UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DR. JAMES M. SWANSON,

Plaintiff,

v.

ALZA CORPORATION,

Defendant.
_____/

No. C 12-4579 PJH

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Defendant's motion for summary judgment came on for hearing before this court on February 4, 2015. Plaintiff appeared by his counsel Robert Yorio, Brian Bathhurst, Michael Adelsheim, and Bryan Boyle; and defendant appeared by its counsel George Pappas, Kurt Calia, and Courtney Forrest. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby GRANTS defendant's motion.

BACKGROUND

Defendant ALZA Corporation ("ALZA") developed and commercialized a prescription drug product known as Concerta® – a medication designed for the treatment of attention-deficit disorder ("ADD") and attention-deficit hyperactivity disorder ("ADHD") in children and adults. Concerta® is covered by several patents, including U.S. Patent No. 6,930,129 B2 ("the '129 patent," issued August 16, 2005), and U.S. Patent No. 8,163,798 B2 ("the '798 patent," issued April 24, 2012) ("the ALZA patents").

The ALZA patents are directed towards "Methods and Devices for Providing Prolonged Drug Therapy." They share the same specification and generally describe and claim compositions and methods for once-a-day treatment of ADD/ADHD with the drug methylphenidate ("MPH").

ALZA asserts that its scientists conceived of the inventions in the ALZA patents, and

that 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/ADD. This once-a-day treatment was considered to be an improvement over conventional MPH therapy, which was offered in two forms – Ritalin®-IR (an immediate-release or "IR" form, which required multiple daily MPH doses to achieve symptom control), and Ritalin®-SR (a once-daily sustained-release or "SR" form, which was allegedly not entirely effective at controlling symptoms).

Plaintiff Dr. James M. Swanson is Professor Emeritus of Pediatrics at the University of California, Irvine. He alleges that he is the inventor, or at least the co-inventor, of some of what is claimed in the ALZA patents. In the present action, he seeks an order declaring that he is the true inventor of the ALZA patents, or, in the alternative, an order invalidating the patents and/or finding them unenforceable for inequitable conduct.

Dr. Swanson began working in the field of ADHD research in 1977, focusing primarily on studying ADHD in children. In the course of his research, he developed procedures for monitoring the cognitive effects of stimulant medication using MPH, and he also participated in pioneering the development of improved methods for measuring the plasma concentration of MPH and its metabolite, in order to relate plasma concentrations to clinical efficacy. In addition, he collaborated on work on the biochemical and genetic factors related to ADHD. Declaration of James M. Swanson in Support of His Inventorship Contentions ("Inventorship Decl.") (Doc. 223-6) at 6.

In 1993, Dr. Swanson became a member of the NIMH-funded Psychopharmacology Committee of the Multimodal Treatment Study of ADHD ("the MTA Committee"). At that time, the MTA Committee was evaluating evidence and experience regarding the treatment of ADHD, including the optimal use of stimulant medication. Declaration of Dr. James M. Swanson in Support of Dr. Swanson's Responsive Claim Construction Brief ("Cl. Constr. Decl.") (Doc. 113) ¶ 18.

Dr. Swanson contends that as part of its determination of the optimal medication treatment regimen for the study, the Committee considered whether to use twice-a-day

("BID") dosing or three-times-a-day ("TID") dosing. He claims that BID dosing had been the standard for decades, with TID dosing used only in "atypical cases." Based on his earlier research, Dr. Swanson recommended TID dosing. See Plaintiff's Opposition to ALZA's Motion for Summary Judgment (Doc. 223-3) at 3-4.

The Committee decided to proceed with TID dosing, although the members of the Committee did not agree regarding the administration of the third dose of the TID regimen. Dr. Swanson advocated for an "unsculpted" or "equal dose" regimen – that is, one in which the third dose is equal to the first two doses administered. Cl. Constr. Decl. ¶ 19. He believed that an unsculpted TID regimen would result in more stable efficacy across the day. He asserts that he published work in 1988 showing that "the TID regimen produced profiles of serum levels that had peaks and valleys but were substantially ascending across the school day." He found that "this dosing was the best way to maintain the desired therapeutic effect in children suffering from ADHD." See Inventorship Decl. at 6-8, 15.

Dr. Swanson contends that despite his demonstration regarding the efficacy of the unsculpted TID regimen, a majority of the MTA Committee voted to use a "sculpted" TID regimen – one in which the third administration was reduced to approximately half the dose used in the first two administrations. Because he believed that the sculpted TID regimen approved by the Committee resulted in more of a "roller-coaster" effect throughout the day, he challenged the Committee's decision in September 1993, and asked for another vote. Nevertheless, he did not succeed in persuading the Committee to modify its decision. Cl. Constr. Decl. ¶ 19.

On December 6, 1993, Dr. Swanson participated in a meeting at ALZA's corporate headquarters. Inventorship Decl. at 9. Before that meeting, ALZA required that he sign a consulting agreement. Id. He asserts that this consulting agreement "pertained to the treatment of ADHD in children, which had nothing to do with ALZA's business activities, as ALZA was only a drug delivery company at that time." Id. Dr. Swanson contends that as of the time of the meeting, no one at ALZA knew anything about the treatment of ADHD in children. See id.

Dr. Swanson states that his presentation to ALZA on December 6, 1993, included his own work on pharmacokinetics and pharmacodynamics of stimulant medications. Id. at 9-10. The attendees at the meeting included individuals later named as inventors on the ALZA patents – Suneel K. Gupta, Andrew C. Lam, Carol A. Christopher, and Samuel R. Sacks. Id. at 9. Dr. Swanson could not recall anyone from ALZA at the December 1993 meeting making a contribution to his recommendation, or offering any recommendation except as to an 8-hour duration (which he claims would equate to BID dosing). Id. at 13.

Dr. Swanson contends he "had a strong opinion about the efficacy of the serum concentration dosing profile achieved by three times a day dosing, which was 'substantially ascending' with peaks and valleys associated with the multiple bolus doses[,]" which he considered to be the "gold standard of treatment for ADHD" with MPH. Id. at 12. He asserts that he spoke to the ALZA group for two hours about his work on MPH, and also spoke about the pharmacokinetics and behavioral time course of various drugs used for treatment of ADHD, describing the problems with each drug and their formulations. Id. at 12-13. He claims that at the meeting, in addition to discussing his theory of appropriate TID dosing, he also mentioned the need for a once-a-day pill (a dose that would last for approximately 12 hours) and/or "recommended" that such a pill be developed. Id.

Dr. Swanson asserts that after the December 1993 meeting, he participated in numerous conference calls and meetings discussing work that he and ALZA would be jointly performing, in which ALZA would confirm his recommendations for treatment of children with ADHD. Dr. Swanson describes the two "sipping studies," which occurred after the first meeting with ALZA in December 1993. See id. at 14-19. In particular, he states that he prepared the necessary consent forms to inform the parents and get their permission for their children to participate in the first sipping study. Id. at 16.

Dr. Swanson concedes that ALZA had "involvement" in the first sipping study, but argues that his work on it was at least a significant contribution to "the joint arrival at a definite and permanent idea of the element of the invention 'to achieve a substantially ascending methylphenidate plasma concentration over about a time period of 8 hours

following said administration." Id. at 17. He also claims that ALZA named him the principal investigator in the first study and that he wrote much of the protocol. Id. at 16. He asserts that he was the first person to analyze the data that resulted from that first study. Id.

Dr. Swanson contends that he wrote up the report and presented it to ALZA on December 6, 1994. On January 13, 1995, he presented ALZA with a final report. Id. at 18. He subsequently helped develop the protocol for ALZA's second study. Id. at 19-20.

Dr. Swanson, who claims he did not learn of the existence of the ALZA patents until April 2011, filed the original complaint in this action on August 30, 2012, and filed the first amended complaint ("FAC") on November 14, 2012. In the FAC, Dr. Swanson asserted ten causes of action. On March 26, 2013, ALZA filed an answer, and counterclaims alleging breach of contract and negligent misrepresentation.

The court subsequently granted ALZA's motion to dismiss the fourth, sixth, and tenth causes of action. Remaining in the case are the first cause of action for correction of inventorship of the ALZA patents under 35 U.S.C. § 256; the second cause of action for fraud; the third cause of action for breach of fiduciary duty; the fifth cause of action for unfair competition under California Business & Professions Code § 17200; the seventh cause of action for invalidity of the ALZA patents under 35 U.S.C. § 102(f); the eighth cause of action seeking a declaration of unenforceability for inequitable conduct; and the ninth cause of action seeking a declaration of ownership of the ALZA patents.

At the March 28, 2013 Case Management Conference, the court ordered Dr. Swanson to serve contentions identifying each claim of the ALZA patents to which he believed he contributed, specifying the claim element(s) to which he believed he contributed, and identifying all evidentiary bases for his contentions.

On April 25, 2013, Dr. Swanson served Inventorship Contentions alleging sole inventorship of two claims of the '129 patent, and co-inventorship of two claims of the '798 patent. The parties pursued discovery and claim construction based on the Inventorship Contentions, and Dr. Swanson provided responses to interrogatories concerning his alleged invention, which were coextensive with the Inventorship Contentions.

The court issued the Order Construing Claims on April 25, 2014. See Doc. 157. ALZA filed the present motion for summary judgment on June 13, 2014. The court subsequently extended the briefing schedule and continued the hearing date. On July 11, 2014, Dr. Swanson filed a motion for leave to amend his Inventorship and Invalidity Contentions. The court denied the motion on September 9, 2014, finding that it was neither timely nor supported by good cause. See Doc. 217.

ALZA now seeks summary judgment as to the first cause of action for correction of inventorship, and as to the causes of action remaining in the FAC on the basis that they all depend on Dr. Swanson's alleged status as an inventor of the ALZA patents.

DISCUSSION

A. Legal Standards

1. Motions for Summary Judgment

A party may move for summary judgment on a "claim or defense" or "part of . . . a claim or defense." Fed. R. Civ. P. 56(a). Summary judgment is appropriate when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Id.

A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion, and of identifying those portions of the pleadings and discovery responses that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Material facts are those that might affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. Id.

Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. Soremekun v. Thrifty Payless, Inc., 509 F.3d 978, 984 (9th Cir. 2007). On an issue where the nonmoving party will bear the burden of proof at trial, the moving party can prevail merely by pointing out to the court that there is an absence of evidence to support the

nonmoving party's case. Celotex, 477 U.S. at 324-25. If the moving party meets its initial burden, the opposing party must set out specific facts showing a genuine issue for trial in order to defeat the motion. Anderson, 477 U.S. at 250; see also Fed. R. Civ. P. 56(c), (e).

When deciding a summary judgment motion, a court must view the evidence in the light most favorable to the nonmoving party and draw all justifiable inferences in its favor. Anderson, 477 U.S. at 255; Hunt v. City of Los Angeles, 638 F.3d 703, 709 (9th Cir. 2011).

2. Inventorship

Inventorship is a question of law. Nartron Corp. v. Schukra U.S.A. Inc., 558 F.3d 1352, 1356 (Fed. Cir. 2009). The issuance of a patent creates a presumption that the named inventors are the true and only inventors. General Elec. Co. v. Wilkins, 750 F.3d 1324, 1329 (Fed. Cir. 2014). Thus, a person claiming to be an inventor must show by clear and convincing evidence that he contributed to the conception of the invention. Id.; see also Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1358, 1363 (Fed. Cir. 2004). The clear and convincing standard protects against a "strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention," particularly where "the patent has been outstanding for a considerable time and the patented device has been successful." Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997).

An inventorship analysis "begins as a first step with a construction of each asserted claim to determine the subject matter encompassed thereby." Trovan, Ltd. v. Sokymat SA, Irori, 299 F.3d 1292, 1302 (Fed. Cir. 2002). The next step is "to compare the alleged contributions of each asserted coinventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named." Id. "Conception is the touchstone of inventorship, the completion of the mental part of invention. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227-28 (Fed. Cir. 1994). Thus, "[d]etermining 'inventorship' is nothing more than determining who conceived the subject matter at issue." Sewall v. Walters, 21 F.3d 411, 415 (Fed. Cir. 1994).

Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention." Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998). The conceived idea – whether conceived by a single inventor or by joint inventors – must include every feature of the claimed subject matter, id., and for the idea to be "definite and permanent," only ordinary skill must be necessary to reduce it to practice, Burroughs, 40 F.3d at 1228. "An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." Id. In contrast, a person has not conceived of the invention, and is not an inventor, where he only "suggests" an idea or "simply provides the inventor with well-known principles or explains the state of the art." Ethicon, 135 F.3d at 1460; see also Hess, 106 F.3d at 980-81.

B. Defendant's Motion

ALZA contends that the court's claim construction forecloses Dr. Swanson's claim of inventorship of the '129 and '798 patents, and that the remaining causes of action in the FAC fail because they depend on the flawed inventorship claim.

Dr. Swanson alleges in his Inventorship Contentions that he alone conceived of the subject matter recited in claims 1 and 2 of the '129 patent, and that he did so prior to meeting with ALZA. These claims recite a method for treating ADD/ADHD, wherein the method comprises administering a pharmaceutically acceptable composition comprising MPH "in a manner that achieves a substantially ascending methylphenidate plasma drug concentration" over a time period of about 8 hours (Claim 1) or 9.5 hours (Claim 2) following administration. See '129 Patent, Claims 1 and 2.

ALZA argues that Dr. Swanson's Inventorship Contentions, discovery responses, and evidence all reflect his belief that the claims of ALZA's patents encompass TID dosing. Indeed, ALZA notes that Dr. Swanson pursued claim constructions that encompassed this TID unsculpted regimen ("one of more approximately equal doses of methylphenidate per day"). See Resp. Claim Constr. Br. at 10. However, ALZA asserts, that method of TID dosing is distinct from the '129 patent's "administering a pharmaceutically acceptable

composition" comprising MPH "in a manner that achieves a substantially ascending plasma drug concentration as described in the claims of the patent" as construed by the court. ALZA contends that Dr. Swanson's inventorship theory necessarily does not disclose a once-daily MPH product or method with a "substantially ascending" plasma profile (i.e., no "peaks and troughs").

ALZA contends that because the claims of the '129 patent are directed to novel once-daily treatment methods, they do not encompass the subject matter that Dr. Swanson alleges he invented. See Order Construing Claims at 13. ALZA asserts that while Dr. Swanson alleges that he conceived of the plasma drug concentration profile resulting from equal doses of IR-MPH given TID spaced four hours apart, none of Dr. Swanson's evidence discloses a once-daily MPH product or method with a "substantially ascending" plasma profile as construed by the court.

In the claim construction order, the court determined that the claimed "substantially ascending methylphenidate plasma drug concentration" excludes the plasma drug concentration profile of Plaintiff's "gold standard" TID dosing:

> 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.

Order Construing Claims, at 17.

Thus, ALZA argues, as properly construed by the court, Claims 1 and 2 of the '129 patent encompass "administering a pharmaceutically acceptable composition comprising methylphenidate once-daily in a manner that achieves a profile in which the plasma concentration of methylphenidate generally rises over approximately [8 or 9.5] hours." Id. at 29. ALZA asserts that because Dr. Swanson has never alleged inventive conception of a once-daily method of treatment resulting in the claimed generally rising plasma concentration profile as construed by the court, the court should find that Dr. Swanson is not an inventor of the '129 patent.

In short, ALZA contends that Dr. Swanson cannot be an inventor of the '129 patent

because the concepts he alleges he conceived differ from the subject matter claimed and because all of his allegedly inventive contributions were known in the prior art. ALZA argues that no genuine disputes of material fact exist on these points, and ALZA is thus entitled to summary judgment as a matter of law that plaintiff is not an inventor of Claims 1 and 2 of the '129 Patent.

Similarly, ALZA argues, Dr. Swanson cannot show inventorship of the claims of the '798 patent, because his Inventorship Contentions allege only conception of subject matter that is not claimed; because presentation and explanation of prior art knowledge to the true inventors does not constitute inventive contribution; and because he has not alleged that his purported inventive contributions were made in collaboration with the ALZA inventors.

Dr. Swanson asserts that he solely conceived of certain elements in Claims 1 and 7 of the '798 patent, and that he jointly conceived of all other claim elements. The '798 patent claims "an oral tablet dosage form" of MPH with an "immediate release portion" (or "immediate release coating"), and a sustained release portion that releases MPH over three (or four) sequential one-hour time intervals, with more MPH being released during each sequential interval than during the prior interval. '798 Patent, Claims 1 and 7. Dr. Swanson contends that he solely conceived of the preamble language in Claims 1 and 7. Inventorship Contentions at 11, 17. He also claims sole conception of "an immediate release portion comprising methylphenidate or a pharmaceutically effective salt thereof" recited in Claim 1, and otherwise alleges joint conception of the remaining claim elements. Id. at 12-20.

Dr. Swanson supports his claim of inventorship of the "oral dosing form" recited in claims 1 and 7 by pointing to his concern over the difficulties with the midday dose of MPH with multiple adminstrations of IR-MPH to children during the school day. See Inventorship Decl. at 12. However, ALZA asserts, these difficulties with administering MPH during the school day were well-known in the prior art, and were in fact what had prompted the development of the earlier MPH-SR formulations that would allow once-a-day dosing.

In his claim construction briefing, Dr. Swanson also took the position that "an oral

tablet dosage form" meant "one or more dosage forms" and that "an immediate release portion comprising methylphenidate" should encompass "a first oral dose of instant release methylphenidate," which would implicitly be followed by subsequent doses. See Plaintiff's Responsive Claim Construction Statement ("Resp. Cl. Constr. Br.") (Doc. 112) at 22-23; Cl. Constr. Decl. ¶ 51. He also urged a claim construction that would encompass TID dosing and resulting "time course effects." See Inventorship Contentions at 11-20; Resp. Cl. Constr. Br. at 22-24.

ALZA argues that a comparison of Dr. Swanson's alleged invention to the properly-construed claims of the '798 patent confirms that his alleged invention does not fall within the scope of the '798 patent. ALZA reiterates that the court found that the '798 patent "does not claim an 'immediate release portion' that is one dose, and subsequent, separate doses," but rather claims a once-daily dosage form having an IR portion and a SR portion. See Order Construing Claims at 21. Similarly, ALZA asserts, neither the claim language nor the specification supported plaintiff's attempt to interpret the '798 patent claims to "refer to the 'effect-time profile' and/or therapeutic efficacy 'similar' to that of TID dosing;" instead, the claims cover a once-daily oral dosage form with increasing release of MPH in sequential time intervals. Order Construing Claims at 20, 25-26. Accordingly, ALZA asserts, Dr. Swanson cannot be an inventor (joint or otherwise) of Claims 1 and 7 of ALZA's '798 patent.

ALZA also contends that Dr. Swanson's presentation of what was known in the prior art does not constitute inventive contribution. To support his inventorship claim to the '798 patent, Dr. Swanson couples his prior work on IR-MPH administered BID or TID with the well-understood need for a once-daily product that would avoid the embarrassment and inconvenience associated with multiple administrations during the day. In his declaration, Dr. Swanson states that he "recommended" that ALZA develop a once-daily dosage form. See Inventorship Decl. at 12. However, ALZA argues, the need for an effective once-daily MPH product avoiding the mid-day dose in BID and TID was well known in the art long before Plaintiff visited ALZA in late 1993. See Order Construing Claims at 2 (referring to

ineffective once-daily Ritalin®-SR product).

ALZA argues that BID and TID IR-MPH regimens, including Dr. Swanson's own work, were also prior art. ALZA contends that Dr. Swanson's presentation to ALZA of known BID and TID regimens and the need to eliminate multiple daily dosing does not make him a co-inventor, as a person will not be a co-inventor if he/she does no more than explain to the real inventors concepts that are well known and the current state of the art.

As for whether Dr. Swanson can claim to be an inventor of the "once-daily pill," ALZA notes that Dr. Swanson has admitted that ALZA was already considering a once-daily pill prior to the December 1993 meeting. For example, he stated in his Inventorship Declaration that "I also recommended the need for a once a day pill that was being considered by the ALZA group." Inventorship Decl. at 12. In other words, ALZA asserts, Dr. Swanson merely "recommended the need." However, he did not propose the solution to meet that need. ALZA argues that a "recommendation" does not amount to an inventive contribution supporting co-inventorship, and Dr. Swanson has provided no evidence that he made any contributions to the inventions of the disputed claims of the '798 patent in collaboration with the ALZA inventors.

In sum, ALZA contends that Dr. Swanson cannot be a joint inventor of the '798 patent because the concepts he alleges he conceived differ from the subject matter claimed, because all of his allegedly inventive contributions were known in the prior art, and because he did not collaborate with the actual inventors to "jointly arrive" at the invention. ALZA argues that no genuine disputes of material fact exist on any of these points, and the court should therefore grant summary judgment as a matter of law that Dr. Swanson is not an inventor of any claims in the '798 patent.

In opposition, Dr. Swanson asserts that he is the sole inventor of claims 1 and 2 of the '129 patent, and that he is at least a co-inventor of the '129 patent and the '798 patent. He contends that because of the evidence that relates to his "key role" in the development of the patents-in-suit, many triable issues of fact remain, and ALZA’s motion should be denied.

In his first main argument, Dr. Swanson asserts that he is the sole inventor of claims 1 and 2 of the '129 patent. He first points to the term "administering a pharmaceutically acceptable composition comprising methylphenidate," which the court construed as meaning "administering a pharmaceutically acceptable composition comprising methylphenidate once-daily." See Order Construing Claims at 8-13. He claims he conceived of the "inventive step" of "administering a pharmaceutically acceptable composition comprising methylphenidate once-daily" and that this is specifically addressed in his Inventorship Declaration, where he stated, "I also recommended the need for a once a day pill that was being considered by the ALZA group[;], and further, that based on the December 6, 1993 agenda, "ALZA still had not decided upon the methylphenidate delivery system to employ," i.e., TTS® skin patch or OROS® pill.[1]

Dr. Swanson takes issue with ALZA's contention that his Inventorship Contentions allege only methods and compositions involving IR-MPG given TID in equal doses. He contends that this representation is false because at the time of the December 1993 meeting, he was "recommending" a once-daily pill delivery system. He also notes that he mentioned this recommendation in his Inventorship Declaration. See Inventorship Decl. at 12 & n.14. He asserts that ALZA has presented no evidence showing that he did not conceive of the idea of utilizing a once-daily administration of MPH as claimed in the '129 patent.

Dr. Swanson claims that he also conceived of the novel discovery recited in claims 1 and 2 of the '129 patent – "[in a manner that achieves] a substantially ascending methylphenidate plasma drug concentration over a period of about [x] hours following said administration." The court construed this term as meaning "a profile in which the plasma concentration of methylphenidate generally rises over approximately [x] hours" – with [x] hours being either 8 hours or 9.5 hours, depending on claims 1 or 2, respectively.

Dr. Swanson contends that he discussed this "substantially ascending" discovery

[1] OROS® is a controlled-release oral drug delivery system in the form of a tablet.

with ALZA at the December 6, 1993 meeting. He also provides declarations from former colleagues and/or students stating that the idea of administering MPH in a manner that results in a gradually ascending MPH concentration was his alone. He asserts that his work "demonstrated that MPH exhibits linear of 'first order kinetics,'" and that it was a combination of his "unique knowledge" with "pharmacokinetic principles known in 1993" that produced claims 1 and 2 of the '129 patent.

The gist of his argument is that ALZA's lack of experience in treating ADD/ADHD patients with MPH, viewed in conjunction with his own extensive experience in treating ADD/ADHD patients with MPH, plus his advocacy of TID unsculpted dosing to produce a generally ascending profile (plus his recommendation of single daily pill dosing), can mean only that a material issue of fact exists with regard to whether he invented this claim element.

As for the element "over a time period of about [8 or 9.5] hours following said administration," Dr. Swanson contends that ALZA "reached out" to him for his concepts about how long the treatment coverage should last. He cites a January 6, 1994 e-mail from Dr. Christopher of ALZA, in which she asked questions regarding matters that had been raised at an ALZA meeting the previous day, including whether providing 24-hour delivery is important. She stated that Dr. Swanson's response was that they should focus on providing 8 hours of constant delivery – which would represent a significant advantage over the swings in plasma levels a child experiences over 3-4 hours.

In another e-mail, Dr. Christopher stated that at Dr. Swanson's recommendation, she had talked to two other doctors, both of whom recommended a duration of 12-16 hours (as opposed to 8 hours advocated by Dr. Swanson). Dr. Swanson contends that this demonstrates that he had a "clear and concise idea about the period of treatment, namely 8 hours," which is the same period of treatment that appears in claim 1 of the '129 patent. He argues that the fact that ALZA's patent uses this 8-hour period – but that ALZA (according to him) never actually claimed that its scientists came up with a concept of 8 hours of treatment – shows that there are triable issues with regard to whether he is the sole

inventor of claims 1 and 2 of the '129 patent.

Dr. Swanson asserts that he was never informed by ALZA that it had filed a patent application that included elements of what he had presented to ALZA at the December 1993 meeting, and that other facts that raise triable issues with regard to whether he invented what is claimed in the '129 patent include the fact that ALZA needed a person with his expertise with MPH treatment for ADD/ADHD; the fact that that he had an extensive background with MPH and treating patients with ADD/ADHD; the fact that ALZA proposed that he and ALZA work together on the MPH project; the fact that he and ALZA had a business relationship based on his status as a "consultant;" the fact that he worked with ALZA for "years;" and the fact that there is a similarity between ALZA's "invention" and his own work with TID unsculpted dosing.

In his second main argument, Dr. Swanson asserts that at a minimum, he is at least a co-inventor of the '129 patent and the '798 patent. With regard to the '129 patent, he argues that in working with the ALZA employees, he contributed to both the conception and the reduction to practice of the claims of the '129 patent, and that this entitles him to at least joint inventorship status. He contends that the court's construction of claim 1 as including once-daily dosing does not eliminate the other significant contributions that he made, which he asserts create a genuine issue of material fact as to whether he is a co-inventor on the claims of the '129 patent.

Similarly, with regard to the '798 patent, Dr. Swanson reiterates that he "advocated" and "contributed" to the conception of an oral pill form, since ALZA (as of the December 1993 meeting) had not determined whether to proceed with a pill form or a skin patch form. He bases this assertion on the list of agenda items for the December 1993 meeting, which he has incorporated into his Inventorship Declaration. He argues that the fact that he recommended a once-a-day pill to ALZA shows that he contributed to the "oral table dosage form" term of claims 1 and 7 of the '798 patent. In addition, he points to his statement in his Inventorship Declaration that following the initial meeting at ALZA in December 1993, he had numerous conference calls and meetings discussing the work that

he was going to do jointly with ALZA. See Inventorship Decl. at 15.

He asserts further that during the first sipping study, he recommended that the study use "an initial bolus followed by an ascending profile," but that ALZA's Dr. Gupta recommended an ascending profile without a bolus. Id. at 15, 17. He contends that this fact shows his contribution to the patent claims because the initial bolus concept became the "immediate release" portion or coating. He cites the declaration of his colleague Dr. Tim Wigal, who states that Dr. Swanson suggested that "a slightly ascending pattern of drug plasma concentration (rather than flat) would combat some of the acute tolerance [that patients sometimes experienced] and maintain efficacy."

Dr. Swanson argues that based on the testimony in his Inventorship Declaration, plus the corroborating evidence in the Wigal Declaration, there remain material issues of fact as to whether he is at least a co-inventor of claims 1 and 7 of the '798 patent. He asserts that his own declaration shows that he was the first person to recommend to ALZA that it use an oral dosage form instead of a patch, and that he was the sole person to advocate for the use of MPH instead of other stimulant drugs being considered by ALZA.

Finally, with regard to ALZA's argument that the remaining claims should be dismissed because they are all dependant on the inventorship claim, Dr. Swanson responds that given the existence of triable issues as to his status as the inventor of the '129 and '798 patents, summary judgment cannot be granted as to the remaining claims.

The court finds that the motion must be GRANTED. The first step in the inventorship analysis is determining the scope of the claimed invention. Trovan, 299 F.3d at 1302. Here, the court has performed that first step in the claim construction order. See Order Construing Claims. All that remains is to compare Dr. Swanson's alleged contributions with the subject matter of the claims as construed.

Dr. Swanson conducted research for years on treatment of ADHD in children – including treatment with MPH. He at some point reached a conclusion that TID dosing, using equal doses throughout the day, produced the optimal results. Inventorship Decl. at 6-8, 12. He published research to this effect, and it was one of the options that the MTA

Committee considered for its study protocol in 1993 (although the Committee voted instead to adopt the sculpted TID dosing for the study). However, as the court made clear in the claim construction order, the unsculpted TID dosing that Dr. Swanson was advocating is different from the method that ALZA adopted in its patented claims.

Moreover, the Inventorship Contentions rely exclusively on multiple administrations of MPH (TID unsculpted). Dr. Swanson is bound by the theories and evidence disclosed in his Inventorship Contentions, as they serve a function similar to that of infringement or invalidity contentions: "[T]o prevent the parties from shuffling or re-framing their theories in reaction to adverse substantive rulings." See CBS Interactive, Inc. v. Etilizie, Inc., 257 F.R.D. 195, 202 (N.D. Cal. 2009); see also O2 Micro Int'l Ltd. v. Monolithic Power Sys. Inc., 467 F.3d 1355, 1366 n.12 (Fed. Cir. 2006)). Dr. Swanson cannot now rely on theories and evidence outside of his Inventorship Contentions in an attempt to defeat summary judgment when his request to amend them was denied as untimely and unjustified.

Dr. Swanson contends he made three potential inventive contributions to claims 1 and 2 of the '129 patent – the "substantially ascending" plasma drug profile, the recommendation to develop a once-daily pill rather than a transdermal patch, and the recommendation that the duration of treatment be about 8 hours. With regard to the "substantially ascending" plasma drug profile, the court previously determined in the claim construction order that ALZA's invention is not the peaks-and-troughs plasma profile produced by unsculpted TID dosing. See Order Construing Claims at 17 (construing claimed "substantially ascending plasma drug concentration" as one that "generally rises," and finding that it was clearly distinguished in the patent from prior art TID regimens having peaks and troughs). It follows that the prior art peaks-and-troughs profile does not "generally rise," regardless of whether the peaks ascend.[2]

Dr. Swanson's discussion of "first order kinetics" boils down to an argument that ascending peaks and troughs result from the unsculpted TID regimen because each

[2] The '129 Patent itself distinguishes the claimed experimental regimen from the prior art IR-MPH administered TID in equal doses. See '129 Patent at 21:24-22:27 & Fig. 4.

successive dose is given before the previous dose has been fully eliminated from the body, and if those peaks and troughs were evened out, what would remain would be a profile that "generally rises." This theory fails for several reasons. First, it was not specifically disclosed in the Inventorship Contentions. Dr. Swanson proffers a declaration by an expert – Dr. C. Lindsay DeVane – in support of his opposition to the present motion, but Dr. DeVane did not submit a declaration in support of the Inventorship Contentions and none of Dr. DeVane's opinions were disclosed to ALZA until Dr. Swanson filed his opposition. While Dr. Swanson did attempt to amend his Inventorship Contentions to add this "first order kinetics" theory after ALZA filed its motion for summary judgment, the court denied the motion. He thus cannot rely upon it, or the DeVane Declaration, to avoid summary judgment.

The court previously rejected similar arguments that Dr. Swanson made during claim construction. For example, Dr. Swanson stated in his claim construction declaration that his "gold standard" unsculpted TID regimen produces peaks and troughs in plasma drug concentration, but "[b]ased on the basic principles of clinical pharmacology, each successive peak and trough is higher than the previous peak and trough until a steady state is reached." Cl. Constr. Decl. ¶ 24. However, this theory simply repackages the prior argument that the ascending peaks-and-troughs profile resulting from unsculpted TID administration falls within the scope of ALZA's patents. The court's construction of the disputed terms makes clear that it does not. See Order Construing Claims at 17-19.

Moreover, the prior art TID profile is not, as Dr. Swanson claims in the opposition, the basis for the invention of the '129 patent. This argument appears to be an attempt to resurrect the failed claim construction argument that the claims are directed to an "effect-time profile" and/or therapeutic efficacy "similar" to TID dosing. See Order Construing Claims at 15-17. ALZA's goal was to invent a once-daily method of treatment having similar efficacy to TID, but with a different plasma drug concentration profile. However, ALZA's desire to develop a once-daily drug that was at least as effective as the prior art does not make Dr. Swanson an inventor of ALZA's invention.

With regard to the second potential inventive contribution – the once-daily pill – the record shows that a once-daily MPH treatment for ADHD already existed in the prior art as Ritalin SR®. Thus, even assuming that Dr. Swanson did advocate for a once-daily pill, this is insufficient to render him an inventor of the '129 patent. Dr. Swanson conceded in his opposition to the present motion that ALZA was already considering a once-daily pill before the December 6, 1993 consultant meeting. Dr. Swanson's alleged recommendation of one design choice or the other is not an inventive contribution. See Burroughs, 40 F.3d at 1228.

With regard to the third potential inventive contribution – the duration of treatment (whether 8 or 9.5 hours) – treating ADD/ADHD throughout the school or work day was well known in the prior art. Moreover, merely explaining to the real inventors "concepts that are well known and the current state of the art" does not transform a person into a joint inventor. See Fina Oil and Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). It is undisputed that at least twice-daily (BID) IR-MPH had been used to treat ADD/ADHD for 8 hours for many years prior to ALZA's invention. See, e.g., FAC ¶ 175. By contrast, ALZA's invention produced a novel once-daily product and method of treatment for ADD/ADHD that maintained efficacy across the same or similar periods of time.

Dr. Swanson's argument regarding duration of treatment also conflicts with his prior representations about who initially recommended an 8-hour duration of treatment. He states in his opposition that he was the only one to recommend to ALZA that the once-daily treatment for ADHD should last 8 hours – and that the other two consultants told ALZA's Dr. Christopher that the treatment should last 12-16 hours. However, in the FAC, Inventorship Contentions, and Inventorship Declaration, he asserted that he recommended that the duration of treatment exceed 8 hours, and that it approximate the 12-hour duration of his "gold standard" unsculpted TID regimen:

> Dr. Swanson also recommended at the December 6, 1993 meeting at ALZA in Palo Alto, CA the need for a once a day pill. His recommendation included a pill with effects lasting for a school day. With early morning dosing, this would be longer than 8 hours (the duration for twice a day (BID) dosing regimen of immediate release methylphenidate) and more in line with a

> 12-hour duration of the three times a day (TID) regime that he had used in his early work on the pharmacokinetic (PK) properties of this drug.

FAC ¶ 43.

> My recommendation included a pill with effects lasting for a school day. With early morning dosing, this would be longer than 8 hours (the duration for BID dosing regimen of immediate-release methylphenidate) and more in line with a 12 hour duration of the TID regime that I used in my early work on the PK properties of the drug.

Inventorship Contentions at 12.

> Importantly, I do not recall that anyone from the ALZA group at the December 6, 1993 meeting contributed to my recommendation or offered any recommendation, other than to insist on an 8-hour duration (equivalent to the BID standard) rather than a 12-hour duration (equivalent to a TID standard) that I had emphasized in my research and had described in publications about my work in Toronto and at UCI.

Inventorship Decl. at 13.

The claims of the '129 patent, as construed by the court, do not encompass the subject matter that Dr. Swanson alleges he invented, and he has failed to identify any inventive contributions to any element in claims 1 or 2 of the '129 patent.

Nor can Dr. Swanson show any disputed issue with regard to the inventorship of the '798 patent. He asserts that he "recommended" or advocated for the use of a once-daily pill. However, the fact that he now claims that he "recommended" that ALZA develop a once-daily dosage form does not support his claim to be a co-inventor of the '798 patent, as the need for an effective once-daily MPH product was well known in the art long before he visited ALZA in December 1993. Moreover, ALZA was already considering a once-daily pill as of the time of the December 1993 meeting; and Ritalin®-SR was already being administered as a once-daily pill, so the concept was clearly part of the prior art.

Finally, Dr. Swanson has not alleged any basis on which his work with ALZA in or after December 1993 amounts to joint inventorship of either patent. While persons may be joint inventors even though they do not physically work on the invention together or at the same time, joint inventorship, by definition "requires at least some quantum of collaboration or connection." Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co. Inc., 973 F.2d 911, 917 (Fed. Cir. 1992); see also Falana v. Kent State Univ., 669 F.3d 1349, 1357 (Fed. Cir.

2012); Eli Lilly, 376 F.3d at 1359. "[E]ach inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice." Burroughs, 40 F.3d at 1229.

Dr. Swanson specifically alleges that his entire conception occurred before he ever met with ALZA, which allegation forecloses the possibility of any collaboration or open lines of communication with the ALZA inventors. He has consistently maintained that his conception of the claims at issue occurred prior to his December 1993 consultancy with ALZA, and that his inventive conception was complete by November 17, 1993, before he alleges he first met with ALZA. Thus, as he cannot demonstrate any aspect of collaboration with ALZA, his position cannot be reconciled with a claim of joint inventorship.

> I was one of the first researchers in the ADHD field to describe "a substantially ascending methylphenidate plasma drug concentration" in the treatment of ADHD which is a critical element of Claim 1 of the '129 patent. [In my early work,] I described a blood plasma curve depicting a substantially ascending pattern for TID dosing for methylphenidate. . . .

Inventorship Decl. at 6-7.

> My work published in 1988 showed that the TID regimen produced profiles of serum levels that had peaks and valleys but were substantially ascending across the school day.

Inventorship Decl. at 8.

> [B]efore ever meeting with anyone from ALZA . . . I had a strong opinion about the efficacy of the serum concentration dosing profile achieved by three times a day dosing, which was "substantially ascending" with peaks and valleys associated with the multiple bolus doses.

Id. at 12.

> These plasma concentrations [from my previous research] achieved successively higher peaks and thus a 'substantially ascending' methylphenidate plasma drug concentration throughout the school day. I recommended this as the 'gold standard' . . . ."

Id. at 15.

> The sipping studies confirmed what my previous work had shown prior to ever meeting with ALZA – that dosing regimens with equal bolus doses at each administration, expected to produce a substantially ascending concentration of methylphenidate in the blood over the course of the day, would be optimal treatment for ADHD.

Id. at 17.

In his responses to interrogatories, Dr. Swanson confirmed that each element of the claims identified in his Inventorship Contentions was "conceived of no later than November 17, 1993," which was before his initial meeting with ALZA in December 1993. Later, at the claim construction hearing, Dr. Swanson's counsel reiterated that Dr. Swanson "invented this invention prior to ever coming to ALZA." Markman Hearing Transcript, Feb. 20, 2013 (Doc. 57) at 8.

There is no material dispute that the allegations and evidence provided by Dr. Swanson and his corroborators concerning facts prior to December 1993 relate only to multiple daily administrations of IR-MPH and the resulting peaks-and-troughs plasma drug concentration profiles. Thus, even assuming all of Dr. Swanson's allegations to be true, none of his evidence concerns "substantially ascending" serum levels resulting from once-daily administration, as claimed in ALZA's patents. See Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1328-29 (Fed. Cir. 2004).

As for Dr. Swanson's description of the post-December 1993 interactions between himself and ALZA, he does not explain how that relationship constitutes a contribution to the conception of a joint invention. See Wilkins, 750 F.3d at 1332; Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297, 1303 (Fed. Cir. 2010). Instead, he offers a new theory in his opposition – that the "initial bolus concept [that he allegedly recommended prior to the first sipping study] became the immediate release portion or coating" in Claims 1 and 7 of the '798 patent. See Opp. at 27. Because Dr. Swanson has alleged conception of each element of the disputed claims before ever meeting with ALZA, his claims about his much later work on the sipping study are irrelevant to a determination whether he was an inventor of the '798 patent.

The Inventorship Contentions never connect Dr. Swanson's alleged recommendation of an "initial bolus" for the first sipping study to the claims of the '798 Patent. The Inventorship Contentions cite only the 1978 Bloomingdale reference in support of his alleged conception of this element. This, like all the other prior art references cited in the Inventorship Contentions, relates to multiple daily doses of IR-MPH, not an "immediate

release portion" of a once-daily product that also contains a sustained release portion, as claimed in the '798 patent.

Ideas that Dr. Swanson allegedly conceived independently, long before his first meeting with ALZA, cannot be ideas that he and the ALZA inventors conceived "jointly" within the meaning of § 116(a). See Vanderbilt Univ., 601 F.3d at 1303. Moreover, to the extent that he is suggesting that ALZA's inventors built upon his presentation regarding BID and TID administration of IR-MPH and the associated plasma drug concentration profiles in developing the claimed once-daily dosage form, such information is not an inventive contribution because it simply reflects what was known in the prior art.

Nor has Dr. Swanson shown that his work from the sipping studies provided any inventive contribution to the claims as construed by the court; rather, he has indicated that the studies – which he conducted after the December 1993 meeting with ALZA – served only to confirm concepts he had discovered prior to his consultancy with ALZA. See Inventorship Contentions at 11-17; Inventorship Decl. at 17 ("[t]he sipping studies confirmed what my previous work had shown prior to ever meeting with ALZA . . ."); 20 (describing the second sipping study as "really not necessary" and "intended to be a confirmatory study"). In addition, the sipping study did not involve a once-daily product and thus was not an embodiment of the invention.

Dr. Swanson has failed to identify any inventive contributions to any element in Claims 1 or 7 of the '798 patent that he allegedly jointly made with ALZA's inventors, or communicated to ALZA during their collaboration.

CONCLUSION

In accordance with the foregoing, the court finds that ALZA's motion for summary judgment must be GRANTED. There is no evidence sufficient to establish inventorship by clear and convincing evidence, or to create a material dispute of fact regarding Dr. Swanson's alleged contributions to either the '129 patent or the '798 patent.

The undisputed facts establish that the patents at issue, ALZA's U.S. Patent Nos. 6,930,129 and 8,163,798 as construed by the court do not claim the subject matter Dr.

Swanson alleges he invented, and therefore ALZA is entitled to summary judgment as a matter of law that Dr. Swanson is not an inventor of ALZA's patents.

Accordingly, the first cause of action in the FAC is DISMISSED with prejudice. Moreover, because each remaining cause of action in the FAC depends on Dr. Swanson's alleged status as an inventor of ALZA's patents and the court has found that he is not, the remaining causes of action fail as a matter of law. Accordingly, the second (fraud), third (breach of fiduciary duty), fifth (unfair business practices), seventh (invalidity), eighth (unenforceability), and ninth (declaration of ownership) causes of action are also DISMISSED with prejudice. Finally, because the court previously dismissed the fourth, sixth, and tenth causes of action, the FAC is DISMISSED with prejudice in its entirety.

Remaining in the case are ALZA's counterclaims, for breach of contract and negligent misrepresentation. The parties shall meet and confer, and shall thereafter either notify the court no later than April 16, 2015 whether the counterclaims can be settled, or appear at a case management conference on April 23, 2015, at 2:00 p.m., for the purpose of setting pretrial and trial dates for the counterclaims.

IT IS SO ORDERED.

Dated: March 20, 2015

PHYLLIS J. HAMILTON
United States District Judge