UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., ET AL.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS (MEJ)

DISCOVERY ORDER

Re: Dkt. Nos. 254-56, 260-61

United States District Court
Northern District of California

INTRODUCTION

On June 30, 2017, Plaintiffs Amgen Inc. and Amgen Manufacturing, Ltd. (collectively, "Amgen") and Defendants Sandoz, Inc.; Sandoz International GmbH; and Sandoz GmbH (collectively, "Sandoz") filed two joint discovery letters concerning disputes over Amgen's Rule 30(b)(6) notice. First Ltr., Dkt. No. 255; Second Ltr., Dkt. No. 256. Following an in-person meet and confer session on July 12, 2017 (*see* Dkt. No. 257), the parties submitted a third joint discovery letter, which narrows the issues and clarifies the parties' positions as to the outstanding disputes. Third Ltr., Dkt. No. 261. In addition, Sandoz has filed Motions to File under Seal the First and Third Letters. Mot. re: First Ltr., Dkt. No. 254; Mot. re: Third Ltr., Dkt. No. 260. This Order addresses the parties' remaining discovery disputes and the Motions to Seal.

MOTIONS TO SEAL

A. Legal Standard

There is a "strong presumption in favor of access" by the public to judicial records and documents accompanying dispositive motions. *Kamakana v. City & Cty. of Honolulu*, 447 F.3d 1172, 1178-79 (9th Cir. 2006) (citing *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003)). To seal judicial records relating to motions that are "more than tangentially

related to the merits of a case," *Center for Auto Safety v. Chrysler Grp., LLC*, 809 F.3d 1092, 1098 (9th Cir.), *cert. denied sub nom. FCA U.S. LLC v. Ctr. for Auto Safety*, 137 S. Ct. 38 (2016), a party must "articulate compelling reasons supported by specific factual findings," *Kamakana*, 447 F.3d at 1178 (internal quotation marks and citation omitted). Indeed, such showing is required even where "the [] motion, or its attachments, were previously filed under seal or protective order." *Kamakana*, 447 F.3d at 1179.

The strong presumption of public access to judicial documents applies to such motions because the resolution of a dispute on the merits is at the heart of the interest in ensuring that the public understands the judicial process. *Id.* The presumption does not apply in the same way to motions that are "not related, or only tangentially related, to the merits of a case." *Center for Auto Safety*, 809 F.3d at 1099. With such motions, "the usual presumption of the public's right of access is rebutted." *Id.* at 1179 (citing *Phillips v. Gen. Motors Corp.*, 307 F.3d 1206, 1213 (9th Cir. 2002). A party seeking to seal documents attached to such motions nevertheless must meet the lower "good cause" standard under Rule 26(c). *Pintos v. Pac. Creditors Ass'n*, 605 F.3d 665, 678 (9th Cir. 2010). This requires the party to make a "particularized showing" that "specific prejudice or harm" will result if the information is disclosed. *Phillips*, 307 F.3d at 1211. "Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not satisfy the Rule 26(c) test." *In re Roman Catholic Archbishop of Portland in Or.*, 661 F.3d 417, 424 (9th Cir. 2011) (internal quotation marks and edits omitted).

B. Discussion

As this is a discovery matter only tangentially related to the merits of the case, the Court applies the "good cause" standard when evaluating the Motions to Seal. *See Phillips*, 307 F.3d at 1213 ("Much of the information that surfaces during pretrial discovery may be unrelated, or only tangentially related, to the underlying cause of action.").

Sandoz seeks to seal the First and Third Letters on the ground that it contains material designated "Highly Confidential – BLA Material" pursuant to the parties' protective order. First Mot. re: First Ltr. at 2; Mot. re: Third Ltr. at 2. In support, Sandoz submits two declarations from Josephine Liu, Sandoz Inc.'s Head of U.S. Intellectual Property Litigation. First Liu Decl. ¶ 1,

Dkt. No. 254-1; Second Liu Decl. ¶ 1, Dkt. No. 260-1. Liu declares the two Letters "contain[] information concerning Sandoz's manufacturing and purification processes for Sandoz's biosimilar filgrastim and pegfilgrastim products" as well as "confidential information regarding communications between Sandoz and the FDA about Sandoz's pegfilgrastim product." *Id.* ¶ 2 (both). Liu avers "Sandoz would suffer substantial harm if this information were disclosed to the public or Sandoz's competitors": Sandoz's competitors could use this information to Sandoz's disadvantage. *Id.* (both).

1. The First Letter

The Court DENIES the Motion to Seal the First Letter. The request is not "narrowly tailored to seek sealing only of sealable material[.]" Civ. L.R. 79-5(b). While much of the information contained in the First Letter is protectable, not all portions of the Letter concern confidential information. For instance, the First Letter references information that exists, but is not sealed, elsewhere in the record. In other places, the parties simply cite case law. The Court sees no reason to seal such information given that it is publicly available. As such, the Court DENIES the Motion WITHOUT PREJUDICE. No later than July 24, 2017, Sandoz may renew its Motion and propose redactions that are narrowly tailored to address only sealable material.

2. The Third Letter

In its Motion, Sandoz "move[s] to file under seal portions of the parties' Joint Letter regarding discovery disputes set forth in Dkt[.] Nos. 255 and 256 which relate to Sandoz's financial and regulatory strategy, and its plans to respond to the FDA's complete response letter." Mot. re: Third Ltr. at 2. However, it is unclear exactly which portion(s) of the Third Letter Sandoz seeks to seal. The redacted versions do not attach the Letter itself; only the parties' attestation that they met and conferred. *See* Dkt. Nos. 261, 260-3 (redacted versions); *see also* Dkt. No. 260-2 (proposed order seeking to seal "[c]onfidential information concerning Sandoz's manufacturing and purification processes, financial and regulatory strategy, and its plans to respond to the FDA's complete response letter.").

At this point, the undersigned cannot determine whether Sandoz's request is narrowly tailored to redact only sealable material. *See* Civ. L.R. 79-5(b). For that reason, the undersigned

DENIES the Motion WITHOUT PREJUDICE. No later than July 24, 2017, Sandoz may file a renewed motion to seal the Third Letter identifying which portions it contends are sealable. *See id.*; Civ. L.R. 79-5(d)(D).

DISCOVERY DISPUTES

A. Legal Standard

Federal Rule of Civil Procedure 26 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[.]" Fed. R. Civ. P. 26(b)(1). Factors to consider include "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." *Id.* Discovery need not be admissible in evidence to be discoverable. *Id.* However, "[t]he parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." Fed. R. Civ. P. 26 advisory committee notes to 2015 amendments. Thus, there is "a shared responsibility on all the parties to consider the factors bearing on proportionality before propounding discovery requests, issuing responses and objections, or raising discovery disputes before the courts." *Salazar v. McDonald's Corp.*, 2016 WL 736213, at *2 (N.D. Cal. Feb. 25, 2016); *Goes Int'l, AB v. Dodur Ltd.*, 2016 WL 427369, at *4 (N.D. Cal. Feb. 4, 2016) (citing advisory committee notes for proposition that parties share a "collective responsibility" to consider proportionality and requiring that "[b]oth parties . . . tailor their efforts to the needs of th[e] case").

Rule 26(c) "confers broad discretion on the trial court to decide when a protective order is appropriate and what degree of protection is required." *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984). "The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense," including by (1) prohibiting disclosure or discovery; (2) conditioning disclosure or discovery on specified terms; (3) preventing inquiry into certain matters; or (4) limiting the scope of disclosure or discovery to certain matters. Fed. R. Civ. P. 26(c)(1).

B. Discussion

The parties' disputes concern Amgen's Rule 30(b)(6) notice, specifically, documents and testimony requested in topics 12 through 17.

1. The First Letter

The First Letter concerns Amgen's request for discovery regarding Sandoz's regulatory strategy and plans to respond to the Food and Drug Administration's ("FDA") complete response letter ("CRL").[1] *See* First Ltr. As an example, the parties cite topic 12 of Amgen's Rule 30(b)(6) notice, which seeks "[t]he Complete Response regarding [Abbreviated Biologics License Application ('aBLA')] No. 761045, including but not limited to, the deficiencies identified, SANDOZ's plan to remedy the identified deficiencies, the status of remedying the identified deficiencies, and when SANDOZ expects to resubmit its aBLA." *Id.* at 1.

During the parties' meet and confer session, Amgen "offered to withdraw its request for documents concerning clinical trials and an overall regulatory strategy, and to seek only documents that describe the existing and any proposed changes to the manufacturing and purification process for Sandoz's pegfilgrastim product and documents that show when Sandoz expects to resubmit its aBLA." Third Ltr. at 1. In response, "Sandoz has offered to produce any documents related to the CRL response that address any proposed changes to the anion exchange ('AEX') step[.]" *Id.* However, Sandoz requests "a protective order that only prevents Amgen from seeking discovery on Sandoz's proposed, future response to the CRL to the extent that Amgen seeks information beyond the AEX step it has accused of infringement." *Id.* at 2.

The AEX step is at the heart of Amgen's infringement claims as to its Patent No. 8,940,878. *See* First Ltr. at 1 ("Amgen's complaint alleges that the purification procedures Sandoz uses to manufacture its pegfilgrastim product infringe and will infringe Amgen's patent"; specifically, "that Sandoz's use of [AEX] chromatography infringes claims of the '878 patent."); Third Ltr. at 1 ("Amgen accuses the AEX step of Sandoz's manufacturing process of

[1] The parties explain "[t]he FDA sends a biosimilar applicant a CRL 'if the agency determines that [it] will not approve the application or abbreviated application in its present form.'" First Ltr. at 1 (quoting 21 C.F.R. § 314.110(a)).

infringement."); *id.* at 4 ("A central dispute for trial is how Sandoz's AEX step functions and what impurities it removes."). [redacted].

Sandoz offers to produce only information about its anticipated CRL response that relates to the AEX step. Third Ltr. at 1; *see* First Ltr. at 4 (requesting protective order that prohibits "Amgen from seeking discovery on the CRL, beyond confirmation that the response [redacted]). Amgen contends broader discovery is necessary, as "documents that describe, explain, or propose [redacted]." *Id.* at 4.

Sandoz argues "discovery relating to anything other than the AEX step, such as pegfilgrastim regulatory strategy and status would serve only to provide Amgen irrelevant, but highly valuable competitive intelligence regarding Sandoz's pegfilgrastim product and its timetable for approval." Third Ltr. at 2. This appears to ignore Amgen's "offer[] to withdraw its request for documents concerning clinical trials and an overall regulatory strategy[.]" *Id.* at 1. Nonetheless, Amgen does not explain how documents relating to the purification process as a whole are proportional to the needs of the case. Amgen itself asserts "[a] central dispute for trial is how Sandoz's AEX step functions and what impurities it removes." *Id.* at 4. It does not assert Sandoz's other purification steps infringe on its patents, and Amgen offers no reason as to why limited discovery as to changes or modifications to the AEX step does not suffice. [redacted]" (Third Ltr. at 4) does not mean Sandoz will not submit them to the FDA as it updates is response to the CRL—and thus make them available to Amgen as part of its rolling production—in the future. Nor does Amgen explain how documents relating [redacted]." *Id.*

Amgen simply has not demonstrated that ordering production of all documents concerning

Sandoz's manufacturing and purification process, or testimony related to these topics, would be proportional to the needs of this case. Sandoz's production and testimony shall be limited to that which relates to the proposed changes to the AEX step.

2. The Second Letter

The Second Letter concerns topics 13-17 of the Notice:

> 13. SANDOZ's projected sales of SANDOZ's biosimilar pegfilgrastim product in the United States by volume and revenue.
> 14. SANDOZ's projected costs and profit of SANDOZ's biosimilar pegfilgrastim product sold in the United States.
> 15. SANDOZ's projected pricing and pricing strategy for SANDOZ's biosimilar pegfilgrastim product in the United States including, but not limited to, Wholesale Acquisition Cost ("WAC") pricing, discounting, rebates, and promotions.
> 16. SANDOZ's marketing strategies for its biosimilar pegfilgrastim product.
> 17. Competition between SANDOZ's biosimilar pegfilgrastim product and any other product or treatment (such as, without limitation, Neulasta®) including assessment of market share, market analysis, consumer surveys, consultant surveys, or market segment analysis.

Second Ltr. at 1; Notice at 3-4. The parties clarify their dispute over Sandoz's forecasts for approval and sale of its pegfilgrastim product concerns "when and to whom Sandoz will produce these documents, not about the scope of the requests." Third Ltr. at 1; *see* Second Ltr. at 1 ("Sandoz is not seeking to prevent access to this information, just to limit when it can be produced and how broadly it can be shared." (emphasis omitted)). Sandoz seeks a protective order that (1) precludes discovery into the information regarding the CRL response other than information regarding proposed changes to the AEX step; (2) defers discovery into expected pegfilgrastim approval, marketing, and sales until after the trial currently scheduled for March 26, 2018; and (3) limits all such discovery to outside counsel only. Third Ltr. at 1-2. Amgen contests the need for a protective order and argues Sandoz should produce the requested discovery now. *Id.* at 2.

Amgen argues it needs this evidence for trial so it can support its request for an injunction and also for settlement purposes.[2] *Id.* at 4-5. Amgen contends that "a component of their discussions may involve a date by which Sandoz may enter the market. If Amgen does not know

[2] A Court-ordered mediation session is scheduled for September. Third Ltr. at 3.

when Sandoz expects to do so absent a settlement, it cannot assess whether any agreed-on date is actually a compromise." *Id.* at 4. Sandoz responds "[t]he purpose of discovery is to gather information needed to prove or disprove claims, not for settlement talks." *Id.* at 2. It also contends "the jury in this case cannot award damages for sales of Sandoz's pegfilgrastim product because Sandoz will not launch its pegfilgrastim product until after trial." *Id.*; *see id.* at 3 ("Sandoz agrees not to launch its product before the March 2018 trial; and Sandoz will further agree not to launch its product until 90 days after the March 2018 trial."). Sandoz therefore argues "[t]here is no need to try the issue of injunctive relief to the jury, and if required, Sandoz will seek to bifurcate this issue." *Id.*

Unless and until Sandoz seeks bifurcation, and the Presiding Judge limits the issues to be heard at trial, Amgen's claims for injunctive relief are set to be tried before a jury in March 2018. As such, the undersigned finds Amgen is, at this point, entitled to discovery about Sandoz's expected pegfilgrastim approval, marketing, and sales. If Amgen's injunctive relief claim is later bifurcated, the parties may raise this issue anew with the undersigned.

IT IS SO ORDERED.

Dated: July 17, 2017

MARIA-ELENA JAMES
United States Magistrate Judge

United States District Court
Northern District of California