UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION	Case No.: 13md2452 AJB (MDD) **ORDER GRANTING COMPREHENSIVE MOTIONS TO SEAL DOCUMENTS AND BRIEFING FILED IN SUPPORT OF THE PARTIES' CROSS-MOTIONS FOR SUMMARY JUDGMENT** **(Doc. Nos. 1339, 1340, 1448)**

I. INTRODUCTION

Presently before the Court are motions to seal documents related and attached to the parties' cross-motions for summary judgment on the affirmative defense of preemption. (Doc. Nos. 1339, 1340, 1448.) Defendants Novo Nordisk, Inc. ("Novo"), Merck Sharp & Dohme, Corp. ("Merck"), Amylin Pharmaceuticals, LLC ("Amylin") and Eli Lilly and Company, ("Lilly") have each moved to seal portions of the summary judgment briefing and attached exhibits. Plaintiffs oppose the motions to seal and filed an opposition on September 4, 2015. (Doc. No. 1403.)

On November 9, 2015, the Court issued an order on the parties' cross-motions for summary judgment, granting Defendants' motion and denying Plaintiffs' cross-motion. (Doc. No. 1539.) Having addressed the merits of the motions for summary judgment, the

Court now turns to the motions to seal.

II. LEGAL STANDARD

Courts have historically recognized a "general right to inspect and copy public records and documents, including judicial records and documents." *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597 & n.7 (1978). "Unless a particular court record is one 'traditionally kept secret,' a 'strong presumption in favor of access' is the starting point. *Kamakana v. City and Cnty. of Honolulu*, 447 F.3d 1172, 1178 (9th Cir. 2006) (quoting *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003)). To overcome this strong presumption, a party seeking to seal a judicial record must articulate justifications for sealing that outweigh the public policies favoring disclosure. *See id.* at 1178–79. In turn, the court must "conscientiously balance the competing interests" of the public and the party who seeks to keep certain judicial records secret. *Id.* After considering these interests, if the court decides to seal certain judicial records, it must "base its decision on a compelling reason and articulate the factual basis for its ruling, without relying on hypothesis or conjecture." *Id.* (citing *Hagestad v. Tragesser*, 49 F.3d 1430, 1434 (9th Cir. 1995)). The strong presumption of access to judicial records applies fully to dispositve pleadings, including motions for summary judgment and related attachments. Thus, to warrant sealing documents in connection with a dispositive motion, the party must show "compelling reasons." *Kamakana*, 447 F.3d at 1179. Relevant factors include the "public interest in understanding the judicial process and whether disclosure of the material could result in improper use . . . ." *Pintos v. Pacific Creditors Ass'n*, 605 F.3d 665, 659 (9th Cir. 2010) (citations omitted).

Courts have long-acknowledged that the risk of competitive harm through disclosure of confidential and proprietary information warrants maintaining documents under seal, even in light of the general presumption of public access to judicial documents. *See Nixon v. Warner Communications*, 435 U.S. 589, 598 (1978) (the court may ensure its records are not used "as sources of business information that might harm a litigant's competitive standing"); *Valley Broadcasting Co. v. U.S. District Court*, 798

F.2d 1289, 1294 (9th Cir. 1996) (noting considerations that weigh against disclosure include "the likelihood of an improper use, including. . . trade secret materials; infringement of fair trial rights of the defendants or third persons; and residual privacy rights") (internal quotation and citation omitted); *Sullivan v. Deutsche Bank Americas Holding Corp.*, No. 08CV2370, 2010 WL 3448608, at *2 (S.D. Cal. Aug. 31, 2010) (finding the "likelihood of improper use by competitors and the proprietary nature of the confidential information" was a compelling reason to seal documents).

In an unpublished opinion, the Ninth Circuit has defined a trade secret in the context of a motion to seal as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." *In re Elec. Arts, Inc.*, 298 Fed. Appx. 568, 569 (9th Cir. 2008) (quoting Restatement of Torts § 757, cmt. b). Other courts applying this definition have concluded that detailed product-specific financial information, customer information and internal reports are appropriately sealable under the compelling reasons standard where that information could be used to the company's competitive disadvantage. *Apple Inc. v. Samsung Electronics Co., Ltd.*, 727 F.3d 1214, 1226, 1228 (Fed. Cir. 2013); *see also Asetek Danmark A/S v. CMI USA, Inc.*, No. 13CV00457, 2015 WL 4116738, at *2 (N.D. Cal. July 7, 2015). Similarly, courts have maintained documents under seal where the information contained therein could permit competitors to "gain access to operational and personnel information, projections and modeling, and strategic positioning vis-a-vis its competitors." *Rich v. Shrader*, No. 09CV652, 2013 WL 6190895, at *2 (S.D. Cal. Nov. 26, 2013).

III. DISCUSSION

A. Relevant Legal Standard

Amylin and Lilly's motion to seal challenges whether Plaintiffs' motion for summary judgment is a dispositive motion such that the higher "compelling reasons" standard should apply to the motions to seal. (Doc. No. 1339 at 6 n.5.) The Ninth Circuit has not expressly delineated what constitutes a dispositive motion in the context of a

motion to seal. *See Select Portfolio Servicing v. Valentino*, No. 120334, 2013 WL 1800039, at *2 (N.D. Cal. Apr. 29, 2013) ("The Ninth Circuit has not provided guidance on distinguishing dispositive from non-dispositive motions, in the sealing context."); *In re Nat'l Sec. Agency Telecommunications Records Litig.*, 2007 WL 549854 (N.D. Cal. Feb. 20, 2007) (noting a "lack of explicit guidance on this issue"). Motions for summary judgment, however, are viewed as dispositive in the context of a motion to seal, *see Kamakana*, 447 F.3d at 1179, and even motions to dismiss are typically treated as dispositive. *See BT Collective v. IP Holdings, LLC*, 2011 WL 5873388, at *3 (S.D. Cal. Nov. 23, 2011) (citing *In re PPA Products Liability Litigation*, 460 F.3d 1217, 1231 (9th Cir. 2006) ("Motions to dismiss are typically treated as dispositive.").

In the absence of further authority on this point, district courts have looked to the underlying rationale for distinguishing between dispositive and non-dispositive motions when determining what standard to apply to a motion to seal. *See Select Portfolio Servicing*, 2013 WL 1800039, at *2 (quoting *In re Nat'l Sec. Agency Telecommunications Records Litig.*, 2007 WL 549854 ("Absent specific guidance 'the court looks to the underlying rationale for distinguishing between dispositive and non-dispositive motions.'")). For example, documents attached to non-dispositive motions are generally marginally relevant to the merits of the underlying litigation, and thus warrant application of a lower standard to justify prohibiting public access. *Oliner v. Kontrabecki*, 745 F.3d 1024, 1026 (9th Cir. 2014) ("The rationale underlying the good cause standard for nondispositive orders, namely that the public has less of a need for access to court records attached only to non-dispositive motions because those documents are often unrelated, or only tangentially related, to the underlying cause of action.") (internal citation and quotation marks omitted); *Kamakana*, 447 F.3d at 1179 ("Nondispositive motions are often unrelated, or only tangentially related, to the underlying cause of action, and, as a result, the public's interest in accessing dispositive materials does not apply with equal force to non-dispositive materials.") (internal citation and quotation marks omitted). In contrast, documents attached to dispositive motions generally relate

directly to the merits of the litigation and thus carry a greater presumption of public access, justifying the compelling reasons standard. *Id.*

Having ruled on the parties' cross-motions for summary judgment and finding Defendants' motion dispositive of Plaintiffs' failure-to-warn claims, the Court finds the compelling reasons standard is applicable to the instant motions to seal. Though Plaintiffs filed the documents at issue in connection with their affirmative motion for summary judgment, a court must consider the evidence submitted with cross-motions for summary judgment regardless of which party submitted the evidence. *Tulalip Tribes of Wash. v. Washington*, 783 F.3d 1151, 1156 (9th Cir. 2015). Thus, the Court will evaluate Defendants' motions under the compelling reasons standard.

B. Plaintiffs' opposition

Pursuant to the agreement of the parties, Plaintiffs filed a single opposition addressing each of Defendants' motions to seal. (Doc. No. 1403.) In opposition to sealing documents, Plaintiffs argue the instant litigation greatly affects public concerns regarding the drugs at issue and the actions by the FDA. Plaintiffs also argue Defendants have not established compelling reasons to seal the information at issue because (1) the public is entitled to a balanced portrayal of available science; (2) potential public confusion is insufficient to seal information; and (3) speculative commercial harm is also insufficient to seal information. (*See generally id.*)

C. Motions to seal [1]

Amylin and Lilly request the Court strike or seal limited redactions to exhibits attached to Plaintiffs' motion for summary judgment. Amylin and Lilly contend the information at issue contains competitively sensitive and confidential information that could lead to competitive harm to Amylin and Lilly, as well as confusion to the public if

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[1] Though each defendant filed individual motions to seal, Defendants have jointly submitted proposed redactions to all documents referenced in the motions to seal with the declaration of Ana Reyes. (Doc. No. 1448-1.)

disclosed and available publicly.

Novo moves to seal several exhibits as well as portions of Plaintiffs' affirmative motion for summary judgment and Plaintiffs' opposition to Defendants' motion for summary judgment. (Doc. No. 1340.) Novo similarly cites to the risk of competitive harm from disclosure of the information it seeks to seal, as well as foreign privacy laws which govern some of the information at issue.

Merck also moves to seal several exhibits attached to Plaintiffs' memorandum in support of summary judgment, as well as any reference to that information in the parties' summary judgment briefing. (Doc. No. 1448.) Merck raises similar arguments in support of its motion to seal as the other defendants—specifically that the information is confidential and proprietary and could lead to competitive harm if available publicly. Merck also seeks to seal communications with the FDA as well as foreign regulatory agencies.

Upon review of each motion to seal, the declarations filed in support therewith, as well as Plaintiffs' opposition, the Court finds Defendants have established compelling reasons to maintain the information at issue under seal. Much of the information is confidential and proprietary information specific to each drug at issue and the development, testing, and regulation of each drug. Such information is readily subject to improper use resulting in significant competitive harm if disclosed publicly and available to competitors. In addition, the scientific data and evaluations that Defendants seek to seal bring a significant risk of confusion to the public if disclosed in the limited context of adversarial cross-motions for summary judgment. This is particularly true as the Court limited its analysis in the motions for summary judgment to a review of FDA action, exclusive of an evaluation or analysis of the specific data considered by the FDA or other foreign regulatory agencies. (*See* Doc. No. 1539 at 8 n.5.) Because the Court did not evaluate the data underlying the FDA's actions or the information allegedly withheld from the FDA, (*see id.* at 29), such information will shed no light on the judicial process and bears the risk of causing confusion to the public through the limited disclosure of

traditionally confidential data and regulatory submissions.

Novo's reliance on foreign privacy laws, as well as Merck's citation to Health Canada's designation of information as confidential are also highly persuasive. That Health Canada considers communications with sponsors to be confidential, and the Court's limited consideration of FDA action, as opposed to that of other regulatory agencies, further supports sealing the Health Canada assessment and any reference to that information. Moreover, to the extent the Court did not consider certain information at issue, either as outside the scope of the Court's preemption analysis or because it is unrelated to pancreatic safety, that information is appropriately sealed.

Thus, the Court finds the threat of competitive harm from disclosure and the potential to confuse and mislead the public outweigh the public's right of access and amount to compelling reasons to maintain the information at issue under seal. Accordingly, any reference to that information in the parties' briefing on the cross-motions for summary judgment should also be maintained under seal in the form of limited redactions. This conclusion is consistent with the Court's general reference to the existence of data allegedly not considered by the FDA. Though the Court refers to the existence of certain data in its order on the parties' motions for summary judgment, any reference is general in nature and made to provide context to the Court's *Buckman* analysis. Compelling reasons exist to maintain the underlying data, as well as the parties' interpolations of that data, under seal. The same rationale, however, does not apply to the Court's general reference to that data.

IV. CONCLUSION

As set forth more fully above, each of Defendants' motions to seal are **GRANTED**. Accordingly, the following documents are to be sealed in their entirety or in the form of limited redactions: [2]

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[2] Although Amylin and Lilly alternatively request the Court strike the information it seeks to seal, the Court declines to do so and finds maintaining that information under seal as

- Doc. No. 1166 in the form of limited redactions as demonstrated in Exhibit 1 to the declaration of Ana Reyes, Doc. No. 1448-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 3 to Doc. No. 1166 in the form of limited redactions as demonstrated in Exhibit 2 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 18 to Doc. No. 1166 in the form of limited redactions as demonstrated in Exhibit 3 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 23 to Doc. No. 1166 form of limited redactions as demonstrated in Exhibit 4 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Doc. No. 1215 in the form of limited redactions as demonstrated by Exhibit 5 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit CC to Doc. No. 1215 in the form of limited redactions as demonstrated by Exhibit 6 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Doc. No. 1218 in the form of limited redactions as demonstrated by Exhibit 7 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 2 to Doc. No. 1218 in the form of limited redactions as demonstrated by Exhibit 8 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 5 to Doc. No. 1218 in the form of limited redactions as demonstrated by

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part of the record on the underlying cross-motions for summary judgment is more appropriate.

Exhibit 9 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.

- Exhibit 7 to Doc. No. 1218 in the form of limited redactions as demonstrated by Exhibit 10 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 8 to Doc. No. 1218 in the form of limited redactions as demonstrated by Exhibit 11 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 9 to Doc. No. 1218 in the form of limited redactions as demonstrated by Exhibit 12 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Doc. No. 1285 in the form of limited redactions as demonstrated by Exhibit 13 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exhibit 2 to Doc. No. 1285 in the form of limited redactions as demonstrated by Exhibit 14 to the declaration of Ana Reyes, Doc. No. 1148-1. Defendants are directed to provide a redacted version within ten (10) days of the date of this order.
- Exs. 7, 12, 13, 14, 15, 21, and 24 in their entirety.

IT IS SO ORDERED.

Dated: November 18, 2015

Hon. Anthony J. Battaglia
United States District Judge