UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

KRISTI LAURIS, et. al., Plaintiffs, v. NOVARTIS AG, et al., Defendants.	Case No. 1:16-cv-00393-LJO-SAB ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION TO COMPEL (ECF Nos. 60, 61, 62, 78)

Currently before the Court is Plaintiffs' motion to compel production and entry of search protocol. The Court heard oral argument on Plaintiffs' motion on November 16, 2016. Counsel Richard Elias and Brande Gustafson appeared in person and Tamara Spicer appeared telephonically for Plaintiffs. Counsel Robert Johnston and Kelly Matoyoshi appeared in person and Andrew Reissaus appeared telephonically for Defendant Novartis Pharmaceuticals Corp., and Julie Park appeared telephonically for Defendant Novartis AG. Having considered the moving, opposition and reply papers, the joint statement, the declarations and exhibits attached thereto, arguments presented at the November 16, 2016 hearing, as well as the Court's file, the Court issues the following order.

I.

RELEVANT BACKGROUND

Defendants manufactured Tasigna which is a prescription medication for the treatment of chronic myeloid leukemia ("CML".) (First Am. Compl. ¶ 12, ECF No. 28.) CML is a cancer that starts in the blood forming stem cells of the bone marrow. (Id.) Tasigna is a tyrosine-kinase

inhibitor that blocks chemical enzymes in the cancer cells called tyrosine kinases inhibiting their growth and division. (Id.)

Dainis Lauris ("decedent") was diagnosed with CML in 2001, and in October 2012, decedent was prescribed Tasigna by his oncologist. (Id. at ¶ 26.) After taking Tasigna, decedent developed severe, accelerated, and irreversible atherosclerosis-related conditions. (Id.) Around September 2013, decedent was diagnosed with peripheral arterial occlusive disease which required immediate surgery. (Id. at ¶ 31.) In November 2013, decedent's oncologist happened upon an article discussing the link between Tasigna and severe, accelerated atherosclerosis-related conditions. (Id. at 32.) The oncologist immediately called decedent, told him not to take another Tasigna pill, and switched Plaintiff to a different medication. (Id. at ¶ 32.)

On March 28, 2014, decedent had an angioplasty performed on his left leg and during the procedure the surgeon punctured his artery which caused a drop in his blood pressure. (Id. at ¶ 34.) Due to a 70 percent occlusion in the cerebral arteries allegedly caused by the Tasigna, decedent suffered a major stroke. (Id. at ¶ 34.) He went into a coma and died on March 31, 2014.[1] (Id.) An autopsy after death, revealed pervasive atherosclerosis in decedent's middle cerebral arteries. (Id. at ¶ 35.)

On March 22, 2016, decedent's surviving wife, Kristi Lauris, and two children, L.L. and Taylor Lauris, filed the complaint in this action. (ECF No. 1.) Plaintiffs bring this action alleging strict products liability, negligence, wrongful death, and a survival cause of action. On August 31, 2016, the scheduling order issued in this action. (ECF No. 57.) On October 19, 2016, Plaintiffs filed a motion for discovery. (ECF No. 60.) On November 9, 2016, the parties filed a joint statement regarding the discovery dispute and a declaration of counsel in support of the motion. (ECF No. 61, 62.) Oral argument was held on November 16, 2016, and the parties were able to resolve several of the outstanding disputes. The parties were to continue to meet and confer on the marketing requests and provide supplemental briefing informing the Court of

[1] The first amended complaint asserts that decedent died on March 31, 2014, however in the current motion the date of death is stated as March 31, 2014. (ECF No. 61 at 14.) The Court assumes that the first amended complaint incorrectly states the date of death.

the issues remaining following the meet and confer. On November 30, 2016, the parties filed a supplemental joint statement regarding the marketing issues still in dispute. (ECF No. 78.) This order addresses only those areas of dispute that remain outstanding.

II.

LEGAL STANDARD

Rule 34(a) provides that a party may serve a request that the other party produce or permit the requesting party to inspect, copy, test or sample materials, including electronically stored information within the scope of Rule 26(b). Fed. R. Civ. P. 34(a)(1)(A). The rule is "designed to permit the broadest sweep of access." U.S. ex rel. Carter v. Bridgepoint Educ., Inc., 305 F.R.D. 225, 236 (S.D. Cal. 2015) (citations omitted). Electronic documents are no less subject to disclosure than paper records provided that the relevance standard is satisfied. Carter, 305 F.R.D. 236. Discovery is not limited to the issues raised in the pleadings but encompasses any matter that bears on or reasonably could lead to other matter that bears on any issues that is or may be in the case. Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978). However, discovery does have ultimate and necessary boundaries. Oppenheimer Fund, Inc., 437 U.S. at 351. Rule 1 of the Federal Rules of Civil Procedure provides that the Federal Rules should be administered to "secure the just, speedy, and inexpensive determination of every action and proceeding."

Rule 26, as recently amended, provides that a party "may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). Information need not be admissible in evidence to be discoverable. Fed. R. Civ. P. 26(b)(1). The December 2015 amendment to Rule 26 was to restore the proportionality factors in defining the scope of discovery. See Advisory Committee Notes to Rule 26(b)(1) 2015 Amendment. Under the amended Rule 26, relevancy alone is no longer sufficient to obtain discovery, the discovery

requested must also be proportional to the needs of the case. In re Bard IVC Filters Prod. Liab. Litig., __ F.R.D. __, 2016 WL 4943393, at *2 (D. Ariz. Sept. 16, 2016).

III.

DISCUSSION

The parties in this action have met and conferred regarding an Electronically Stored Information ("ESI") protocol to produce documents responsive to Plaintiffs' discovery requests. The parties have agreed upon a number of search terms and custodians to be searched. However, Plaintiff seeks the addition of several custodians. Defendants argue that Plaintiffs have not propounded a search protocol request in discovery; and therefore, the issues are not appropriately before the Court as a motion under Rule 37(a). Defendants contend that Plaintiffs have cited no case in which a court has imposed search protocol as a Rule 37(a) order compelling discovery that is completely divorced from the discovery requests that the party has propounded.

Plaintiffs contend that there are three major deficiencies in Defendants' production. Defendants have refused to:

(1) search for or produce documents in the files of any individual custodian after March 31, 2014, even though Defendant disputes general causation and there is evidence that Defendants' employees concluded after that date that Tasigna causes the atherosclerosis related conditions that decedent suffered and died from;

(2) search for or produce documents related to Defendants' aggressive marketing, sales, promotional, and revenue-generating efforts, which, discovery to date has revealed influenced Defendants' decision not to warn American doctors of the known risks of atherosclerosis associated with Tasigna; and

(3) include in its search for responsive documents important custodians, including key custodians involved in analyzing and addressing the risks of Tasigna and atherosclerosis-related events and custodians who made key decisions on Defendants' messaging related to risks. (Joint Statement Re Discovery Dispute 3-4,[2] ECF No. 61.)

[2] All references to pagination of specific documents pertain to those as indicated on the upper right corners via the CM/ECF electronic court docketing system.

Defendants argue that the discovery requests that have been propounded and agreed upon production are anticipated to exceed $1 million. The protocol proposed by Plaintiffs will at least double the anticipated expense of production and is not proportional to the case. Defendants argue that they have selected eight employees that served as initial custodians due to the employees' primary roles in evaluation of the available scientific data regarding Tasigna and the potential risk of atherosclerosis and in preparing Tasigna labeling. Due to their role, these individuals would likely have been copied on all significant communications regarding the evaluation of the safety and benefits of Tasigna during the relevant time period. Defendants also argue that the additional terms sought by Plaintiffs are redundant and will return few relevant documents not encompassed in Defendants' proposed search protocol.

A. Apex Custodians

During the November 16, 2016 hearing, the parties indicated that the only remaining dispute regarding the custodians to be searched deals with four apex custodians: Hugh O'Dowd, Chief Commercial Officer, Novartis Oncology; Alessandro Riva, Global Head, Novartis Oncology Development and Medical Affairs and interim President of Oncology; Herve Hoppenot, President of Novartis Oncology and Chief Commercial Officer; and Phillipe Drouet, Hematology Franchise Head Novartis Oncology. Relying upon the apex doctrine, Defendants argue that these apex custodians should not be subjected to discovery as the vast majority of all relevant documents will be included in the responsive discovery of the currently agreed upon custodians.

Apex employees are defined as high level corporate executives. See Simmons v. Morgan Stanley Smith Barney, LLC, No. 11CV2889-WQH MDD, 2012 WL 6725844, at *2 (S.D. Cal. Dec. 27, 2012). Courts recognize that a party seeking the deposition of a high-level executive creates a tremendous potential for abuse or harassment. Apple Inc. v. Samsung Elecs. Co., Ltd, 282 F.R.D. 259, 263 (N.D. Cal. 2012). "In determining whether to allow an apex deposition, courts consider (1) whether the deponent has unique first-hand, non-repetitive knowledge of the facts at issue in the case and (2) whether the party seeking the deposition has exhausted other less intrusive discovery methods." Apple Inc., 282 F.R.D. at 263 (citations omitted). In a large

multinational corporation, such as at issue here, courts have considered not only the materiality of the executive's knowledge of pertinent facts and the availability of other means for the party to access that knowledge, but the degree of closeness to these factors. Apple Inc., 282 F.R.D. at 263.

Defendants seek to invoke the apex doctrine to avoid e-discovery of these executives. Plaintiffs respond that the apex doctrine precludes the deposition of high level executives and should not be used to shield the discovery at issue here. The Court is not persuaded that the apex doctrine applies to the discovery at issue here. In this instance, Plaintiffs are not seeking to take depositions of high level employees, but are seeking e-discovery on the knowledge the corporation had regarding the risks of atherosclerosis from the use of Tasigna. This is not the type of discovery which would create the risk of abuse or harassment. Further, in order to obtain an apex deposition the deposing party must show unique personal knowledge of the high level corporate executive. Apple Inc., 282 F.R.D. at 263. If discovery of high level executive is precluded due to the their position in the company a litigant would be hard pressed to ever show that the high level executive possessed personal knowledge regarding the allegations in the complaint.

However, a court can limit discovery where "the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive[.]" Fed. R. Civ. P. 26(b)(2)(C). Additionally, the Court must consider if the discovery is proportional to the needs of the case by "considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1).

Here, Plaintiffs seek e-discovery of four high level executives arguing that Defendants cannot show that the searches are unlikely to yield relevant information. But the right to even plainly relevant discovery is not limitless. Amini Innovation Corp. v. McFerran Home Furnishings, Inc., 300 F.R.D. 406, 409 (C.D. Cal. 2014). Defendants argue that the vast majority

of relevant information would be included in the discovery provided from the key custodians involved with the medical issues in this action. Defendants have agreed to run searches of nine key employees who had primary roles in evaluation of the scientific data regarding Tasigna and the potential risk of atherosclerosis and in preparing the labeling for Tasigna. Defendants object to the inclusion of any additional custodians because they are unlikely to result in production of a significant quantity of unique relevant documents that have not already been captured by the search of the identified custodians.

A litigant does not have to examine every document in its voluminous files to comply with discovery obligations. Treppel v. Biovail Corp., 233 F.R.D. 363, 374 (S.D. N.Y. 2006). Rather, a litigant has to conduct a diligent search which involves developing a reasonably comprehensive search strategy. Treppel, 233 F.R.D. at 374. "Such a strategy might, for example, include identifying key employees and reviewing any of their files that are likely to be relevant to the claims in the litigation." Id. "Defined search strategies are even more appropriate in cases involving electronic data, where the number of documents may be exponentially greater." Id.

Plaintiffs argue that their suggested search protocol is reasonable and proportional and that they are not seeking near the discovery that was ordered in In re: Benicar (Olmesartan) Prod. Liab. Litig., No. 15-2606 (RBK/JS), 2016 WL 5817262 (D.N.J. Oct. 4, 2016). However, the Court finds Olmesartan to be distinguishable from this action. Discovery in Olmesartan dealt with approximately 1,800 Multidistrict Litigation actions in which the plaintiffs were alleging injury, id. at *1, whereas this action deals with a single decedent allegedly injured through use of Tasigna. At issue here is whether the four apex custodians should be added to the search protocol considering the nine custodians that Defendants have already included. As Plaintiffs set forth, the key issue in this action is general causation: whether Tasigna causes atherosclerosis-related events.

Defendants have agreed to search the files of nine key custodians: Calvin McNeill, Executive Director Brand Safety (2008-2013); Mary Aghoghovbia, Pharmacovigilance Leader (2013-2015); Frank Hong, Executive Director and Senior Brand Safety Leader (2008-2012);

Karen Habucky, Executive Director, Global Program Regulatory Director for Tasigna and Gleevec (2012-2015); Katie Chon, Director, Drug Regulatory Affairs (2013-present); Aby Buchbinder, Global Clinical Program Head for Tasigna (2013-present); Neil Gallagher, Global Program Head for Tasigna, Global Clinical Program Head for Tasigna (2006-2016); Richard Woodman, Senior Vice President and Head of North America Oncology Clinical Development & Medical Affairs, Global Brand Medical Director (2006-2013); and Rebecca Jolley, Brand Leader for Tasigna (2012-2014). Defendants argue that communications regarding Tasigna and atherosclerosis-related events would have passed through these document custodians.

Considering the factors identified in Rule 26(b)(1), these appear to be appropriate document custodians to obtain the relevant discovery regarding whether Tasigna caused atherosclerosis-related events. Due to their position within the organization, information regarding Tasigna and atherosclerosis related side effects would be expected to be communicated though these individuals. Defendants have asserted, and Plaintiffs do not dispute, that the e-discovery costs to date will exceed $1 million. While recognizing the importance of the issues addressed here, the Court also considers that this is an action involving a single individual in Fresno, California. Plaintiffs have not shown that the discovery plan proposed by Defendants would not produce responsive documents and given the costs of e-discovery here, the Court will require more than mere speculation to order Defendants to include the apex custodians in the search protocol.

The Court denies Plaintiffs' request to expand the list of custodians without prejudice finding that the additional burden or expense of the proposed discovery outweighs its likely benefit. If, after production of responsive documents based upon the search of these nine custodians, the parties dispute whether further production is warranted, the Court will revisit the scope of discovery and who should bear the cost of production.

B. Timeframe

Defendants agree to search for responsive documents through March 31, 2014, the date of decedent's death. Plaintiffs counter that the search should be through the current date as the information sought is relevant to the issue of causation.

Plaintiffs argue that documents after March 31, 2014 are discoverable relying on In re Fosamax Prod. Liab. Litig., No. 1:06-MD-1789 (JFK), 2008 WL 2345877 (S.D.N.Y. June 5, 2008). Again, In re Fosamax was a multidistrict litigation that included over 550 actions. Id. at *1. The plaintiffs were alleging claims similar to those at issue here based upon their use of the drug Fosamax. Id. The court considered the time period for discovery where the plaintiffs were alleging that the company knew or should have known about the association between the drugs and the side effects when the plaintiffs were taking the drugs. Id. at *9. The court found the defendant's "decision to cut off production of certain PIR responses and sales representative materials at a date six months following a given plaintiff's last prescription of Fosamax is unjustified. Merck's communications with a plaintiff's physician, either before or after the plaintiff used Fosamax, may contain evidence of notice or causation that is relevant to that plaintiff's case or the cases of other plaintiffs." Id. Since this action deals with only a single individual's use of Tasigna the court does not find In re Fosamax to be particularly persuasive authority on the issue addressed here.

Plaintiffs contends that Defendants are intentionally withholding information that goes to the heart of the core issue, documents related to the conclusions of internal doctors and scientists that Tasigna causes severe accelerated atherosclerosis. Plaintiffs argue that sometime in 2014, after the decedent's death, Defendants concluded that there was a sufficient causal link between vascular risks associated with taking Tasigna to warrant elevating it to an important identified risk. Plaintiffs argue that despite undeniable evidence, Defendant continues to dispute causation.

Defendants counter that they have produced over 1.9 million pages of discovery which includes all the scientific evidence relied on by Defendants and the Food and Drug Administration in obtaining marketing approval for Tasigna. Defendants contend that they have produced interim data and reports regarding Tasigna with information on recently completed and ongoing studies. Defendants argue that even if a statement by an employee regarding causation existed after March 2014 it would not help Plaintiffs meet their evidentiary burden because it would not meet the Daubert standard. Defendants further argue that the burden associated with conducting searches over the expanded date range creates a significant burden not proportional

to the needs of the case.

The issue here is that documents that are created after the date of decedent's death could bear on Defendants' earlier knowledge regarding whether Tasigna caused atherosclerosis-related events. Hill v. Novartis Pharm. Corp., 944 F. Supp. 2d 943, 961 (E.D. Cal. 2013). Plaintiffs assert that in 2014 the vascular risks from taking Tasigna were recognized and elevated to an important identified risk. Therefore, in considering the burden and expense of expanding the time period of the search criteria, the Court determines that the time period up to and including December 31, 2014 would be most likely to contain communication regarding the causal link between vascular risks associated with taking Tasigna to warrant elevating it to an important identified risk. Additionally, the Court considers that Defendants assert they have produced over 1.9 million pages of discovery, including information on currently conducted and on-going studies, and Plaintiffs do not dispute that they have received such discovery. Accordingly, in addressing the proportionality of the search requested here, the search period shall be extended to December 31, 2014 to address the period of time in which the Court determines it would be most likely to find communication regarding the risk of taking Tasigna that are at issue in this action.

C. Marketing Related Searches

It appears to the Court that the motion to compel the marketing related searches was premature. Initially, at the November 16, 2016 hearing, Plaintiff asserted that the parties had not discussed what marketing searches would entail because Defendants were refusing to produce any marketing materials. Hearing re: plaintiff's motion to compel 23:2-18, ECF No. 76. During the hearing, Plaintiffs stated that they wanted to see "board presentations and things like that" that discussed marketing strategies of pushing Tasigna over Gleevec. Id. at 23:14-21. Plaintiffs opined that Defendants should be able to obtain this information by asking the proper person who had these internal presentations. Id. at 23:21-25. If Plaintiffs were able to obtain these documents and any power point presentations they may not need or would be able to "vastly narrow" any search request. Id. at 24:1-10. In response, Defendants countered that board minutes are currently being reviewed for privileged information and would be produced when the review is complete. Id. at 29:18-30:3.

The parties continued to meet and confer on which documents should be produced. In the supplemental joint statement, Plaintiffs have narrowed their marketing requests to the following:

1. Marketing and training material provided to Tasigna sales representatives in the region that includes Fresno, California;
2. Tasigna marketing materials sent to doctors in the region including Fresno, California, including all marketing materials sent to Dainis Lauris's treating oncologist, Dr. Klaus Hoffmann;
3. Board and marketing-related committee meeting minutes and notes where Tasigna marketing and revenue-generating strategies and budgets were discussed;
4. Internal Tasigna marketing-related newsletters—this includes the BOOST newsletter where various marketing campaigns related to Tasigna, including the "Eraser" and "Freedom" campaigns, were discussed (See Ex. A);
5. Internal presentations related to Tasigna marketing and revenue-generating strategies, and budgeting for the same, including presentations describing the Eraser and Freedom campaigns.

(ECF No. 78 at 3.[3]) Defendants argue that they have not had an opportunity to consider the burden of producing the newly narrowed marketing requests which were received on November 28, 2016. Defendants seek to have an opportunity to respond to these requests prior to the Court issuing an order addressing them.

The Court notes that the current motion is not a motion to compel production of documents, but is seeking an e-discovery search protocol. Plaintiff is now requesting that Defendants engage in a reasonable search for these newly requested documents by asking employees sitting on the relevant marketing committees to locate relevant marketing related presentations and minutes. (Id.) Although Plaintiffs assert that there were requests for production previously propounded, the parties have not had an opportunity to address the specific documents that Plaintiffs are now seeking to have produced.

Defendants contend that they are currently identifying and attempting to produce documents responsive to requests no. 1 and 2. Defendants also contend that documents responsive to request no. 3 have been produced or are currently being reviewed for future production. Defendants further contend that request no. 4 seeks documents that are not relevant as the BOOST newsletter appears to have been produced for Europe and the Freedom campaign

[3] For convenience in discussing these requests, they shall be referred to as request no. 1 through 5 as numbered herein.

in the United States was not implemented until after the decedent's death. Finally, Defendants contend that documents responsive to request no. 5 are currently being reviewed for production. Accordingly, the only issue as to these requests that appear to be in dispute is request for production no. 4 which seeks the BOOST newsletters and Freedom campaign information.

Since the request for these specific documents was only made on November 28, 2016, the parties have not had an opportunity to brief the relevancy of these documents or if the burden of producing them would be proportional in this action. Accordingly, the Court shall deny the current motion to compel marketing documents without prejudice.

IV.

CONCLUSION AND ORDER

Based on the foregoing, IT IS HEREBY ORDERED that Plaintiff's motion for discovery is GRANTED IN PART AND DENIED IN PART as follows:

1. Plaintiffs' request to include the four apex custodians in the search protocol is DENIED;
2. Plaintiffs' motion regarding the date for the search protocol is GRANTED IN PART and the search protocol shall include up to and including December 31, 2014; and
3. Plaintiffs' request for marketing search protocol search terms is DENIED without prejudice.

IT IS SO ORDERED.

Dated: **December 7, 2016**

UNITED STATES MAGISTRATE JUDGE