UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DR. JAMES M. SWANSON,

Plaintiff,

v.

ALZA CORPORATION,

Defendant.
_____/

No. C 12-4579 PJH

ORDER CONSTRUING CLAIMS

Plaintiff Dr. James M. Swanson alleges that he invented what is claimed in three patents that are presently assigned to defendant ALZA Corporation ("ALZA") – U.S. Patent No. 6,930,129 B2 ("the '129 patent"); U.S. Patent No. 8,163,798 B2 ("the '798 patent"); and U.S. Patent No. 6,919,373 B1 ("the '373 patent"). He also asserts that the patents-in-suit are invalid and unenforceable.

ALZA developed and commercialized a prescription drug product known as Concerta® – a once-a-day treatment containing a medication prescribed for the treatment of Attention-Deficit Disorder ("ADD") and Attention-Deficit Hyperactivity Disorder ("ADHD") in children age six and older, adolescents, and adults up to the age of 65. Concerta® is covered by several patents, including the patents-in-suit.

The '129 patent was issued on August 16, 2005, and the '798 patent was issued on April 24, 2012. Both patents (referred to herein as "the ALZA patents") are directed towards "Methods and Devices for Providing Prolonged Drug Therapy." The '129 patent is based on Application No. 09/802,709. The '798 patent is based on Application No. 10/639,355, which is a continuation of Application No. 09/802,709 (the '129 patent), which

in turn is a continuation of Application No. 09/253,317 (the '373 patent, formerly part of this case, but now dismissed).

The claimed inventions work by delivering the drug methylphenidate (or "MPH") – the active ingredient in ALZA's Concerta® – via a novel "ascending" release rate, and by producing a novel "substantially ascending" concentration of drug in the patient's blood. The ALZA patents share the same specification and generally describe and claim compositions and methods for once-a-day treatment of ADD/ADHD with MPH.[1]

ALZA claims that its scientists conceived of the inventions in the ALZA patents that led to Concerta® in the early 1990s, at which time they conducted a series of studies that showed for the first time that ascending drug release and ascending plasma drug concentrations could provide effective once-daily treatment for ADHD and the related condition, ADD.

This once-a-day treatment was an improvement over conventional MPH therapy, which was offered in only two forms at that time – Ritalin®-IR (an immediate release product that required multiple daily MPH doses to achieve symptom control), and Ritalin®-SR (a once-daily sustained release MPH product that was not very effective in symptom control). The ALZA patents claim the "ascending" features for once-a-day ADD/ADHD treatment.

The parties now seek construction of eight disputed terms from the '129 patent and the '798 patent. ALZA also seeks an order striking some of the evidence submitted in support of Dr. Swanson's responsive claim construction brief on the basis that the evidence was not timely disclosed.

BACKGROUND

ADD and ADHD are developmental disorders that typically manifest during childhood. Patients diagnosed with these disorders typically exhibit inappropriate levels of inattention and/or hyperactive-impulsive behavior. '129 Patent 6:60-7:8. The medications

[1] All citations to the common specification of the patents will refer to the '129 patent.

most frequently prescribed for treatment of ADD and ADHD are varieties of stimulants, such as MPH and amphetamines. Id. 6:61-65.

Immediate-release MPH drug products release their drug load rapidly after ingestion. The duration of drug efficacy is brief, typically only two-three hours, with the greatest degree of efficacy coming one-two hours after administration. Because of the short duration of the effect, individuals using the immediate-release form of the drug must take multiple doses throughout the day. '129 Patent 2:29-45, 7:14-15. For children, this means that at least one dose must be administered during the school day, which poses problems such as the need for adult supervision and the possibility of stigmatization. Id. 7:14-34. In addition, the rising and falling levels of drug can create a "roller coaster" effect. Id. 2:7-14. Based on this need, Ritalin®-SR was developed in the late 1970s, but proved not to be entirely effective. Id. 7:35-49.

ALZA claims that in 1993, it began its efforts to develop an effective once-a-day MPH dosage form, and conducted extensive studies in this pursuit. Among other things, ALZA compared the effectiveness of three "plasma profiles" – the "saw-tooth" plasma profile represented by the conventional multiple-daily IR dosing, the "flat" plasma profile represented by conventional sustained-release MPH dosage forms, such as Ritalin®-SR, and the "ascending" plasma drug concentration profile, in which the profile substantially ascended during the course of the day.

According to ALZA, these studies demonstrated that ALZA's novel, "substantially ascending," plasma drug concentration profile was more effective than the flat plasma drug concentration profile of Ritalin®-SR, and at least as effective as the "saw-tooth" multi-dose IR concentration profile in controlling the symptoms of ADD/ADHD throughout the course of the day.

ALZA claims that this discovery ran counter to the then-prevailing wisdom – that a flat drug concentration profile was the preferred approach to delivering drugs via an extended-release formulation, and that the steep rises and falls in blood concentration of MPH that occurred with multiple IR dosing were not required to achieve prolonged

effectiveness. According to ALZA, clinical acceptance of Concerta® has been widespread, and within a year of its introduction into the market, it had obtained 23% of the entire U.S. ADD/ADHD market, and continues to lead the market among long-acting MPH formulations.

THE PATENTS

The patents-in-suit describe methods and devices for prolonging the therapeutic effects of MPH for the treatment of ADD/ADHD via a single administration, which typically occurs in the morning.

The specification teaches drug release rates and blood plasma profiles[2] that solved the then-existing problems associated with IR and SR MPH dosage forms. See, e.g., '129 Patent 4:10-31, 7:42-8:30, 21:25-22:27. As described in Example 7, while multiple dosing with IR MPH resulted in "peaks and troughs," the single dose of ALZA's "experimental regimen" resulted in a "substantially ascending plasma drug concentration" and maintained efficacy throughout the 12-hour study period. See id. 21:63-22:22; see also Fig. 4.

Generally, while both patents include the same specification, the '129 patent concerns "methods for treating" ADD/ADHD, while the '798 patent concerns "dosage forms for the treatment of" ADD/ADHD. That is, the disputed '129 patent claims relate to the discovery that achieving a substantially ascending MPH plasma drug concentration over an extended period of time could provide daylong control of ADD/ADHD symptoms, while the disputed '798 patent claims are directed to oral tablet dosage forms rather than to methods for treating ADD/ADHD.

In addition, the '798 patent claims concern the release rate of MPH (or amount of MPH released from the dosage form per unit time), rather than to MPH plasma

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[2] According to one of ALZA's experts, "drug release rate" refers to the amount of drug that is released from a dosage form over time. Drug release rates are commonly measured by in vitro dissolution, where the dosage form is placed in artificial gastric fluid or other media and the amount of drug released into the media is measured over time. "Plasma drug concentration" is an in vivo measurement and refers to the amount of drug in a person's bloodstream. Plasma drug concentration is usually measured over time by performing periodic blood draws after administering the drug. See Declaration of Kennerly S. Patrick ("Patrick Decl.") ¶¶ 15-16.

concentration, as in the ’129 patent. The two disputed claims in the '798 patent – claim 1 and claim 7 – describe dosage forms having immediate-release (IR) and sustained-release (SR) portions, and further specify that the SR portion releases increasing amounts of MPH during sequential one-hour time intervals.

DISCUSSION

A. Legal Standard

Patent infringement analysis involves a two-step process. First, the court must determine as a matter of law the correct scope and meaning of disputed claim terms. Second, the properly construed claims are compared to the accused device to see whether the device contains all the limitations (literally or by equivalents) in the claims at issue. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996).

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citation and quotation omitted); see also Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998) (claim construction "begins and ends" with the actual words of the claims). The terms used in the claims bear a “heavy presumption” that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citation omitted).

A patentee is presumed to have intended the ordinary meaning of a claim term in the absence of an express intent to the contrary. See York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996). The ordinary and customary meaning of a claim term is " the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313. The person of ordinary skill in the art is "deemed to read the claim term not only in the context of the particular claim . . . but in the context of the entire patent, including the specification." Id. The words in the claim may also be interpreted in light of the prosecution history, if in evidence. Teleflex, Inc. v. Ficosa North Am. Corp., 299 F. 3d 1313, 1324-25 (Fed. Cir.

2002) (citations omitted).

"[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, Inc., 90 F. 3d 1576, 1582 (Fed. Cir. 1996). Only if an analysis of the intrinsic evidence fails to resolve any ambiguity in the claim language may the court then rely on extrinsic evidence, such as expert declarations. Id. at 1583 ("In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper.").

B. Claim Construction

ALZA contends that because its own proposed constructions are based on the plain and ordinary meaning of the claim terms and the specification's explicit teachings, the court should adopt its constructions. ALZA also asserts that the constructions proposed by the plaintiff are unsupported, and that they simply refer to "outcome" (efficacy or therapeutic effect) but fail to take into consideration whether the outcome is achieved by the novel once-a-day treatment methods and dosage forms that are described and claimed in the ALZA Patents, or by methods and dosage forms described and practiced in the prior art, namely multiple daily administrations of IR MPH.

'129 Patent

The '129 patent contains two independent claims – claim 1 and claim 2 – which are identical except for the referenced time period. The first four disputed terms appear in both claim 1 and claim 2 of the '129 patent.

Claim 1 of the '129 patent recites

> **[a] method for treating Attention-Deficit Disorder or Attention-Deficit Hyperactivity Disorder in a patient,** wherein the method comprises **administering a pharmaceutically acceptable composition comprising methylphenidate** and a pharmaceutically acceptable carrier to said patient **in a manner that achieves a substantially ascending methylphenidate plasma drug concentration over a time period of about 8 hours following said administration.**

Claim 2 of the '129 patent recites

> **[a] method for treating Attention-Deficit Disorder or Attention-Deficit Hyperactivity Disorder in a patient**, wherein the method comprises **administering a pharmaceutically acceptable composition comprising**

methylphenidate and a pharmaceutically acceptable carrier to said patient **in a manner that achieves a substantially ascending methylphenidate plasma drug concentration over a time period of about 9.5 hours following said administration.**

1. Term 1: "**A method for treating Attention-Deficit Disorder or Attention Deficit Hyperactivity Disorder in a patient**" ('129 Patent, claims 1 and 2)

ALZA proposes that this term be construed using its plain and ordinary meaning – "a method for treating ADD or ADHD in an individual." Plaintiff's proposed construction is "methylphenidate in ADD children who had been receiving the drug for ADD."

The parties' dispute centers on whether the term should be limited to construe "patient" as "child;" and on whether it should be further narrowed to apply to only those children who had previously been receiving methylphenidate for treatment of ADD or ADHD.[3]

Terms carry their plain and ordinary meaning unless "there is support for the limitation in the words of the claim, the specification, or the prosecution history." 3M Innovative Props. Co. v. Tredegar Corp., 725 F.3d 1315, 1333 (Fed. Cir. 2013). Absent disavowal, claims are not limited to the embodiments described in the specification. Phillips, 415 F.3d at 1323. The court should not "read limitations from the specification into claims" and should not "redefine words." Thorner v. Sony Comp. Enter. Am., 669 F.3d 1362, 1366 (Fed. Cir. 2012).

The court finds that ALZA's proposed construction is supported by the claim language and the specification, and also finds no need to go beyond the plain meaning of the words of the term. Plaintiff asserts that the '129 patent does not expressly define the term "patient" in either the specification or the claims, and that the "Detailed Description of the Invention" identifies that the disclosure and claims are directed towards children, and more specifically, school-age children having ADHD and who have previously received the

[3] ALZA also indicated that the parties disputed whether the term applies to ADD only, or whether it also applies to ADHD, but plaintiff did not address this issue in his responsive brief.

drug methylphenidate. In particular, plaintiff claims that the '129 patent interchangeably uses the terms "children with ADHD" and "patient" (citing '129 Patent, 6:66-7:13 (referencing methylphenidate therapy for treatment of ADHD in children)).

The court finds no support in the claims, however, to limit "patient" to children. Moreover, the specification expressly refers to children and adults. See, e.g., '129 Patent, 6:53-61 (ADD and ADHC are "commonly diagnosed in children but can also occur in adults"). Likewise, plaintiff's reliance on clinical studies related to children described in the specification is unavailing because those studies merely describe specific, non-limiting embodiments, and claims cannot be confined to those embodiments unless the patentee "has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Aria Diagnostics, Inc. v. Sequenom, Inc., 726 F.3d 1296, 1301 (Fed. Cir. 2013).

Finally neither the claims nor the specification state that the method claimed by the invention must be limited to administration of MPH to children who have previously been administered MPH.

2. Term 2: "**administering a pharmaceutically acceptable composition comprising methylphenidate**" ('129 Patent, claims 1 and 2)

ALZA asserts that the term "administering" means "administering once-daily;" and that "a pharmaceutically acceptable composition comprising methylphenidate" means "a pharmaceutical composition that includes a dose of methylphenidate." Plaintiff's proposed construction is "one or more approximately equal doses of methylphenidate per day."

The parties' dispute centers on whether "administering" a "composition comprising methylphenidate" refers to only once-a-day dosing, or whether it can include multiple doses over the course of a day. The parties do not disagree about the meaning of "administering," apart from the question of the number of doses or number of times per day a dose will be provided. In addition, neither side proposes a construction of "pharmaceutically acceptable composition comprising methylphenidate" that involves anything other than the plain and ordinary meaning of the words.

ALZA contends that the claim language, the specification, and the file history clearly show that the claims are directed to a once-daily treatment. ALZA also argues that plaintiff's additional limitation of "equal doses" of MPH in separate administrations finds no support in the claim language, the specification, or the prosecution history.

ALZA asserts that in claim 1, it is the "administering" step that "achieves" the recited drug plasma profile, which occurs "over a time period of about 8 hours following said administration." '129 Patent 23:12-19. ALZA contends that it is clear that "said administration" refers to a single time point – and that it is only by reference to this single time point that it is possible to determine "a time period of about 8 hours following said administration," or conversely, that said administration" must refer to a single time point in order to give meaning to the recited element "about 8 hours," and "administering" must thus also refer to a single time point.

ALZA contends that the specification also conveys that the claimed invention is directed to once-daily treatment. ALZA notes that each of the exemplary embodiments of the claimed dosage forms and methods provides the claimed ascending plasma profiles via a single administration; and the specification discusses the multiple-dosing regimens of the prior art only when contrasting them to the novel, once-a-day treatment methods. See '129 Patent 7:14-34; see also id. 2:7-8, 40-3:13; 6:36-47. In addition, ALZA asserts that the specification clearly and explicitly distinguishes the claimed once-daily methods from conventional multiple-daily administrations using IR MPH dosage forms. See, e.g., id. 7:14-55.

In opposition, plaintiff asserts that when the indefinite article ("a" or "an") is used in a claim term, it is presumed to mean "one or more," and that this is especially true when the word "a" is used with the open-ended antecedent "comprising." For this reason, he argues, the use of the indefinite article "a" in the term "a pharmaceutically acceptable composition comprising methylphenidate" compels the conclusion that the administration of "one or more" pharmaceutical compositions may be used to achieve the claimed results, which he claims supports his proposed construction of "one or more approximately equal doses of

methylphenidate per day."

Plaintiff notes that the patent Abstract also refers to "oral dosage forms that release drug within the gastrointestinal tract at an ascending release rate over an extended time period[,]" which "dosage forms may additionally comprise an immediate-release dose of drug." '129 Patent, Abstract. Plaintiff contends that this shows that something more than a once-a-day dosage form is intended by the patent claimants.

Plaintiff asserts further that the body of the specification includes a number of references that can be interpreted to refer to multiple dosing. He cites to the statement in the "Brief Summary" that "the present invention also pertains to improving drug therapy for ADHD by eliminating the need for multiple daily doses of methylphenidate yet providing therapeutic efficacy throughout the day that compares to the therapeutic efficacy provided by multiple doses of immediate release methylphenidate." '129 Patent 5:58-62. He contends that the use of "also" shows that the patent is directed at more than single-daily-dose administration, and that while one once-a-day treatment might be beneficial, it is not the only disclosure contained in the patent.

Plaintiff also points to the statement in the "Detailed Description" that "[d]epending on the dose of drug desired to be administered, one or more of the dosage forms may be administered." '129 Patent 9:19-20. He claims that this means that the inventions contemplate the administration of "one or more" doses per day. Plaintiff asserts further that only one of the nine examples provided in the "Detailed Description" – Example 7 – expressly describes the administration of a single dose as a means to practice the claimed invention, and argues that the claims of the patent thus plainly cover more than is disclosed in that single example.

The court finds that ALZA's proposed construction is supported by the claim language and the specification, and that the term refers to administration at one point in time. It is true that the indefinite article ("a" or "an") "carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'" Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1342-43 (Fed. Cir. 2008) (quoting KCJ Corp. v. Kinetic

Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000)).

> That "a" or "an" can mean "one or more" is best described as a rule, rather than merely as a presumption or even a convention. The exceptions to this rule are extremely limited: a patentee must "evince[ ] a clear intent" to limit "a" or "an" to "one." . . . The subsequent use of definite articles "the" or "said" in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning. An exception to the general rule that "a" or "an" means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule. See, e.g., Abtox Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997); Insituform Techs., Inc. v. Cat Contracting, Inc., 99 F.3d 1098 (Fed. Cir. 1996).

Id.; see also SanDisk Corp. v. Kingston Tech. Co., Inc., 695 F3d 1348, 1360 (Fed. Cir. 2012); Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1359 (Fed. Cir. 2005) (a "comprising" claim may be limited to "one" rather than "more than one" when the specification or prosecution history show that the term is used in its singular sense).

Here, however, plaintiff's argument regarding the presumption created by the use of the indefinite article "a" is misdirected. The use of "a" in front of the noun phrase "pharmaceutically acceptable composition comprising methylphenidate" means that there may be one or more "pharmaceutically acceptable compositions," the administration of which comprises part of the method taught by claim 1 – not that one or more doses are "administered." The indefinite article "a" modifies "composition," not "dose." The term "dose" does not appear in the claim and does not equate to "composition," which is closer in meaning (though not identical) to "dosage form."

The '129 patent, which is entitled "Methods and Devices for Providing Prolonged Drug Therapy," refers throughout the specification to drug "dosage forms," and further, distinguishes "conventional oral dosage forms" (also known as "immediate-release" dosage forms), see, e.g., '129 Patent 2:7-10; from various "non-immediate-release delivery systems" (or "sustained-release" oral dosage forms) previously known in the art, see e.g., id. 2:46-4:7; and distinguishes those forms from a sustained-release oral dosage form adapted to provide "administration of a drug at a release rate that is substantially ascending," see id. 4:10-6:14, of which "osmatic dosage forms . . . have been notably successful at providing constant-release of drugs over extended time periods," id. 3:14-16.

Similarly, the patent distinguishes "[b]i-layer oral osmotic dosage forms" previously known in the art from the "bi-layer oral osmotic dosage forms" of the present invention. See '129 Patent 10:53-13-53. Further, each of the nine Examples in the Detailed Description of the Invention describes a preferred embodiment of either a "bi-layer oral osmotic dosage form" or a "tri-layer oral osmotic dosage form." It is clear from this discussion of "dosage forms" that what is meant is the form or composition of the drug delivery system – not a "dose" or an amount of the drug that is to be ingested at a particular time. See also '129 Patent 2:8-11 ("immediate-release" oral-dosage form is one in which "entire dose of drug is released from the dosage form within a very short period").

With regard to plaintiff's citation to the specification's use of "one or more dosage forms," '129 Patent 9:15-20, this description supports ALZA's construction because it explicitly refers to the "desired administration period" and to examples of administration periods that are "every" 12 hours or 24 hours. From the context of the specification, it is clear that the reference to "one or more dosage forms" is a way to reference the amount of drug to be given at one point in time, not to multiple doses to be administered throughout the day. Indeed, the specification refers to the multiple-dose regimen only in the context of contrasting the prior art with the invention disclosed in the '129 patent – particularly in the "Background of the Invention," in the "Brief Summary of the Invention," and in the "Detailed Description of the Invention." See id. 2:29-6:14; 6:66-7:22.

For example, the "Brief Summary of the Invention" explains that "oral methylphenidate sustained release dosage forms that provide an ascending release rate of a drug over an extended time period can be used to provide effective once-a-day therapy for ADHD[;]" and that "the present invention also pertains to improving drug therapy for ADHD by eliminating the need for multiple daily doses of methylphenidate yet providing therapeutic efficacy throughout the day that compares to the therapeutic efficacy provided by multiple doses of immediate release methylphenidate." '129 Patent 5:54-63.

Similarly, the "Detailed Description of the Invention" explicitly discusses the "therapeutic effectiveness of single doses," and teaches in Example 7 that "[a]n effective

once-a-day therapy for ADHD provides many advantages and offers a significant improvement in drug therapy by eliminating the need for multiple daily doses of methylphenidate while providing continued therapeutic efficacy throughout the day." '129 Patent 21:25-31; 22:22-27; see also id. 13:45-54.

The "Detailed Description" also emphasizes the advantages of the claimed invention in the treatment of children with ADHD – explaining that single-dose administration is preferable because of the problems inherent in dose administration throughout the school day. See, e.g., id. 7:14-8:16. These teachings, along with the file history, indicate that the claimed inventions concern once-daily administration.

3. Terms 3 and 4: "**[in a manner that achieves] a substantially ascending methylphenidate plasma drug concentration over a period of about [x] hours following said administration**" ('129 Patent, claims 1 and 2)

ALZA argues that "a substantially ascending methylphenidate plasma drug concentration over a period of about [x] hours following said administration" should be construed as "a profile in which the plasma concentration of methylphenidate generally rises over approximately [x] hours, but may include a slight dip." Plaintiff asserts that the term should be construed as "an effect-time profile similar to three doses of immediate release methylphenidate given approximately every 4 hours for approximately 12 hours per day."

The basis of the parties' dispute is whether "substantially ascending" can include a slight dip; and whether "substantially ascending methylphenidate plasma drug concentration" refers to a measurement of plasma drug concentration or to an "effect-time profile similar to" methylphenidate administered TID (three times a day).

The court finds no support in the claim language for adding the limitation "can include a slight dip." ALZA relies only on the explanation in Example 7 in the Detailed Description of the Invention, and the accompanying illustration in Fig. 4. Example 7 explains that the "[t]herapeutic effectiveness of single doses of tri-layer osmotic dosage forms containing 14 mg of methylphenidate and additionally comprising an immediate-

release drug overcoat containing 4 mg of methylphenidate was studied and compared to multiple doses of immediate-release methylphenidate." '129 Patent 21:25-30.

Example 7 explains further that this comparison is reflected in the graph in Fig. 4, which shows that the plasma drug concentration following administration of the immediate-release dose "rises fairly rapidly and then declines at a generally characteristic rate until the next dose is administered[;]" and that the tri-layer osmotic dosage form "exhibits an initial relatively rapid rise due largely to release of drug from the immediate-release drug overcoat[,]" but subsequently, "the plasma drug concentration does not decline but continues to substantially ascend (save for a slight 'dip' between t=5.5 hours and t=6.5 hours) through a time period of 9.5 hours." '129 Patent 21:63-22:7; Fig. 4. ALZA contends that because Example 7 refers to "a slight dip," this term should be construed to include that limitation.

The term "substantially ascending" communicates that the plasma drug concentration mostly or generally ascends or rises. "Substantially" is a descriptive term commonly used in patent claims, where it can denote either language of approximation or language of magnitude. Enzo Biochem, Inc. v. Applera Corp., 599 F.3d 1325, 1333 (Fed. Cir. 2010); see also Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1329 (Fed. Cir. 2006) ("substantially" implies "approximate," rather than "perfect"); Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc., 347 F.3d 1314, 1322-23 (Fed. Cir. 2003) ("substantially" can mean "significantly," "considerably," "largely," or "essentially").

Here, the intrinsic evidence indicates that "substantially" is used in the claims of the '129 patent as a term of approximation, to modify the word "ascending." That is, in the context of the claim language, the use of "substantially" indicates that the plasma concentration generally rises, but that the rise is not necessarily uniform, and that some variation is permitted. See, e.g., Fig. 4 (showing that there can be a variation in the amount of the drug in the plasma of a patient during the course of treatment). To account for this inherent variability, the plasma curve is described as "substantially" ascending.

The court finds no basis to read the "slight dip" limitation into the claims of the '129 patent. Nothing in the claims requires that the plasma drug concentration "dip" during the course of its gradual ascent, and nothing in the specification or prosecution history includes a contrary definition regarding "substantially ascending." To the extent that "can include a slight dip" simply reinforces the concept that the plasma drug concentration "substantially" or "generally" or "approximately" rises, but may also briefly descend, it is superfluous.

Turning to the remaining dispute regarding the construction of this term – whether "substantially ascending methylphenidate plasma drug concentration" refers to a measurement of plasma drug concentration or to an "effect-time profile similar to" methylphenidate administered TID – the court finds that ALZA's proposed construction is consistent with the language of the claims and the specification. On the other hand, plaintiff's proposed construction is improper because it does not address the phrase "plasma drug concentrations" and focuses on efficacy, rather than on plasma drug concentrations; and also because it appears to involve an attempt to include TID dosing.

Claims 1 and 2 expressly refer to "plasma drug concentration," which is defined in the specification. See '129 Patent 1:44-51 ("plasma drug concentration" is "the concentration of drug that is obtained within the blood or plasma, or other appropriate body fluid or tissue of a patient following administration of the drug," and the term is "intended to be inclusive of drug concentration measured in any appropriate body fluid or tissue"); see also Example 7 (contrasting plasma drug concentration following administration of multiple doses of immediate release drug ("standard regimen"), and following administration of the "experimental regimen").

Because "plasma drug concentration" is defined in the specification, the construction of the disputed term should reflect that definition. However, plaintiff's proposed construction – "effect-time profile" – includes no reference to the concentration of the drug in plasma, which is an essential element of the claims. Nor does it take into account the "striking . . . "difference" between ALZA's claimed "substantially ascending" profile and the "standard" TID regimen. See '129 Patent 22:3-15. Instead, he focuses on therapeutic

effect.

Plaintiff asserts that the term at issue covers both once-a-day dosing and the administration of multiple doses over the course of a day. He contends that the '129 patent claims its earliest priority date to provisional application No. 60/030,514 ("the '514 provisional application"), filed on April 22, 1997. Contained within the '514 provisional application is language that plaintiff believes provides the easiest to understand construction of the disputed claim term.

The '514 provisional application refers to "[a] delivery system" that is "provided by the invention which releases the drug resulting in an ascending plasma methylphenidate concentration time profile that . . . maintains the desired pharmacological effect;" and provides "[a]s an example," a delivery system that "achieve[s] an effect-time profile similar to the three doses of immediate release given every 4 hours for 12 hours every day, TID." '514 Application, Example 6.

Thus, plaintiff asserts, in the application that provides the effective filing date of the '129 patent, ALZA expressly discloses that the claimed method for treatment is designed to achieve an effect time profile similar to TID dosing of methylprenidate. He argues that the dosage form provides efficacy "similar to" TID; and that the way in which the dosage form accomplishes this efficacy ("substantially ascending" plasma concentration) "derive[s] its meaning" from TID's "effect-time profile."

Plaintiff contends that his proposed construction is further bolstered by the '129 patent specification. He points to the Detailed Description, which teaches that "development of acute tolerance to methylphenidate has been proposed as an explanation for the unsatisfactory decrease in therapeutic effectiveness that has been observed in some cases," and that "an ascending-release regimen . . . was shown to maintain therapeutic efficacy throughout the prolonged therapy period." '129 Patent 8:17-30. He claims that this paragraph (8:17-30), when read in conjunction with the '514 application cited above (referring to TID regimen of three equal doses given at periods spaced four hours apart) shows that his proposed construction is correct.

The '514 provisional application distinguishes between efficacy on the one hand, and plasma drug concentrations on the other. However, it is the latter (plasma drug concentrations) to which the '129 patent is directed. TID dosing involves three IR administrations spaced hours apart, and results in "peaks and troughs" in plasma drug concentrations. By contrast, ALZA's invention concerns a once-daily dosage form resulting in "substantially ascending plasma drug concentration" over time, which is clearly distinguished in the patent from the prior art TID regimes. See, e.g. '129 Patent, 22:3-15; Example 7; Fig. 4.

'798 Patent

The '798 patent also contains two independent claims – claim 1 and claim 7. Term 5 appears in claim 1 and claim 7. Terms 6 and 7 appear in claim 1 only. Term 8 appears in claim 7 only.

Claim 1 of the '798 patent recites

> **An oral tablet dosage form for the treatment of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder in a subject comprising**: **an immediate release portion comprising methylphenidate** or a pharmaceutically effective salt thereof; and a sustained release portion comprising methylphenidate or a pharmaceutically effective salt thereof and a pharmaceutically acceptable carrier, wherein: said dosage form releases said methylphenidate over a period comprising first, second, and third sequential one-hour time intervals, and **said sustained release portion releases more of said methylphenidate during said second interval than during said first interval, and more of said methylphenidate during said third interval than during said second interval**.

Claim 7 of the '798 patent recites

> **An oral tablet dosage form for the treatment of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder in a subject comprising**: an immediate release coating comprising methylphenidate hydrochloride; and a sustained release portion comprising methylphenidate hydrochloride and a pharmaceutically acceptable carrier, wherein: said dosage form provides release of said methylphenidate hydrochloride over a period comprising first, second, third, and fourth sequential one-hour time intervals; said **sustained release portion releases more of said methylphenidate hydrochloride during said second interval than during said first interval, more of said methylphenidate hydrochloride during said third interval than during said second interval, and more of said methylphenidate hydrochloride during said fourth interval than during said third interval**; the methylphenidate hydrochloride released during said first interval only includes methylphenidate hydrochloride released from said immediate release coating.

4. Term 5: "**An oral tablet dosage form for the treatment of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder in a subject comprising**" ('798 Patent, claims 1 and 7)

ALZA asserts that the plain and ordinary meaning of this should apply, and that it should be construed as "a pharmaceutical composition in the form of a tablet that is intended to be administered orally to an individual who is being treated for [ADD] and/or [ADHD]." Plaintiff's proposed construction is "methylphenidate in children who have been receiving the drug for the treatment of ADD."

Similarly to term 1, above, the parties' dispute centers on whether the term should be limited to construe "subject" as "child;" on whether it should be further narrowed to apply to only those children who had previously been receiving methylphenidate for treatment of ADD or ADHD.

The court finds that ALZA's proposed construction is supported by the claim language and the specification, and finds no need to go beyond the plain meaning of the language in the claim term. The word "subject" appears twice in the preambles of independent claims 1 and 7, and four times in the Detailed Description in Example 7. Plaintiff asserts that just as the '129 patent does not provide a definition of "patient," the '798 patent does not expressly define the term "subject" in either the specification or the claims; but argues that the specification of the '129 patent (of which the '798 patent is a continuation application) provides enabling disclosure only for children who had been receiving the drug for the treatment of ADD. Thus, plaintiff asserts, the '798 patent is also enabled only for the same category of "subjects."

For the reasons stated above with regard to term 1, the court finds no support in the claims to limit "subject" to children. Plaintiff's main argument is based on the discussion in the "Detailed Description" of the use of the claimed method in treating children. But plaintiff has taken one small part of the specification out of context. The "Background of the Invention" does not mention children at all; nor does the "Brief Summary of the Invention."

As for the "Detailed Description," that portion of the specification begins by

discussing sustained release drug therapies in general, then states that "[t]here are clinical situations . . . where the constant-release dosage form has unexpectedly exhibited decreases in therapeutic effectiveness . . . ." '129 Patent 6:37-52. The specification goes on to provide "[o]ne example" of such a clinical situation, which is the use of central nervous system stimulant drugs "to treat various conditions and disorders including [ADD and ADHD]. These disorders are commonly diagnosed in children but can also occur in adults." '129 Patent 6:53-61.

From there, the specification goes on to say that about 25 years ago, "methylphenidate replaced amphetamine as the primary stimulant prescribed to treat ADHD in children." '129 Patent 6:63-65. Only after that does the specification discuss the need for symptom control during the school day, and the efficacy of the "substantially ascending release rate" in situations where the patient may have a problem taking multiple doses throughout the day. Example 7, which is the main portion of the specification that uses the word "subject," appears to equate "subject" with "study participant." Example 7, however, does not expressly state whether those participants were children or adults. In addition, neither the claims nor the specification state that the method claimed by the invention must be limited to administration of MPH to children who have previously been administered MPH.

Likewise, as stated above, plaintiff's reliance on clinical studies related to children described in the specification is unavailing because those studies merely describe specific, non-limiting embodiments, and claims cannot be confined to those embodiments unless the patentee "has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Aria Diagnostics, 726 F.3d at 1301.

5. Term 6: "**an immediate release portion comprising methylphenidate**" ('798 Patent, claim 1)

ALZA's proposed construction of this term is "a portion of the oral tablet dosage form containing an amount of methylphenidate that is substantially completely released within a time period of about 1 hour or less." Plaintiff's proposed construction is "first oral dose of

instant release methylyphenidate."

The dispute between the parties centers on whether the patent claims multiple-daily-dose administration, or single daily dose; and, relatedly, whether the "portion" disclosed in this claim limitation refers to only "one part" of an "oral tablet dosage form."

ALZA contends that its proposed construction adopts the plain and ordinary meaning of the words "portion" of "an oral tablet dosage form." ALZA also argues that its construction of "immediate release portion" is consistent with the use of that term in the specification, as the specification defines "immediate release" to mean a drug that is "substantially completely released within a time period of about 1 hour or less." See '129 Patent 9:42-53. The court finds that ALZA's proposed construction is supported by the claim language and the specification, and also finds no need to go beyond the plain meaning of the words in the term.

Plaintiff contends that "an immediate release portion" should be construed as meaning a "first oral dose of instant release methylphenidate," which encompasses "multiple doses" of "instant release" MPH administered at various time points (i.e., first dose, second dose, and possibly third dose). Plaintiff again cites to the '514 provisional application, arguing that it describes ALZA's "sustained-release ascending profile" as of the effective filing date of the '798 patent. Plaintiff asserts that this "profile" is exhibited by administering varying doses of methylphynidate every half hour, starting with "zero hour" and continuing to 6.5 hours, to achieve a particular ascending sustained release profile. Based on this, plaintiff argues that the claimed "immediate release portion compromising methylphenidate" is the "first oral dose" of instant-release methylphenidate as indicated by the steeply ascending first portion of the plasma concentration that rises through approximately one hour.

Plaintiff also notes that claim 1 recites "an" oral dosage form – which means "one or more." For this reason, plaintiff asserts, the claimed portion of "one or more" oral tablet dosage forms does not preclude an "immediate release portion" that comprises a "first oral dose of instant release methylphenidate." He argues that ALZA is improperly attempting to

read in extra limitations to the claim term – namely, that the "portion" disclosed in this claim limitation refers to only "one part of one oral tablet dosage." Plaintiff contends that just as the '129 patent, the '798 patent is not limited to one dosage, and thus, ALZA's construction, while it might be relevant to one embodiment disclosed in the specification, would limit claim 1 to that preferred embodiment.

Plaintiff's proposed construction is inconsistent with the language of claim 1, which refers to a "portion" of an "oral tablet dosage form," and not to an entire dose. The claims make clear that they are directed to a "dosage form" having two components – an IR portion, and an SR portion, "wherein said dosage form releases said methylphenidate over a period comprising first, second, and third sequential one-hour time intervals . . . ." See '798 Patent, claim 1.

In other words, claim 1 teaches an oral dosage form that comprises both "an immediate release portion" and "a sustained release portion." The patent does not claim an "immediate release portion" that is one dose, and subsequent, separate doses. Moreover, for the reasons explained above (in particular with regard to the construction of term 2), the specification indicates that the patent is directed towards treating ADD/ADHD by means of a once-a-day-dosage form, not with dosage forms administered multiple times per day. The ordinary meaning of this term is that what is claimed is an oral dosage in the form of a tablet, which includes a portion that is initially substantially completely released, and a portion that is released over an extended period of time (here, sequential one-hour intervals), so as to delay or extend the action of the active ingredient.

By contrast, Example 1 of the ’514 provisional application (part of the "Detailed Disclosure") describes comparative clinical studies involving the administration of an "immediate release" tablet and a "sustained release" nonascending tablet, followed by an "ascending profile sustained release," with the administration and results illustrated in Figs. 1-5. Example 1 illustrates a “sustained-release ascending profile” not via administration of an oral dosage form with an IR portion and an SR portion, as required by claims 1 and 7 of the '798 patent, but rather via administration of small amounts of IR MPH at 30-minute

intervals (starting at 1.5 hours) to simulate drug release from an SR portion. This example includes no sustained release component at all, and is therefore not directed to the oral tablet dosage form of claims 1 or 7.

Indeed, Example 1 involves no fewer than 12 administrations of IR MPH, starting at zero hour, and continuing in varying amounts every half hour for the next six hours. This type of administration would run counter to the purpose of ALZA's claimed invention – which provides "oral methylphenidate sustained release dosage forms [with] an ascending release rate . . . over an extended time period . . . to provide effective once-a-day therapy for ADHD." '798 Patent, 5:54-57.

Moreover, it is improper to ignore the language of the claims and the specifications of the patent, and to instead look only at an earlier patent application. The Federal Circuit has instructed that courts must first "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention," and that second to the claim language is the specification, which the court should review "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Vitronics, 90 F.3d at 1582.

6. Term 7: "**said sustained release portion releases more of said methylphenidate during said second interval than during said first interval, and more of said methylphenidate during said third interval than during said second interval**" ('798 Patent, claim 1)

Term 8: "**said sustained release portion releases more of said methylphenidate hydrochloride during said second interval than during said first interval, more of said methylphenidate hydrochloride during said third interval than during said second interval, and more of said methylphenidate hydrochloride during said fourth interval than during said third interval**" ('798 Patent, claim 7)

These two terms are similar. The preamble is identical in claim 1 and claim 7 – "[a]n oral tablet dosage form for the treatment of [ADD] or [ADHD] in a subject comprising . . . ."

In claim 1, the dosage form comprises "an immediate release portion comprising methylphenidate" and "a sustained release portion comprising methylphenidate[.]" In claim 7, the dosage form comprises "an immediate release coating comprising methylphenidate hydrocholoride" and "a sustained release portion comprising methylphenidate hydrochloride [plus a carrier].

In claim 1, the dosage form releases the methylyphenidate "over a period comprising first, second, and third sequential one-hour time intervals[,]" and in claim 7, the dosage form releases the methylphenidate "over a period comprising first, second, third, and fourth sequential one-hour time intervals." In addition, claim 7 recites that drug released during the first time interval includes drug released from the IR coating.

This is followed in each instance by the portion of the claims to be construed, which is "said sustained release portion releases more of said methylphenidate . . . during said second interval than during said first interval [and] more of said methylphenidate . . . during said third interval than during said second interval . . ."

ALZA argues that the plain and ordinary meaning of the language in claims 1 and 7 should apply, to describe the amount of drug released during sequential time intervals. ALZA's proposed construction for the term in claim 1 is "the sustained release portion releases more of said methylphenidate during the second interval than during the first interval (if any), and more of said methylyphenidate during the third interval than during the second interval; and further, that the amount of methylphenidate 'said sustained release portion releases' is determined by an appropriate in vitro dissolution test."

ALZA's proposed construction of the term in claim 7 is "the sustained release portion releases more of said methylphenidate hydrochloride during the second interval than during the first interval (if any), and more of said methylyphenidate hydrochloride during the third interval than during the second interval, and more of said methylphenidate hydrochloride during the fourth interval than during the third interval; further, the amount of methylphenidate hydrochloride 'said sustained release portion releases' is determined by an appropriate in vitro dissolution test."

Plaintiff's proposed construction for the term in both claim 1 and claim 7 is "release rates corresponding to the plasma methylyphenidate concentrations that achieve an effect-time profile similar to three doses of immediate release methylphenidate given approximately every 4 hours for approximately 12 hours per day."

The dispute between the parties involves whether the construction should refer to release of the SR portion or whether it should refer to the "effect-time profile" and/or to therapeutic efficacy "similar" to that of TID dosing; whether the term must be construed to require testing of the amount of drug released by an "appropriate in vitro dissolution test;" and whether construction of these terms should differentiate between claim 1 and claim 7.

ALZA argues that claims 1 and 7 employ plain and ordinary language to describe the amount of drug released during sequential time intervals, and that in contrast to its own proposed construction, plaintiff's proposed construction fails to employ ordinary language. ALZA argues that plaintiff's attempt to broadly define the claim scope as incorporating an "effect-time profile" – "three doses of immediate release methylphenidate given approximately every 4 hours for approximately 12 hours per day" as well as multiple-daily dosing – is improper, because the claims of the '798 patent, like the claims of the '129 patent, include no terms relating to therapeutic efficacy.

ALZA contends that by proposing a construction reciting the "release rates corresponding to" plasma drug levels "that achieve an effect-time profile similar to" thrice-daily dosing, plaintiff advocates a construction that would encompass drug release rates that produce a peak-and-trough plasma curve, i.e., drug release from three separate immediate releases of drug, spaced approximately 4 hours apart. ALZA argues that the claim language does not describe separate immediate releases of MPH spaced hours apart. ALZA also contends that plaintiff's proposed construction would conflict with the plain language of the claims reciting a "dosage form" that includes with both IR and SR "portions," causing drug release "over a period comprising first, second, and third sequential one-hour time intervals," with increasing amounts of drug released during each subsequent time interval. See '798 Patent, claim 1.

With regard to the inclusion in its proposed construction of the clause "the amount of methylphenidate 'said sustained release portion releases' is determined by an appropriate in vitro dissolution test," ALZA argues that a skilled person would understand that drug release is determined by dissolution testing. ALZA asserts that this contrasts with the claimed “plasma drug concentration” of the ’129 patent, which it claims is a measurement of in vivo MPH concentration in blood plasma.

In opposition, plaintiff argues that the intrinsic evidence from the '798 patent supports his proposed construction. He asserts that Example 1 of the '514 provisional application demonstrates a sustained-release ascending profile achieved through multiple dosings of instant release methylphenidate; and that Example 6 of the '514 application shows that ALZA's goal was to achieve an effect-time profile similar to TID. Plaintiff argues that taken together, these two examples from the '514 application reflect ALZA's intent to achieve "an effect-time profile similar to the three doses of immediate release given every 4 hours for 12 hours every day, TID."

Plaintiff argues that his proposed construction is further supported by the prosecution history of the ‘798 patent. On May 27, 2011, the USPTO issued an office action rejecting the claims of Application No. 10/639,355 (the Application that issued as the ‘798 Patent) under various grounds, including a nonstatutory obvious-type double patenting rejection of the claims of the ‘798 patent over claims 1 and 2 of the ‘129 patent. The Examiner found that, although the claims were not identical, they were not patentably distinct.

In responding to the office action, ALZA filed a terminal disclaimer to negate the double patenting rejection. Plaintiff asserts that ALZA did this instead of arguing that the claims covered different subject matter (MPH plasma drug concentrations versus ascending drug delivery), and argues that based on this, it is clear that the claims cover the same subject matter, and it is therefore reasonable to construe the claims of the ‘798 patent in terms of release rates that correspond to MPH concentrations.

The court finds that the first part of ALZA's proposed construction is supported by

the claim language and the specification, and finds no need to go beyond the plain meaning of the language when construing the term. ALZA's proposed construction of the "sustained release" portion of the claimed "oral tablet dosage form" tracks the plain and ordinary language of claims 1 and 7, and describes the amount of MPH released during sequential time intervals. That is, a construction specifying the nature of the claimed "release," as opposed to its therapeutic effect, gives expression to the claims' plain words.

Plaintiff's proposed construction, which refers to "release rates corresponding to . . . concentrations that achieve an effect-time profile similar to" three doses of immediate release methylphenidate given TID, improperly focuses on efficacy, rather than on the amount of the drug released. That is, in arguing that the proper construction is an "effect-time profile similar" to three doses of IR MPH given every four hours, TID, plaintiff has departed from the plain language of the claim – namely, the "release[]" of MPH – and has instead focused on therapeutic efficacy "similar" to that of TID dosing. The court finds no support for this construction in the language of the claims or the specification, and plaintiff has not identified any.

Similarly, plaintiff's argument that the word "treating" in the preamble of claims 1 and 7 compels an interpretation based on the therapeutic effect of MPH is without support. The claims concern "oral tablet dosage forms," and while they are intended for the treatment of ADD/ADHD, the balance of claims 1 and 7 define the IR and SR components and release rate characteristics of the dosage form, as opposed to any therapeutic effect. '798 Patent, claims 1 and 7.

As for plaintiff's citation to the '514 priority application, plaintiff's reliance on language from Example 6 for the source of the "truest" construction of this term is misplaced, as the claims and specification of the patent in question are the first and second sources for guidance on claim construction.

As for plaintiff's citation to the terminal disclaimer filed in the '798 patent examination, the fact that ALZA may have terminally disclaimed coverage beyond the term of the '129 patent does not mean that the '798 and '129 patents cover the same subject

matter, as plaintiff argues in his opposition. A terminal disclaimer cannot overcome a rejection based on claims to the same invention in separate, co-owned applications. See Manual of Patent Examining Procedure § 804.02.

Because a terminal disclaimer can overcome only an obviousness-type double patenting rejection, see id., the claims in question are necessarily directed to different, "patentably distinct" subject matter. "[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert this simple expedient of 'obviation' into an admission or acquiescence or estoppel on the merits." Quad Envtl. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 874 (Fed. Cir. 1991); see also Ventana Med. Sys, Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1184 n.4 (Fed. Cir. 2006) (filing of terminal disclaimer in response to obviousness-type double patenting rejection of claims of patent application over claims of earlier-issued patent does not represent admission by inventor equating all claims of patent application to claims of earlier patent).

In addition, ALZA's proposed construction accounts for the differences in claim language as between claim 1 and claim 7, including the number of time intervals recited (three intervals in claim 1 versus four intervals in claim 7); the form of drug recited (methylphenidate in claim 1 versus methylphenidate hydrochloride in claim 7); and drug release during the first time interval (unlike claim 1, claim 7 recites that drug released "during said first interval only includes" drug released from the IR coating). Plaintiff, on the other hand, proposes the same construction for the term in claim 1 and the similar (though not identical) term in claim 7. This failure to account for the differences between the two claims violates the canon that when the patentee uses different language, different meanings are intended. See Tandon Corp. v. ITC, 831 F.2d 1017, 1023 (Fed. Cir. 1987).

With regard to the second part of ALZA's proposed construction, there is support in the specification for determining a "release rate" by "an appropriate in-vitro dissolution test." The Background of the Invention states that "drug release rates for oral dosage forms" are

"typically measured is an in vitro rate of dissolution." '129 Patent 2:3-6. The Detailed Description teaches that "[d]rug release rates are calculated under in vitro dosage form dissolution testing conditions known in the art," and that as used in the patent, "a drug release rate obtained at a specified time, 'following administration' refers to the in vitro drug release rate obtained at the specified time following implementation of an appropriate dissolution test." Id. 9:23-29. Further, the amount of drug released in all nine Examples in the Detailed Description was measured using a particular type of in vitro dissolution test. See id. 9:29-36.

Nevertheless, the court finds no support for this limitation in the language of the claims. While this limitation is not inconsistent with patent specification, it does not provide any meaning in the context of the preamble of claims 1 and 7 of the '798 patent, namely, "[a]n oral tablet dosage form for the treatment of [ADD] or [ADHD]."

C. Motion to Strike Evidence

ALZA also filed a separate motion seeking an order under Federal Rules of Evidence 26 and 37 and Patent Local Rule 4-3, striking evidence filed in support of plaintiff's responsive claim construction brief. The evidence ALZA seeks to have stricken is Exhibits C, E-I, K, L-R, V, Z, AA, and BB of the Declaration of Gerald Dodson; portions of the Declaration of Dr. James M. Swanson; and the portions of plaintiff's responsive claim construction brief that rely on those references. The court finds that the motion must be DENIED.

As an initial matter, some portions of ALZA's motion can be viewed simply as objections to evidence submitted by plaintiff with his responsive claim construction brief. However, there is no provision in the Patent Local Rules for filing such an objection. Under the Civil Local Rules (which apply in patent cases to the extent they do not conflict with the Patent Local Rules), "[a]ny evidentiary or procedural objections to the motion must be contained within the brief or memorandum" unless the objection is to reply evidence. Civ. L.R. 7-3.

It is true that a motion to strike an expert declaration may be appropriate where the

sponsoring party failed to disclose the expert's identity or his opinions prior to filing the brief. See, e.g., Nordic Naturals v. J.R. Carlson Labs, Inc., 2008 WL 2357312 at *11 (N.D. Cal. June 6, 2008) (granting a motion to strike the declaration of an expert who had not been previously disclosed). Here, however, the court finds no basis for striking any of the evidence submitted by plaintiff, primarily because the court found it unnecessary to rely on any extrinsic evidence in construing the disputed terms.

CONCLUSION

In accordance with the foregoing, the court construes the disputed terms as follows:

1. "a method for treating Attention-Deficit Disorder or Attention Deficit Hyperactivity Disorder in a patient" means **"a method for treating ADD or ADHD in an individual."**

2. "administering a pharmaceutically acceptable composition comprising methylphenidate" means **"administering a pharmaceutically acceptable composition comprising methylphenidate once-daily."**

3. "[in a manner that achieves] as substantially ascending methylphenidate plasma drug concentration over a period of about [x] hours following said administration" means **"a profile in which the plasma concentration of methylphenidate generally rises over approximately [x] hours."**

4. "an oral tablet dosage form for the treatment of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder in a subject comprising" means **"a pharmaceutical composition in the form of a tablet that is intended to be administered orally to an individual who is being treated for ADD and/or ADHD."**

5. "an immediate release portion comprising methylphenidate" means **"a portion of the oral tablet dosage form containing an amount of methylphenidate that is substantially completely released within a time period of about 1 hour or less."**

6. "said sustained release portion releases more of said methylphenidate hydrochloride during said second interval than during said first interval, and more of said methylphenidate during said third interval than during said second interval" means **"the**

sustained release portion releases more of said methylphenidate during the second interval than during the first interval (if any), and more of said methylphenidate during the third interval than during the second interval."

7. "said sustained release portion releases more of said methylphenidate hydrochloride during said second interval than during said first interval, more of said methylphenidate hydrochloride during said third interval than during said second interval, and more of said methylphenidate hydrochloride during said fourth interval than during said third interval" means **"the sustained release portion releases more of said methylphenidate hydrochloride during the second interval than during the first interval (if any), and more of said methylyphenidate hydrochloride during the third interval than during the second interval, and more of said methylphenidate hydrochloride during the fourth interval than during the third interval."**

Pursuant to the court's Standing Order for Patent Cases, a case management conference will be held on May 22, 2014, at 2:00 p.m. The parties may stipulate to change this date for any other Thursday on which the court is available in May or June 2014.

IT IS SO ORDERED.

Dated: April 25, 2014

PHYLLIS J. HAMILTON
United States District Judge