent says. On the contrary, the specification language is mandatory and unequivocal: "Benazepril and amlodipine are physically incompatible substances. Hence, if incorporated into a single dosage form they *must* be kept physically separated." ('802 patent, col. 3, ll. 48-50 (emphasis added).) As Teva's counsel persuasively argued at the hearing, "[the words in the specification] don't say that it would be a good idea if. They don't say that, well, separate them, but only separate them a little, and then we will do a stability test and we will see whether that is enough, which is what Novartis is proposing here. They give an unambiguous instruction to the person of ordinary skill in the art, which instruction is they must be, it is mandatory language, kept physically separated." (Tr. 19:12-19.) Novartis does not have a strong argument in rebuttal, but instead maintains that the *purpose* of the *inclusion* of the "physically separated" language necessarily drives the *definition* of the included language. In essence, Novartis's argument for a functional construction lacks the requisite grammatical, analytical, and legal mooring necessary to prevent it from foundering on the shores of cold hard logic. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1458 (Fed. Cir. 1998) (en banc) (observing patentee's specification language, which "emphasized the *separateness* of [a prior art's design], both *physically and functionally*, as compared to the claimed invention") (emphases added); *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1481 (Fed. Cir. 1997) (utilizing "physically separate" in its ordinary sense to describe how two pharmaceutical ingredients given in separate tablets did not come within patent claim limitation of "combinatory inmixture," which was construed to mean "the two ingredients in a single form such as a tablet or

elixir.").

Regardless, Novartis also points to other patents to support its contention that "bi-layered tablet" means only tablets that are without a barrier between the two layers. Specifically, Novartis points to the McNeil patent, 5,817,340, which utilizes the phrase "bilayer tablet," but makes no reference to any barrier between the two layers. By contrast, Novartis highlights the McNally patent, 5,593,696, which states: "As an alternate embodiment, the dosage form of the invention may comprise a bilayer tablet having one layer of famotidine and one layer of sucralfate, the layers being separated by a protective layer composed of one of the above-described materials." (Novartis Ex. 13, '696 patent, col. 3, l. 66 to col. 4, l. 3.) Novartis's expert, Dr. Byrn, explained that this description of bi-layered is consistent with what a person in the art would understand because it refers to a bi-layered tablet, but then qualifies that description to include a protective layer or barrier separating the two active ingredient layers. (Tr. 56:23 to 57:5.) In other words, Novartis views this patent's use of bi-layered as supporting its own argument that "bi-layered tablet" can only mean two layers in direct contact with each other, unless the specification somehow qualifies that ordinary definition.

But Teva points to the same language of the McNally patent, and argues that this usage of the phrase "bilayer tablet" lends support to *Teva's* argument that "bilayer" can have multiple ordinary meanings to a person of skill in the art. Indeed, on cross-examination, Teva's counsel elicited testimony from Dr. Byrn, in which he described the tablet in the McNally patent as "a modified bi-layered tablet," notwithstanding the fact that the patent itself calls the tablet a "bilayer tablet." (Tr. 61:24 to 64:10.) Dr. Byrn attempted to distinguish between what he called a "pure bi-layered tablet" or "straight bi-layered tablet" and the kind of bi-layered tablet used in the McNally patent. (*See id.*) But Dr. Byrn was forced to acknowledge that his term "modified bi-layered tablet" appeared nowhere in the patent.

In addition to the McNally patent, Novartis directs the Court to a patent application that declares that, "[a]s used herein, 'bilayer tablet' is a tablet which is made up of two or more distinct layers or discrete zones of granulation compressed together with the individual layers lying one on top of another. . . . The operation may be repeated to produce bilayer tablets of more than two layers." (Novartis Ex. 15, U.S. Patent Application 2005/0220877.) Dr. Byrn's testimony again supports Novartis's argument by explaining that a person of ordinary skill in the art would not have read this application to allow more than two layers in the bilayer tablet, but for the express statement contained in the application declaring that a bilayer tablet "is made up of two or more distinct layers or discrete zones of granulation." (*See* Tr. 57:23 to 58:3.)

What Novartis delicately avoids highlighting, but Teva points out, is the fact that the patent application referred to above is Novartis's own patent application. The significance of Novartis's connection to the application centers on Teva's contention that "bi-layered tablet" has more than one meaning in the art, as evidenced by Novartis's own choice of language in the patent application. That is, Dr. Byrn testified that Novartis was simply "redefining the term bi-layered tablet," (Tr. 65:1-2), but such "redefining" does not comport with Novartis's assertion here that a bi-layered tablet with a barrier would be a tri-layered tablet. At the very least, the patent application further muddies the water to the degree that the Court cannot say with any confidence that bi-layered tablet has one, and only one, ordinary meaning in the art, as Novartis postulates.

While it is by no means an easy question, the Court concludes that Teva has the better argument inasmuch as there appear to be multiple ordinary meanings of the term "bi-layered tablet" in the art. For example, the McNally patent lends compelling support to Novartis's argument, but that patent also cuts against Novartis. That is, McNally's description of the compression of the two ingredients with a barrier

in between appears to be what Novartis identifies as a "tri-layered tablet," yet the patent calls it a "bilayer tablet." If it is true, as Novartis posits, that a person of skill in the art would never read "bi-layered tablet" to include a barrier, unless specifically denominated as such in the patent, then why would the McNally patent not simply refer to that formulation as a tri-layered tablet? The same holds true for Novartis's patent application 2005/0220877: If a person of ordinary skill in the art would only call a tablet with two ingredient layers and a barrier, a tri-layered tablet, then why did Novartis call such a tablet a "bilayer tablet" in its application for a different drug? To pose the question suggests that a person of ordinary skill in the art could reasonably understand "bi-layered tablet" to mean more than simply placing two layers of ingredients on top of each other without a barrier. This is especially so in light of the context in which "bi-layered tablet" is found in Novartis's '802 patent.

That context is very important to a determination of whether its inclusion in the specification supports or contradicts Novartis's argument on the meaning of "physically separated." Even Novartis's own expert, Dr. Byrn, testified on cross-examination that context is critical in understanding a patent's language. (Tr. 62:9-10 ("I think you have to read the whole paragraph in context."); *id*. 62:25 to 63:2 ("Well, I think you have to read the whole sentence in context. I think a person skilled in the art would read the whole paragraph in context.").) Indeed, to the extent that an ambiguity exists regarding the meaning of "bi-layered tablet," the canon of construction known as *noscitur a sociis* should apply. *See Markman*, 52 F.3d at 987 ("The more appropriate analogy for interpreting patent claims is the statutory interpretation analogy. Statutory interpretation is a matter of law strictly for the court.") The "commonsense canon of *noscitur a sociis* . . . counsels that a word is given more precise content by the neighboring words with which it is associated. *United States v. Williams*, 128 S. Ct. 1830, 1839 (2008); *see also Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961) (explaining the maxim of *noscitur a*

sociis to mean that "a word is known by the company it keeps") In other words, "which of various possible meanings a word should be given must be determined in a manner that makes it 'fit' with the words with which it is closely associated." *James v. United States*, 127 S. Ct. 1586 (2007) (Scalia, J., dissenting).

Here, all of the items following "bi-layered tablet" in the "myriad ways" listed in the specification contain physical implements preventing contact between the ingredients.[20] That is, the next listed example of accomplishing physical separation is that of "coated pellets of one agent incorporated into a tablet of the other." The next five examples all similarly contain physical barriers separating the benazepril from the amlodipine: "separately coated pellets of each agent . . . coated pellets of one agent . . . microencapsulated separately . . . dual or multiple compartment transdermal device." And the final example notes that the "most desirable oral form" is that of a "coated compressed tablet of benazepril together with amlodipine powder in a capsule." It cannot be disputed, nor has Novartis tried, that all of the "myriad ways" listed after "bi-layered tablets" contain a physical barrier separating the two active ingredients.

Reading "bi-layered tablets" in the context of these other "myriad ways" strongly suggests that the type of "bi-layered tablet" intended must have been the "modified" type that Dr. Byrn testified about,

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[20] Again, the relevant specification language reads: "Benazepril and amlodipine are physically incompatible substances. Hence, if incorporated into a single dosage form they must be kept physically separated. This may be accomplished in any of the myriad ways known in the art, such as bi-layered tablets, coated pellets of one agent incorporated into a tablet of the other, separately coated pellets of one agent in capsule together with powder of the other agent, each agent microencapsulated separately and then blended together for use in a tablet or capsule, use of a dual or multiple compartment transdermal device, etc. Due to the incompatibility, combination products of the two agents in an injectable solution are not really acceptable. For convenience purposes, a coated compressed tablet of benazepril together with amlodipine powder in a capsule has been found to be the most desirable oral form." ('802 patent, col. 3, ll. 48-63.)

and that a person of ordinary skill in the art would clearly understand to have been intended by the specification. That is, the "bi-layered tablets" referenced in the specification are the type of tablets that contain some implement for keeping the two ingredients physically apart. In that regard, the claim limitation of "physically separated" cannot mean what Novartis proposes because such a definition would require reading the arguably ambiguous specification term "bi-layered tablets" to mean something in direct contradiction to the other examples with which it is listed. Furthermore, Novartis's proposed construction of "physically separated" would subvert the ordinary meaning of a claim limitation to a contextually incongruous interpretation of a specification term. Such hermenuetical gymnastics need not be attempted where the specification term can be easily interpreted consistent with its context and the ordinary meaning of the claim term.

After careful analysis of the claim limitation "physically separated" as found in Claims 2 and 19, the Court concludes that the limitation is structural in nature, not functional. Furthermore, the Court finds that the ordinary meaning of "physically separated" applies. Finally, the Court concludes that the inclusion of "bi-layered tablets" in the specification does not alter the ordinary meaning of "physically separated" in its structural sense. Accordingly, the Court adopts the following construction: "Physically separated" means that the two ingredients, benazepril and amlodipine, are not in physical contact with each other.

2. The limitation "physically separated" applies to the Claim 1 term of "a daily dose" only to the extent that "a daily dose" refers to "a single dosage form" of amlodipine and benazepril.

As previously discussed, the second claim construction issue this Court must face involves the interaction of the term "physically separated" as found in Claims 2 and 19 with the term "daily dose" as

found in Claim 1. Recall that Claim 1 covers "[a] method of treating a condition [such as] hypertension . . . in a human need thereof, consisting of administering a daily dose of benazepril . . . and amlodipine." Further recall that Claim 2 covers those administrations of benazepril and amlodipine "in a single dosage form," and that in such form Claim 2 requires that the two ingredients be "physically separated." And Claim 19 covers "a daily dose of benazepril . . . and amlodipine . . . such that the benazepril and the amlodipine are physically separated from one another."

It is undisputed that the term "a daily dose" as used in Claim 1 covers a universe of applications of the two ingredients, i.e. dosage forms. That universe can be cleaved into two analytical halves: (1) administration of the two ingredients in one pill, i.e., a single dosage form; and (2) administration in which the amlodipine is given in one pill, and the benazepril is given in another pill, i.e., separate dosage form. When viewed in this bifurcated manner, it appears that the parties actually agree on the relevance of "physically separated" to Claim 1, although they both vigorously argue that the other side is dead wrong. With that in mind, the Court will attempt to winnow the wheat of agreement from the chaff of zealous argumentation.

Again, both parties agrees that when the two ingredients are placed in a single dosage form, they must be physically separated. In addition, no party disputes that when administered in something other than a single dosage form, the ingredients are by definition physically separated. That is, logic and the laws of physics dictate that when amlodipine is taken in one pill and benazepril is taken in a different pill, even if ingested at the same time, the ingredients are physically separated simply by virtue of being in separate pills. These uncontroversial statements are buttressed by the parties' arguments.

Teva asserts that "[a]lthough claim 1 admittedly does not use the words 'physically separated,' a person of ordinary skill reading the patent and prosecution history would understand that the term 'dose'

in claim 1 is limited to single dosage forms where the benazepril and amlodipine are physically separated." (Teva Br. at 28.) Elsewhere, Teva declares that "the term 'dose' in claim 1 must be construed not to include a single dosage form in which benazepril and amlodipine are not physically separated." (*Id*. at 30.) Freeing Teva's declaration from its double-negative bondage, the Court discerns Teva's intended argument to be that any construction of "dose" in Claim 1 must exclude the "single dosage form," but only to the extent that such form does not require physical separation. Stated differently yet, Teva insists that the universe that "daily dose" covers must require that the two ingredients be physically separated if, and only if, they are included in a single dosage form. Similarly, Novartis asserts that "it is clear that separation is suggested *only* where benazepril and amlodipine are incorporated into 'a single dosage form.'" (Novartis Br. at 13 (emphasis in original).) At the hearing, Novartis's counsel reiterated this point: "My point is I think a very simple point, and that is, when there is a single dosage form . . . there has to be physical separation." (Tr. 90:10-17.)

But then Novartis confuses matters by declaring that "nothing in the specification states that benazepril and amlodipine must be physically separated *in all circumstances*." (Novartis Br. at 13.) This is confusing because it implies that the universe covered by "daily dose" in Claim 1 covers something other than single dosage forms and separate dosage forms. That is, Novartis concedes that when the two ingredients are included in "a single dosage form" they must be physically separated, and Novartis's counsel vigorously argued at the hearing that it is nonsensical to argue against the notion that when the two ingredients are administered in separate dosage forms they are physically separated. Thus, it is unclear what territory remains for Novartis to claim that benazepril and amlodipine need not be physically separated in all circumstances. In other words, if the two ingredients are in a single pill, the patent requires physical separation, and if the two ingredients are not in a single pill, physics requires

physical separation.

At bottom, it appears that Novartis interprets Teva's argument to be that "daily dose" in Claim 1 covers *only* single dosage forms, and because single dosage forms must contain physical separation between the two ingredients, Teva must be arguing for an interpretation of Claim 1 that excludes separate dosage forms. But Teva has made no such an argument.[21] Indeed, at the hearing, Teva's counsel acknowledged that "Claim 1 encompasses both the single dosage form . . . and the separate dosage forms," and thus importing the physically separated requirement into Claim 1 does not render it a nullity in light of Claim 2, but instead the separate dosage form of Claim 1's universe means that "the independent Claim 1 still has life." (Tr. 107:6-13.) Put differently, Teva's counsel explained that the patent "says quite clearly that to the extent it is a single dosage form, which Claim 1 covers, the substances are incompatible and they must be kept physically separated." (Tr. 102:16-19.)

Thus, the parties are talking past each other, and this Court will attempt to facilitate reconciliation because there is really no dispute on this matter. The Court's construction is as follows:

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[21] Again, Teva declares that "the term 'dose' in claim 1 must be construed not to include a single dosage form in which benazepril and amlodipine are not physically separated." (Teva Br. at 30.) But Teva later rephrases to say that "[t]he term 'dose' in Claim 1 must be interpreted . . . as *limited* to single dosage forms that are physically separated." (*Id*. at 31 (emphasis added).) That is somewhat of an expansion of its previous statement because the former construction essentially declares that a single dosage can come within the scope of "a daily dose," but a single dosage in that context must include the physically separated limitation. By contrast, the latter statement by Teva is more restrictive in the sense that it declares that "dose" is *limited* to single dosage forms, rather than "dose" encompassing single dosage forms and other forms as well.

In any event, Teva attempts to further explain its argument by finally declaring that "if [benazepril and amlodipine are included] in a single dosage form, [they] *must* be physically separated." (*Id*. at 33 (emphasis in original).) This third statement by Teva comports more with its first statement, which generally tracks Teva's counsel's statements at the hearing. In navigating this thicket, this Court reads Teva as seeking to import "physically separated" into Claim 1, but only to the extent that Claim 1 covers single dosage forms. To the extent that Claim 1 covers separate dosage forms, the "physically separated" limitation need not be read into the claim because physics requires such separation.

As used in Claim 1, "daily dose" covers more than just "single dosage forms." To the extent that the two agents are given in "a single dosage form," the "physically separated" limitation applies to Claim 1.

3. The limitation "a daily dose" means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period because Teva has not met is burden of demonstrating that the prosecution history amounts to a clear and unmistakable disavowal of this definition.

The final issue this Court must address for purposes of claim construction involves the meaning of "a daily dose" as that limitation is used in Claims 1 and 19. Again, Claim 1 covers "a method of treating . . . hypertension . . . , consisting of administering *a daily dose* of . . . benazepril . . . and amlodipine." ('802 patent, col. 5, ll. 6-21.) Similarly, Claim 19 covers "[a] pharmaceutical composition consisting essentially of *a daily dose* of benazepril . . . and amlodipine." ('802 patent, col. 6, ll. 8-19.) The essential dispute over the term "a daily dose" is whether that term means the total amount of amlodipine and benazepril given in a 24-hour period, or the number of times amlodipine and benazepril are each given in a 24-hour period. More specifically, Teva contends that "a daily dose" means that amlodipine and benazepril are taken only once a day, whether taken in a single dosage form, or in a separate dosage form. (*See* Tr. 119:11-25.) In other words, if you take amlodipine in the morning and benazepril in the afternoon, then that would be "a daily dose" consistent with the patent. But, according to Teva, if you take either of the two ingredients more than once in a 24-hour period, then that would not be covered by the patent, and therefore no infringement would occur. By contrast, Novartis insists that "a daily dose" means the total quantity of amlodipine and benazepril taken in a single day, regardless of whether they are broken into multiple administrations at various intervals throughout the day.

Novartis takes a straightforward dictionary definition approach to conclude that "a daily dose" means the total amount of the ingredients given in a 24-hour period: "Daily dose" is "the total amount of

a remedy that is to be taken within 24 hours." Stedman's Medical Dictionary. Teva engages Novartis in a dictionary debate by observing that Stedman's "first provides a definition of 'dose' as '[t]he quantity of a drug or other remedy to be taken or applied all at one time or in fractional amounts within a given period.'" (Teva Response Br. at 22 (quoting Stedman's Medical Dictionary).) This definition, however, cuts both ways inasmuch as it declares that "dose" means the quantity taken all at once (favoring Teva's position) or in fractional amounts (favoring Novartis's position) within a given period, e.g., 24 hours. Teva then quotes the sub-term "daily dose" found underneath "dose," which clearly supports Novartis's position. Teva concludes by declaring that "[w]hen the entire definition in Stedman's is reviewed, the dictionary explicitly allows that a dose (including a daily dose) can 'be taken or applied all at one time.'" (Teva Response Br. at 22.) Teva is wrong because "dose" is the broader definition that allows for both all-at-once dosing or fractional dosing, but "daily dose" is decidedly more narrow by virtue of the modifier "daily." Moreover, "daily dose" explicitly declares that it is "the total amount of a remedy that is to be taken within 24 hours." Teva inappropriately attempts to apply the broader definition to the more narrow one. On balance, and limiting the analysis to the dictionary definition, Novartis clearly has the winning argument on the meaning of "daily dose."

Teva points to compelling, but ultimately unpersuasive, evidence from the prosecution history that Novartis intended "daily dose" to mean "once-daily," rather than "the total amount of a remedy that is to be taken within 24 hours." Importantly, "where the patentee has *unequivocally disavowed* a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g., Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (emphasis added); *see also id.* ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and

protects the public's reliance on definitive statements made during prosecution."). For example, during the application process, a patent examiner may require the applicant to limit the scope of his or her proposed claims so as not to include prior art within their ambit. An applicant may also limit the scope of his or her proposed claims in the process of distinguishing his or her invention over the prior art in order to obtain a patent. When an applicant surrenders or disclaims subject matter in this manner, the disclaimer becomes part of the prosecution history. If the application ultimately issues as a patent, the patent holder is bound by his or her prior disclaimers. *Spectrum Int'l, Inc.*, 164 F.3d at 1378 ("[E]xplicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim."). Thus, examination of a patent's prosecution history and the application of prosecution disclaimer is a helpful tool during claim construction because it "ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers." *Chimie*, 402 F.3d at 1384.

However, the Federal Circuit has warned that a court's reliance on prosecution history must be tempered with the recognition that "prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." *Phillips*, 415 F.3d at 1317. As such, it is important to acknowledge that prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* Accordingly, prosecution disclaimer is not appropriate in instances "where the alleged disavowal of claim scope is ambiguous," or where remarks made by an inventor to overcome a rejection may be viewed "as amenable to multiple reasonable interpretations." *Omega*, 334 F.3d at 1324 (citing *N. Telecom Ltd.*, 215 F.3d at 1293-95). Thus, "for prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Id.* at 1325-26.

Here, Teva observes that during the prosecution of the '802 patent, Novartis received an "obviousness" rejection from the patent examiner. The patent examiner stated that "[the Maclean reference disclosed] administering captopril (an ACE inhibitor of the same class as benazepril) and amlodipine" and therefore the invention proposed in the '802 patent of administering benazepril and amlodipine was obvious based upon the Maclean reference. (Teva Br. at 37 (quoting Patunas Decl. Ex. 16, at 2).) In response to the patent examiner's rejection, Novartis attempted to distinguish its invention from the Maclean reference with the following argument:

> In this case, there is neither teaching, suggestion or motivation in Maclean to produce Applicants' method of treating hypertension and other conditions consisting of administering ***a daily dose*** of benazepril and amlodipine as claimed nor Applicants' pharmaceutical composition comprising benazepril and amlodipine as claimed. Maclean teaches the therapeutic usefulness of a ***once-daily*** dose of amlodipine (10 mg) given with twice-daily doses (25 mg each) of captopril. This reference does not teach ***a once-daily dose*** of an ACE inhibitor to treat hypertension.

(Teva Br. at 38 (quoting Patunas Decl. Ex. 15 at 3 (Teva's emphases)).) Thus, according to Teva, Novartis "argued that '[its] claimed invention' required 'a once daily dosage.'" (Teva Br. at 38.) That is, Teva maintains that Novartis cannot stand on the dictionary definition of "daily dose" because Novartis provided its own definition of the term in its attempt to distinguish the '802 patent from prior art. In that regard, Teva insists that Novartis should be bound by the equation of "once-daily" with "a daily dose," regardless of the dictionary definition of the latter term.

Novartis rebuts Teva's equation argument by explaining that "Novartis did *not* argue that the '802 Patent taught 'once-daily' administration of benazepril, but only that benazepril's chemical structure was sufficiently different from that of captopril such that once-daily administration was possible and, therefore, the invention embodied in the '802 Patent was not obvious." (Novartis Br. at 23.) Apparently, captopril could not be administered once-daily because of "the elimination half-life of

captopril." (Novartis Br. at 23.) In other words, captopril was not strong enough to remain effective in the body through a once-daily administration, but benazepril had a larger half-life that allowed the agent to be administered once-daily and still be effective. In that regard, Novartis successfully demonstrated that its invention was not an obvious extension of Maclean because the '802 patent has *possible* applications that were *impossible* in Maclean. (Tr. 116:19-24 ("[W]hat Novartis argued to the Patent Office, ultimately successfully, was . . . [that] you can take my combination once a day, and that is one of the things I am patenting. And if you take it once a day, then captopril is not a suitable substitute for benazepril.").)

Novartis supports its argument by referencing *Purdue Pharma v. Endo Pharmaceuticals*, 438 F.3d 1123, 1136 (Fed. Cir. 2006). In that case, the district court found that Purdue's statements to the patent examiner during prosecution amounted to a clear disavowal of claim scope. The Federal Circuit reversed, concluding that "[w]hile it is true that Purdue relied on its 'discovery' of the four-fold dosage range [limitation] to distinguish its claimed . . . formulations from other prior art . . ., Purdue's statements do not amount to a clear disavowal of claim scope." *Purdue Pharma*, 438 F.3d at 1136. Novartis contends that it did "precisely" the same thing "during the prosecution of the '802 Patent, when it argued that the invention disclosed therein permitted certain advantages over prior art, that is, the 'once-daily' administration of the ACE inhibitor, such that Maclean did not render the amlodipine/benazepril combination obvious." (Novartis Br. at 24.) Teva gives short shrift to *Purdue Pharma*, relegating a rebuttal of the published decision by the Federal Circuit to footnote 10 of its response brief. There, Teva declares that "[t]his case is completely different because [t]here is no question that a relevant claim term exists–'consisting of administering a daily dose,'" and that that somehow distinguishes *Purdue Pharma*.

Teva, though, fails to adequately distinguish *Purdue Pharma*. Indeed, the heavy burden is on Teva to demonstrate that Novartis's alleged disavowal is both clear and unmistakable. *See Omega*, 334 F.3d at 1324 (observing that prosecution disclaimer is not appropriate in instances "where the alleged disavowal of claim scope is ambiguous," or where remarks made by an inventor to overcome a rejection may be viewed "as amenable to multiple reasonable interpretations"); *see id*. at 1325-26 ("[F]or prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable."). While Teva has raised a reasonable argument that the prosecution history amounts to a disavowal that "a daily dose" means anything other than "once-daily," Teva has not demonstrated, in the papers or at the hearing, that disavowal to a clear and unmistakable degree. Therefore, this Court rejects Teva's construction of "a daily dose" to the extent that it relies upon a purported claim disavowal in the prosecution history. *See Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Com'n*, 383 F.3d 1352, 1375 (Fed. Cir. 2004) (rejecting theory of claim disavowal or disclaimer where "[patentee] stated only that the . . . reference was incapable of performing a certain type of search, not that the scope of the claimed invention was limited to that particular type of search."). Instead, this Court construes the term in accordance with the dictionary definition in the following manner: "A daily dose" means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day.

III. Conclusion & Order

In summary, the Court concludes that:

(1) "Physically separated" means that the two ingredients, benazepril and amlodipine, are not in physical contact with each other;

(2) as used in Claim 1, "daily dose" covers more than just "single dosage forms." To the extent that the two agents are given in "a single dosage form," the "physically separated" limitation applies to Claim 1; and

(3) "a daily dose" means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day.

Newark, New Jersey
Dated: July 16, 2008

/s/ Harold A. Ackerman
U.S.D.J.