ImprimisRx, LC v. OSRX, Inc. et al

Doc. 54

<u>BACKGROUND</u>

On July 20, 2021, Plaintiff filed its initial complaint commencing this action. ECF No. 1. Defendants filed their answer and counterclaim against Plaintiff on October 22, 2021. ECF No. 5. Plaintiff filed its first amended complaint ("amended complaint") on April 29, 2022. ECF No. 28. On May 13, 2022, Defendants filed their answer to the amended complaint. ECF No. 30.

Prior to the filing of the amended complaint, on February 14, 2022, Plaintiff served its first set of requests for production of documents on Defendant OSRX, Inc. ("Defendant"). Declaration of Matthew L. Venezia ("Venezia Decl."), ECF No. 43-1 at 2. In response, Defendant began producing documents and designated many either "CONFIDENTIAL" or "CONFIDENTIAL – FOR COUNSEL ONLY." Id. Defendant made the designations in accordance with the parties' stipulated protective order that was granted and entered by this Court (with modifications) on March 10, 2022. See ECF Nos. 22, 23. Plaintiff disagreed with many of the designations, and on May 20, 2022, Plaintiff drafted a letter to Defendant explaining the designations are improper. Venezia Decl. at 2; Exhibit A to Venezia Decl. ("Exhibit A"), ECF No. 43-2. On May 31, 2022, Defendant sent a responsive letter indicating that Defendant did not agree to remove the challenged designations. Venezia Decl. at 3; Exhibit C to Venezia Decl. ("Exhibit C"), ECF No. 43-4.

On June 10, 2022, counsel for the parties met and conferred telephonically but did not resolve the dispute. Venezia Decl. at 3. On June 13, 2022, Plaintiff informed Defendant that it intended to file a motion to de-designate unless Defendant removed the challenged designations. <u>Id.</u> Defendant declined to do so on June 15, 2022. <u>Id.</u>; Exhibit D to Venezia Decl. ("Exhibit D"), ECF No. 43-5.

On June 28, 2022, counsel for Defendants, Messrs. Bolton and Liddiard, and counsel for Plaintiff, Mr. Venezia, jointly contacted the Court regarding the discovery dispute. That same day, the Court set a briefing schedule requiring Plaintiff to file its discovery motion no later than July 1, 2022. ECF No. 38. On July 1, 2022, Plaintiff filed its Motion to File Documents Under Seal, its redacted Motion to De-Designate as Confidential, and Request for Judicial Notice. ECF Nos. 41, 43, 44. Additionally, Plaintiff lodged the proposed sealed documents. ECF No. 42;

Exhibit B to Venezia Decl. ("Exhibit B"), ECF No. 42-3. On July 15, 2022, Defendant filed its Opposition to Plaintiff's Motion to De-Designate as Confidential, which included a Request for Judicial Notice. ECF Nos. 47, 47-2. At issue here are the email correspondence between Defendant and customers provided in Exhibit B ("Challenged Materials").¹

LEGAL STANDARD

Generally, "the public is permitted 'access to litigation documents and information produced during discovery." In re Roman Catholic Archbishop of Portland in Oregon, 661 F.3d 417, 424 (9th Cir. 2011) (citing Phillips v. Gen. Motors Corp., 307 F.3d 1206, 1210 (9th Cir. 2002). However, under Federal Rule of Civil Procedure 26, "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, or undue burden or expense." Fed. R. Civ. P. 26(c)(1). When, however, the parties stipulate to a protective order, and no party makes a good cause showing, the party seeking protection bears the burden of proof to show "specific prejudice or harm" will result if the documents are disclosed. In re Roman Catholic Archbishop of Portland, 661 F.3d at 424 ("If a party takes steps to release documents subject to a stipulated order, the party opposing disclosure has the burden of establishing that there is good cause to continue the protection of the discovery material.").

In considering whether good cause exists to continue the protection of a stipulated court order, a court must first "determine whether 'particularized harm will result from disclosure of information to the public." <u>Id.</u> The party opposing disclosure must "allege specific prejudice or harm," and cannot meet their burden with "[b]road allegations of harm, unsubstantiated by specific examples or articulated reasoning." <u>Id.</u> (quoting <u>Beckman Indus., Inc. v. Int'l Ins. Co., 966 F.2d 470, 476 (9th Cir. 1992) (internal quotations omitted). If the court decides that disclosing the documents will cause particularized harm, it must then balance "the public and private interests to decide whether maintaining the confidentiality designation is necessary." <u>Id.</u> (quoting <u>Phillips</u>, 307 F.3d at 1211).</u>

¹ Exhibit B includes both emails and attachments. Both parties agree that only the emails are the subject of Plaintiff's motion. ECF No. 43 at 5; ECF No. 47 at 6.

The Ninth Circuit has directed district courts to consider the factors identified in <u>Glenmede Trust Co, v. Thompson</u>, 56 F.3d 476 (3d Cir. 1995) when balancing the private and public interests. <u>In re Roman Catholic Archbishop of Portland</u>, 661 F.3d at 424 (citing <u>Phillips</u>, 307 F.3d at 1211). The seven <u>Glenmede</u> factors are: (1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate purpose or for an improper purpose; (3) whether disclosure of the information will cause a party embarrassment; (4) whether confidentiality is being sought over information important to public health and safety; (5) whether the sharing of information among litigants will promote fairness and efficiency; (6) whether a party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public.² <u>Id.</u> at 424 n.5 (citing <u>Glenmede</u>, 56 F.3d at 483).

DISCUSSION

I. <u>Motion for De-Designation</u>

Plaintiff seeks an order from the Court that strikes Defendants' designation of the Challenged Materials as "confidential" under the stipulated Protective Order, and files the Challenged Materials under seal. ECF Nos. 41,43. Plaintiff relies on the <u>Glenmede</u> factors to argue that Defendant cannot make a showing of good cause for their continued protection as "confidential," and that public health and safety concerns require the de-designation so Plaintiff can report the alleged violations to the FDA. ECF No. 43 at 1, 5-10. Conversely, Defendants contend that the documents are entitled to continued protection as "confidential" under the stipulated Protective Order because the Challenged Materials are protected business communications. ECF No. 47 at 7. Defendants also argue there is no right to public access that

² In <u>Glenmede</u>, the Third Circuit determined these factors were "neither mandatory nor exhaustive," and the Third Circuit recognized that "the district court is best situated to determine what factors are relevant to the dispute." <u>Glenmede</u>, 56 F.3d at 483.

³ Although the Challenged Materials contain both "confidential" and "confidential – for counsel only," the Court will refer and analyze the designations generally as "confidential." Plaintiff is not challenging the degree of confidentiality; it only is challenging whether the materials should have any level of confidentiality protection.

is applicable here. <u>Id.</u> at 11-13.

A. Protective Order

On March 10, 2022, the Court granted the parties' joint motion for Protective Order and entered the parties' stipulated protective order with modifications ("Protective Order") to incorporate the undersigned's required language, as set forth in her Civil Chambers Rules. <u>See</u> J. Major Civ. Chmbrs. R. § VII; ECF No. 23.

The Protective Order was entered for the purpose of protecting the confidentiality of documents and information that are generally, for competitive reasons, kept confidential by the parties. ECF No. 22 at 1. Such materials "may contain trade secrets or other confidential research, technical, cost, price, marketing or other commercial information, as is contemplated by Federal Rule of Civil Procedure 26(c)(1)(G)." <u>Id.</u> To further this purpose, the Protective Order permits each party to the litigation to designate information as "CONFIDENTIAL" or "CONFIDENTIAL-FOR COUNSEL ONLY." <u>Id.</u> at 5. The Protective Order permits the designations as follows:

- a. Designation as "CONFIDENTIAL": Any party may designate information as "CONFIDENTIAL" only if, in the good faith belief of such party and its counsel, the unrestricted disclosure of such information could be potentially prejudicial to the business or operations of such party.
- b. Designation as "CONFIDENTIAL FOR COUNSEL ONLY": Any party may designate information as "CONFIDENTIAL FOR COUNSEL ONLY" only if, in the good faith belief of such party and its counsel, the information is among that considered to be most sensitive by the party, including but not limited to trade secret or other confidential research, development, financial or other commercial information.

Id. at 5-6.

The Protective Order further provides that "[a]t any stage of these proceedings, any party may object to a designation of the materials as confidential information[.]" <u>Id.</u> at 9.

B. Documents are Business Communications

The Protective Order filed in this case permits a party to designate documents or information produced during the discovery process as "confidential" based on "a good faith belief." Id. at 5-6. Defendants contend that the Challenged Materials are business communications because they "reveal how [Defendants] go about seeking to secure, retain, and

 serve its customers and include information on pricing, product ordering, product delivery," as well as the names and contact information for customers. ECF No. 47 at 7-8. Defendant asserts the information is competitively valuable and could lead to Plaintiff using the material for sales leads. <u>Id.</u> at 8; Declaration of Eric Garner ("Garner Decl."), ECF No. 47-1 at 3. Plaintiff asserts Defendants made the designations in bad faith and are using the designation "to shield compelling evidence that [Defendants] violate[] safety-related laws when manufacturing compounded drugs from the FDA's view." ECF No. 43 at 1, 5.

Defendants have properly designated the Challenged Materials because they made the designation on a good faith belief that "unrestricted disclosure" of the commercial information "could be potentially prejudicial to [their] business or operations []." ECF No. 22 at 5. Courts have held that there are compelling reasons against disclosure where a party's competitive standing may be impacted. See, e.g., Ctr. for Auto Safety v. Chrysler Group, LLC, 809 F.3d 1092, 1097 (9th Cir. 2016) (identifying a compelling reason to seal records where the records are "sources of business information that might harm a litigant's competitive standing"). Here, the parties are competitors, and Defendants cited to significant authority to demonstrate the Challenged Materials are the type of business-related information subject to protection. See ECF No. 47 at 8-9; see also Fed. R. Civ. P. 26(c)(1)(G) (recognizing confidential commercial information as subject to protection). Thus, the Court finds that Defendants have established a particularized harm that will result from the de-designation of the Challenged Materials and good cause to continue the "confidential" designations under the Protective Order. As a result, the Court will consider the Glenmede factors and conduct the required balancing analysis.

C. Glenmede Factors and Balancing Test

Initially, as Defendants point out, Plaintiff "has access to and may use [the Challenged Materials] how it sees fit for purposes of this litigation." ECF No. 47 at 8. Plaintiff agrees and states that it is seeking the de-designation only to enable it to provide the documents to other entities for reasons unrelated to the pending litigation. ECF No. 43 at 1, 7 ("[Plaintiff] seeks only to disclose the material to regulatory agencies like the FDA and state board of pharmacy."). Because both Plaintiff and Defendants have access to the Challenged Materials and are able to

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use them in this litigation, factor five weighs in favor of maintaining the confidentiality.

Second, Plaintiff argues that the de-designation is necessary for public health and safety reasons because it believes that Defendants are violating FDA regulations governing drug compounding and it wants to provide the documents to the FDA and state board of pharmacy.

Id. at 1, 8-9 ("[Plaintiff] believes that the public health and safety requires it to report these violations to the FDA."). However, the specific danger identified by Plaintiff is provided by way of analogy. Plaintiff references another pharmacy, NECC, where patients allegedly became ill from a contaminated drug and voices a concern that a similar harm could occur here.

Id. at 1, 2. Plaintiff provides no evidence that Defendants' products pose a health risk. Indeed, as Defendants point out, Plaintiff's "[c]omplaint is devoid of any allegations that [Defendant's] products pose a health risk to patients using its eye care products." ECF No. 47 at 10.

In addition, Plaintiff does not explain why it needs to provide the Challenged Materials, as opposed to other documents, to the FDA. Plaintiff's amended complaint and substantive portions of Plaintiff's motion are in the public record and contain the relevant allegations. See generally, ECF Nos. 28, 43. Plaintiff could provide those documents to the FDA and if the FDA is concerned about the alleged violations, the FDA has the ability to investigate and obtain the documents it believes are necessary. There is no need, nor does Plaintiff provide any authority that compels Plaintiff, to give the FDA the email correspondence at issue in this motion. As a result, Plaintiff has not established a legitimate purpose⁴ for de-designating the confidentiality or that the de-designation is necessary for health and safety reasons and, therefore, factors 2 and 4 favor maintaining the confidentiality designation.

Third, Plaintiff argues that "this matter involves issues important to the public because the public is the end-consumer of [Defendants'] compounded drugs." ECF No. 43 at 9. Defendant responds that there is no public right to access to the Challenged Materials. ECF No. 47 at 13. Defendant emphasizes that the parties are not at a "stage of the case meriting

⁴ At noted above, Defendants voice a concern that de-designation of the Challenged Materials would enable Plaintiff to use the confidential business information to its advantage in the business realm. ECF Nos. 47 at 8, 47-1 at 3.

consideration of de-designation or unsealing[,]" as the documents are not set to be used as evidence at trial or as part of a dispositive motion. Id. at 14.

"Private material unearthed during discovery" are not part of the judicial record. <u>Pintos v. Pacific Creditors Ass'n</u>, 605 F.3d 665, 678 (9th Cir. 2010). The Ninth Circuit has held that there is no strong or compelling interest in access to "documents produced between private litigants" or in documents submitted with a nondispositive motion. <u>Id.</u> Such motions "are often unrelated, or only tangentially related, to the underlying cause of action." <u>Kamakana v. City & Cnty. of Honolulu</u>, 447 F.3d 1172, 1179 (9th Cir. 2006) (quoting <u>Seattle Times Co. v. Rhinehart</u>, 467 U.S. 20, 33 (1984) (internal citation and quotations omitted).

Here, the parties are private litigants. The Challenged Materials contain confidential commercial information related to Defendants' business. Neither party has submitted the Challenged Materials as part of a dispositive motion and neither party has indicated that the FDA or any member of the public is seeking access to the Challenged Materials. Further, as noted above, Plaintiff does not identify any public health or safety issue aside from FDA regulation, which can be addressed in other ways. As a result, the Court finds that no public right to access has attached to the Challenged Materials and that factors six and seven weigh in favor of maintaining confidentiality.

Finally, the Court notes that Plaintiff's request has the potential to disrupt the discovery process and postpone a resolution of this case on the merits. Discovery in this matter commenced in March of 2022, and the current deadline for completing discovery does not expire until October 3, 2022. Allowing the de-designation of documents for the sole purpose of reporting to a regulatory agency (when public records are available) would be inefficient at best and, as noted by Defendants, could result in additional litigation regarding other confidential documents that should be de-designated for submission to the FDA. ECF No. 47 at 18-19. This outcome could "increase[] the potential for this case to digress into an incivility which would defeat the purpose of our adversarial system, which is intended to 'secure the just, speedy, and inexpensive determination of every action and proceeding." CrossFit, Inc. v. Nat'l Strength & Conditioning Ass'n, 2015 WL 12466532, at *7 (S.D. Cal. 2015) (citing Fed. R. Civ. P. 1).

Thus, the Court finds that the balance of interests does not favor de-designation of the Challenged Materials under the terms of the Protective Order and the Court **DENIES** Plaintiff's motion to de-designate the Challenged Materials.

II. Request for Judicial Notice

Plaintiff and Defendants both request this Court take judicial notice of certain documents. Plaintiff requests that the Court take judicial notice of Congressional Record, 113th Congress, 1st Session, Vol. 159, No. 131 – Daily Edition. ECF No. 44 at 2. Defendants request that the Court take judicial notice of multiple documents: a verified complaint for a case pending in the United Stated District Court in Greenville, South Carolina, and FDA website materials. ECF No. 472-2 at 1.

Federal Rule Evidence 201 permits a court to take judicial notice of an adjudicative fact if it is "not subject to reasonable dispute." Fed. R. Evid. 201(b). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(1)-(2). Additionally, "a court may take judicial notice of 'matters of public record." Fed. R. Evid. 201(b).

Courts regularly take judicial notice of congressional records. <u>See</u>, <u>e.g.</u>, <u>Morning Star Packing Co. v. S.K. Foods, L.P.</u>, 2015 WL 3797774, at *2 (E.D. Cal. June 18, 2015) (taking judicial notice of congressional records); <u>see also Hadley v. Kellogg Sales Company</u>, 243 F. Supp. 3d 1074, 1087 (N.D. Cal. Mar. 21, 2017) (same). Accordingly, the Court **GRANTS** Plaintiff's request for judicial notice of the congressional record.

"Courts have consistently held that courts may take judicial notice of documents filed in other court proceedings." NuCal Food, Inc. v. Quality Egg LLC, 887 F. Supp. 2d 977, 984 (E.D. Cal. 2012). However, "[w]hile the authenticity and existence of a particular order, motion, pleading or judicial proceeding, which is a matter of public record, is judicially noticeable, veracity and validity of its contents ... are not." United States v. S. Cal. Edison Co., 300 F. Supp. 2d 964, 974 (E.D. Cal. 2004). Based on the foregoing authority, the Court **GRANTS** Defendants' request to take judicial notice of the verified amended complaint to the extent that they seek judicial notice of the existence of the document.

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The FDA website materials consist of both website information and PDF downloads. They include: (1) FDA's Compounding Oversight and Compliance Actions ("Exhibit 2"); (2) FDA's Compounding: Inspections, Recalls, and other Others ("Exhibit 3"); (3) an FDA Inspectional Observation Form issued on September 23, 2021, after the observation of Defendant's Missoula, Montana facility from September 15, 2021 to September 23, 2021 ("Exhibit 4"; (4) an FDA Inspectional Observation Form issued on January 29, 2021, after the observation of Plaintiff's Ledgewood, New Jersey facility from September 28, 2020 to January 29, 2021 ("Exhibit 5"); (5) an FDA Warning Letter Issued to Imprimis NJOF, LLC dated June 7, 2019 ("Exhibit 6"); and (6) an FDA's Warning Letter issued to Imprimis Pharmaceutical dated December 21, 2017 ("Exhibit 7"). See Declaration of Thomas J. Martin ("Martin Decl."), ECF No. 47-3.

"[J]udicial notice is appropriate for information obtained from government websites, as well as copies of 'records and reports of administrative bodies." Allergen USA, Inc v. Prescribers Choice, Inc., 364 F. Supp. 3d 1089, 1095 (C.D. Cal. 2019) (quoting United States v. Ritchie, 342) F.3d 903, 909 (9th Cir. 2003). FDA warning letters that are available on the FDA's website are appropriate subjects of judicial notice. See In re ConAgra Foods Inc., 908 F. Supp. 2d 1090, 1104 n.39 (C.D. Cal. 2012) ("The court can take judicial notice of the letter as a report of an administrative body."); see also, Von Koenig v. Snapple Beverage Corp., 713 F.Supp.2d 1066, 1073 (E.D.Cal.2010) ("The warning letters are matters of public record, available on the FDA website."). The Court, however, does not take judicial notice of reasonably disputed facts contained within judicially noticed documents. Allergen, 364 F. Supp. 3d at 1095 (citing Lee v. City of L.A., 250 F.3d 668, 688-89 (9th Cir. 2001). Thus, the Court **GRANTS** Defendant's request for judicial notice as to the existence of the two FDA warning letters, two inspectional observation forms, and two FDA webpages that reference compounding, as identified in Defendant's Request for Judicial Notice [Exhibits 2-7]. However, the Court does not take judicial notice of the facts within the exhibits that are subject to reasonable dispute. See id. (citing Lee, 250 F.3d at 690).

III. Motion to File Under Seal

Plaintiff seeks an order sealing Plaintiff's unredacted Motion to De-Designate as

Confidential and Exhibit B. ECF No. 41 at 2. In accordance with the undersigned's Chambers Rules, Plaintiff filed a redacted version of the Motion to De-Designate and Exhibit B. ECF No. 43, 43-3. Additionally, Defendants filed their response in support of Plaintiff's motion on July 15, 2022. ECF No. 48.

"For discovery motions attached to non-dispositive motions and filed under seal pursuant to a valid protective order, 'the usual presumption of the public's right of access [to court filings is rebutted]."" Orthopaedic Hospital v. Encore Medical, L.P., 2021 WL 5449041, at *2 (S.D. Cal. Nov. 19, 2021) (quoting Phillips, 307 F.3d at 1213). Thus, a showing of good cause is sufficient under Federal Rule of Civil Procedure Rule 26(c). Kamakana, 447 F.3d at 1180 (9th Cir. 2006). "For good cause to exist, the party seeking protection bears the burden of showing specific prejudice or harm will result if no protective order is granted." Phillips, 308 F.3d at 1210-11 (citing Beckman Indus., Inc. v. Int'l Ins. Co., 966 F.2d 470, 476 (9th Cir. 1992). Here, the underlying motions relate to a non-dispositive dispute regarding discovery documents; thus, the good cause standard as noted applies. Further, the undersigned's Chambers Rules, which are incorporated in the parties' protective order outlines, "A sealing order may issue only upon a showing that the information is privileged or protectable under the law." J. Major Civ. Chmbrs. R. at 9; ECF No. 26 at 2.

Based on the motion to file documents under seal [ECF No. 41], good cause shown therein, and this Court's ruling that Defendant's designations are proper, the motion to seal is **GRANTED** and it is hereby **ORDERED** that the following documents be filed under seal: (1) Plaintiff's Motion to De-Designate Documents [ECF No. 42] and (2) Exhibit B [ECF No. 42-1].

CONCLUSION

Based on the foregoing, the Court **DENIES** Plaintiff's request in its motion to dedesignate for an order striking the "confidential" designations of the Challenged Materials that Defendants produced during discovery. Plaintiff may seek to reveal the Challenged Materials in the public record if they are submitted to the District Judge in connection with a dispositive motion or as evidence at trial.

Further, Plaintiff's motion to file documents under seal is **GRANTED**. The Clerk of the

Court is directed to file the unredacted version of Plaintiff's motion [ECF No. 42] and Exhibit B [ECF No. 42-1] under seal. The redacted version of Plaintiff's motion [ECF No. 43] and Exhibit B [ECF No. 43-3] shall continue to be filed in the public record.

The Court further **GRANTS** Plaintiff's request for judicial notice and **GRANTS**Defendant's request for judicial notice as described above.

IT IS SO ORDERED.

Dated: 8/15/2022

Hon. Barbara L. Major

United States Magistrate Judge