UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ISIS PHARMACEUTICALS, INC., a Delaware Corporation, Plaintiff, v. SANTARIS PHARMA A/S CORP., a Delaware Corporation, and SANTARIS PHARMA A/S, a Danish Corporation, Defendants. AND RELATED COUNTERCLAIMS.	Case No. 3:11-cv-2214-GPC-KSC **ORDER DENYING DEFENDANTS' MOTION FOR RECONSIDERATION** **(ECF NO. 258)**

Prior to this patent infringement case's transfer to the undersigned, the Honorable Barry Ted Moskowitz, Chief Judge, denied Defendants' first motion for summary judgment as to whether Defendants' allegedly infringing conduct fell within the "safe harbor" provided by 35 U.S.C. § 271(e)(1). (ECF No. 53.) On February 27, 2014, after a lengthy period of limited discovery, this Court denied Defendants' second motion for summary judgment on the safe harbor issue. (ECF No. 250.)

Presently before the Court is Defendants' motion for reconsideration of this Court's February 27, 2014 order, (ECF No. 258), which has been fully briefed, (ECF

Nos. 266, 268), and which the Court finds suitable for disposition without oral argument, see CivLR 7.1.d.1.

Defendants ask the Court to reconsider three aspects of its February 27, 2014 order:

1. The Court's reading of Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2012), and Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc., 686 F.3d 1348 (Fed. Cir. 2012), as standing for the proposition that, "regardless of the stage of the regulatory process in which a patented invention is used to obtain information, the information derived from using the patented invention must be 'reasonably related' to the type of information required by the FDA at some point during the regulatory process."
2. The Court's conclusion that Santaris's act of entering into contracts with U.S. pharmaceutical companies to discover and develop drugs that the pharmaceutical companies may submit to the FDA does not, as a matter of law, fall within the safe harbor.
3. The Court's conclusion that the term "patented invention," as used in 35 U.S.C. § 271(e)(1), means inventions that would be eligible for a patent extension under 35 U.S.C. § 156 or inventions that are themselves subject to regulatory approval.

(ECF No. 258-1.)

In the alternative, Defendants ask the Court to certify its February 27, 2014 order for interlocutory appeal.

1. Reconsideration

a. Legal Standards

District courts have the discretion to reconsider interlocutory rulings until a final judgment is entered. Fed. R. Civ. P. 54(b); United States v. Martin, 226 F.3d 1042, 1048-49 (9th Cir. 2000). While the Federal Rules of Civil Procedure do not set forth

a standard for reconsidering interlocutory rulings, the "law of the case" doctrine and public policy dictate that the efficient operation of the judicial system requires the avoidance of re-arguing questions that have already been decided. See Pyramid Lake Paiute Tribe of Indians v. Hodel, 882 F.2d 364, 369 n.5 (9th Cir. 1989).

As such, most courts adhere to a fairly narrow standard by which to reconsider their interlocutory rulings. This standard requires that the party show: (1) an intervening change in the law; (2) additional evidence that was not previously available; or (3) that the prior decision was based on clear error or would work manifest injustice. Id.; Marlyn Natraceuticals, Inc. v. Mucos Pharma GmbH & Co., 571 F.3d 873, 880 (9th Cir.2009); Sch. Dist. No. 1J v. ACandS, Inc., 5 F.3d 1255, 1263 (9th Cir.1993).

Reconsideration is an "extraordinary remedy, to be used sparingly in the interests of finality and conservation of judicial resources." Kona Enters., Inc. v. Estate of Bishop, 229 F.3d 877, 890 (9th Cir. 2000). "'A motion for reconsideration is not an opportunity to renew arguments considered and rejected by the court, nor is it an opportunity for a party to re-argue a motion because it is dissatisfied with the original outcome.'" FTC v. Neovi, Inc., 2009 WL 56130, at *2 (S.D. Cal. Jan. 7, 2009) (quoting Devinsky v. Kingsford, 2008 WL 2704338, at *2 (S.D.N.Y. July 10, 2008)).

In addition to these substantive standards, Civil Local Rule 7.1.i.1 requires a party moving for reconsideration to submit an affidavit or certified statement of an attorney

> setting forth the material facts and circumstances surrounding each prior application, including inter alia: (1) when and to what judge the application was made, (2) what ruling or decision or order was made thereon, and (3) what new or different facts and circumstances are claimed to exist which did not exist, or were not shown, upon such prior application.

Rule 7.1.i.2 provides that "any motion or application for reconsideration must be filed within twenty-eight (28) days after the entry of the ruling, order or judgment sought to be reconsidered."

b. Analysis

Before proceeding to the merits of Defendants' motion for reconsideration, the Court addresses Plaintiff's argument that the attorney declaration Defendants filed in support of their motion for reconsideration fails to comply with Rule 7.1.i.1 because it fails to identify new or different facts and circumstances that did not exist before. The Court also addresses Plaintiff's argument that Defendants' motion for reconsideration is untimely under Rule 7.1.i.2 because, more than two years ago, "Judge Moskowitz reached essentially the same conclusions of law about which Santaris now complains." More specifically, Plaintiff asserts "Santaris's contentions that the uncertain nature of its contracts does not vitiate the Safe Harbor protection and that the Safe Harbor extends to situations in which a biological compound is used as a 'research tool' were squarely rejected by Judge Moskowitz."

Here, the Court agrees that Defendants have failed to submit an affidavit or certified attorney statement that complies with Rule 7.1.i.1 because the declaration provided by Defendants does not set forth any new or different facts and circumstances that did not exist before. (See ECF No. 258-2 at 4-5.) Instead, the declaration merely summarizes the arguments Defendants make in their motion for reconsideration. (Id.) This is a sufficient basis on which to deny Defendants' motion for reconsideration. See FTC v. Neovi, Inc., 2009 WL 56130, at *2 (S.D. Cal. Jan. 7, 2009) (Sammartino, J.).

The Court further agrees that Defendants' second and third claims of error are untimely, as they were considered and rejected by Judge Moskowitz in an order issued more than one and a half years before Defendants filed the instant motion for reconsideration. The Court further finds Defendants' second and third claims of error are reiterations of arguments previously made and rejected. The Court will thus explain its reasoning as to the second and third claims of error, after which the Court will address the substance of Defendants' first claim of error.

In their second claim of error, Defendants argue this Court erred in concluding that Santaris's act of entering into collaboration agreements with U.S. pharmaceutical

companies does not fall within the safe harbor as a matter of law but instead requires a factual determination as to whether said act is "reasonably related" to the type of information submitted to the FDA for regulatory approval.

Defendants have now had three opportunities (including Defendants' first motion for summary judgment, second motion for summary judgment, and the instant motion for reconsideration) to argue that the act of entering into the collaboration agreements fell within the safe harbor. In support of their second motion for summary judgment, Defendants argued:

> It is of no moment that Santaris A/S did not yet know the structure of a particular Target or ASO compound [at the time it entered into the collaboration agreements with U.S. pharmaceutical companies], because Information obtained on the binding and other in vitro properties of each Library compound may be relevant to FDA submissions on that compound as an investigational drug.

(ECF No. 213 at 21.) In denying Defendants' second motion for summary judgment, the Court considered these uncertainties, finding:

> the collaboration agreements generally required Santaris to (1) wait for its U.S. collaborators to select a target, (2) develop a library of antisense compounds for each selected target, and (3) screen each compound in the library for its effect on a given target using, among other tools, Isis's patented inventions. Then, after even more work by the U.S. pharmaceutical companies, information from Santaris's research results might be submitted to the FDA in connection with an IND.

(ECF No. 250 at 19.) Then, after noting the dissimilarities between the facts of this case and those of Merck KGaA v. Integra Lifesciences I, Ltd, 545 U.S. 193 (2005), the Court concluded summary judgment was not appropriate. Instead, the Court concluded that

> what is left to determine is whether Santaris's collaboration agreements are "reasonably related" to the type of information submitted to the FDA—that is, whether it was "objectively reasonably for a party in [Santaris's] . . . situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question."

(ECF No. 250 at 20.)

In denying Santaris's first motion for summary judgment, Judge Moskowitz "decline[d] to resolve Santaris's claim to the Safe Harbor exemption without a more specific analysis of Santaris's uses of the allegedly infringing compounds, methods, and processes." (ECF No. 53 at 8.) Judge Moskowitz then stated:

> To the extent Santaris is selling and/or licensing infringing "platform" technology so that another company can "discover and develop" drug candidates—rather than developing and/or licensing/selling specific drug candidates itself—Santaris could be using or selling patented technology to perform "basic scientific research."

[Id. at 9 (citing Merck, 545 U.S. at 207.]

It is thus clear that both this Court and Judge Moskowitz have considered the uncertainties that existed in the collaboration agreements at the time of contracting. And, based on these uncertainties, both this Court and Judge Moskowitz found summary judgment inappropriate. In other words, two courts have now concluded that Santaris's entering into the collaboration agreements is not, as a matter of law, protected by the safe harbor. Thus, in addition to concluding that Defendant's second claim of error is untimely under Civil Local Rule 7.1.i.2, the Court finds Defendants have merely reiterated an argument that two courts have considered and rejected. The Court will therefore deny Defendants' motion for reconsideration as to the second claim of error.

Defendants' third claim of error suffers the same fate. Defendants argue the Court erred in concluding the term "patented invention," as used in 35 U.S.C. § 271(e)(1), means inventions that would be eligible for a patent extension under 35 U.S.C. § 156 or inventions that are themselves subject to regulatory approval. Again, however, two courts have considered and rejected Defendants' position on the meaning of "patented invention" as used in 35 U.S.C. § 271(e)(1).

In support of its second motion for summary judgment, Santaris argued Plaintiff's patented methods and compounds are, as a matter of law, "patented inventions" under § 271(e)(1). (ECF No. 213 at 24-27.) Santaris argued, for example, that "Momenta[, 686 F.3d 1348 (Fed. Cir. 2012),] leaves no room for Isis to argue that

Proveris Scientific Corp. v. Innovasystems, 536 F.3d 1256 (Fed. Cir. 2008), limits the Safe Harbor to the use of patented inventions that are themselves the subject of FDA approval." (Id. at 25.)

In denying Santaris's second motion for summary judgment, this Court considered Santaris's reading of Momenta and Proveris and concluded that Proveris could indeed be read to limit the meaning of "patented invention" as used in § 271(e)(1). (ECF No. 250 at 18 n.6.)

Judge Moskowitz reached the same conclusion, albeit from a slightly different perspective, in denying Santaris's first motion for summary judgment:

> The Safe Harbor does not apply . . . when a biological compound is used to perform "basic scientific research" or as a "research tool." "Basic scientific research" is performed when the researcher "lacks the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce."

[ECF No. 53 at 6 (citing Merck, 545 U.S. at 205-06).] Judge Moskowitz went on to explain "research tools" as

> patented inventions that are "used in the development of . . . regulatory submissions, but [are] not [themselves] subject to the [regulatory] approval process." Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265 (Fed. Cir. 2008). For example, in PSN Illinois, LLC v. Abbott Laboratories, No. 09 C 5879, 2011 WL 4442825, at *4-6 (N.D. Ill. Sept 20, 2011), the [c]ourt found that the defendants' use of a patented protein receptor was a "research tool," where the receptor was used only to perform tests on other drug candidates that did not themselves incorporate the patented invention. "They were using a patented invention to develop their own patentable product. . . . 271(e)(1) offers no protection for such activity." Id. at *6.

(ECF No. 53 at 6-7.)

While Judge Moskowitz did not directly address the meaning of "patented invention" under § 271(e)(1), Judge Moskowitz observed that "research tools" do not qualify for protection under § 271(e)(1). And, based on case law interpreting the term "patented invention" as used in § 271(e)(1), both this Court and Judge Moskowitz found summary judgment inappropriate as to whether Isis's patented methods and compounds are, as a matter of law, "patented inventions" under § 271(e)(1). Thus, in addition to concluding that Defendant's third claim of error is untimely under Civil

Local Rule 7.1.i.2, the Court finds Defendants have merely reiterated an argument that two courts have considered and rejected. The Court will therefore deny Defendants' motion for reconsideration as to the third claim of error.

As such, only Santaris's first claim of error remains. While the Court has found the declaration Defendants submitted in support of their motion for reconsideration does not comply with Civil Local Rule 7.1.i.1, the Court will nonetheless review Defendants' first claim of error, as it is based on arguments that the Court has not previously considered and that Defendants could not have been expected to raise previously.

Defendants argue the Court erred when it read Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2012), and Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc., 686 F.3d 1348 (Fed. Cir. 2012), as standing for the proposition that, "regardless of the stage of the regulatory process in which a patented invention is used to obtain information, the information derived from using the patented invention must be 'reasonably related' to the type of information required by the FDA at some point during the regulatory process." (ECF No. 250 at 16.)

Defendants argue the foregoing reading of Classen and Momenta is contrary to § 271(e)(1) and case law interpreting that section because the safe harbor covers infringing activities that produce the types of information that are "relevant" to FDA submissions—not types of information that are "required" by the FDA. Defendants further argue that, to the extent Momenta and Classen include the "required" language, Momenta and Classen apply only to post-regulatory approval activities. (ECF No. 258-1 at 9-10.) In that vein, Defendants argue "pre-submission experiments . . . fall within the safe harbor as long as such experiments are potentially 'relevant' to an FDA submission." [Id. at 10 (citing Merck, 545 U.S. 207-08).]

Ultimately, whether the Court agrees with Defendants will not change the outcome of this Court's ruling on Defendants' second motion for summary judgment. Regardless of the type of information that Defendants anticipated they would derive

from the collaboration agreements, the Court would still conclude that the uncertainties inherent in the collaboration agreements at the time of contracting preclude summary judgment on the issue of whether Santaris's entering the collaboration agreements fell within the safe harbor.

Turning to the substance of Defendants' arguments, the Court concludes that its reading of Classen and Momenta was not clear error. In Eli Lilly & Co. v. Medtronic, Inc., the Supreme Court qualified the type of information submitted to the FDA as "information necessary to obtain regulatory approval." 496 U.S. 661, 664 (1990) (emphasis added); see also Classen, 659 F.3d at 1071 (quoting "necessary" language from Eli Lilly). In Momenta, the Federal Circuit likewise qualified the type of information as the "necessary information demanded by the 'Federal law.'" 686 F.3d at 1359 (emphasis added). Moreover, Classen makes clear that the type of information derived from infringing activities does matter: "The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." 659 F.3d at 1070.

These qualifications on the type of information derived from otherwise infringing activities find further support in the plain language of § 271(e)(1), which exempts acts of infringement undertaken "solely for uses reasonably related to the development and submission of information under a Federal law." (Emphasis added.) "'Under a federal law' . . . encompasses all 'materials the FDA demands in the regulatory process." Momenta, 686 F.3d at 1356.

Finally, the Court finds no support for Defendants' argument that the type of information derived from infringing activities varies depending on whether the infringing activities take place pre- or post-regulatory approval. To the contrary, at least one other district has concluded, "Momenta clarified that there is no pre/post FDA approval dichotomy under the safe harbor provision." Classen Immunotherapies, Inc. v. Shionogi, Inc., 2014 WL 323947, at *6 (D. Md. Jan. 29, 2014).

Having addressed all three of Defendants' claims of error, the Court concludes

Defendants are not entitled to the extraordinary remedy of reconsideration. The Court next addresses Defendants' alternative request for certification of the February 27, 2014 order for interlocutory appeal.

2. Interlocutory Appeal

District courts may certify an issue for interlocutory appeal upon satisfaction of certain criteria. 28 U.S.C. § 1292(b). Those criteria are: (1) the order involves a controlling question of law; (2) there is substantial ground for difference of opinion; and (3) an immediate appeal from the order may materially advance the ultimate termination of the litigation. In re Cement Antitrust Litigation, 673 F.2d 1020, 1026 (9th Cir. 1982). The court should apply § 1292(b)'s requirements strictly, and should grant a motion for certification only when exceptional circumstances warrant it. Coopers & Lybrand v. Livesay, 437 U.S. 463, 475 (1978). The party seeking certification to appeal an interlocutory order has the burden of establishing the existence of such exceptional circumstances. Id. "Even then, a court has substantial discretion in deciding whether to grant a party's motion for certification." Zulewski v. Hershey Co., 2013 WL 1334159, at *1 (N.D. Cal. Mar. 29, 2013).

Having considered the foregoing criteria, the Court finds that no exceptional circumstances warrant interlocutory review. Determining whether the safe harbor applies is a fact-dependent inquiry. Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d 1334, 1347 (Fed. Cir. 2007). Thus, even if the Federal Circuit ultimately reviews this Court's February 27, 2014 order, the Federal Circuit will be more able to do so with a complete factual record. See McFarlin v. Conseco Servs., LLC, 381 F.3d 1251, 1259 (11th Cir. 2004) ("§ 1292(b) appeals were intended, and should be reserved, for situations in which the court of appeals can rule on a pure, controlling question of law without having to delve beyond the surface of the record in order to determine the facts."). As such, the Court will deny Defendants' alternative request to certify the February 27, 2014 order for interlocutory appeal.

For the foregoing reasons, Defendants' motion for reconsideration, (ECF No.

258), is **DENIED**. The hearing on said motion, currently set for May 30, 2014, is **VACATED**.

DATED: May 28, 2014

HON. GONZALO P. CURIEL
United States District Judge