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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., ET AL.,  
Plaintiffs,

v.

SANDOZ INC., et al.,  
Defendants.

Case No. [16-cv-02581-RS](#) (MEJ)

**DISCOVERY ORDER**

Re: Dkt. No. 64

**INTRODUCTION**

Plaintiffs Amgen, Inc. and Amgen Manufacturing Limited (collectively, “Amgen”) and Defendants Sandoz Inc. and Lek Pharmaceuticals d.d.<sup>1</sup> (collectively, “Sandoz”) disagree about the wording of a provision in their proposed protective order regarding in-house counsel’s access to confidential materials. *Jt. Ltr.*, Dkt. No. 64. Both parties agree that a protective order is necessary, and each has submitted a proposed protective order largely based on the one entered in *Amgen Inc. v. Sandoz Inc.*, 14-cv-4741 (N.D. Cal.) (the “filgrastim case”). The filgrastim case is a related case pending before the presiding judge in this matter, the Honorable Richard Seeborg. The filgrastim protective order is based on the Northern District of California’s Patent Model Protective Order. But Sandoz seeks to modify the filgrastim protective order by adding an additional tier of confidentiality: “HIGHLY CONFIDENTIAL—OUTSIDE COUNSELS’ EYES ONLY” (“OCO”). Amgen opposes including this additional tier. Having considered the parties’ positions, the relevant legal authority, and the record in this case, the Court issues the following order.

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<sup>1</sup> Lek Pharmaceuticals is not a party in the filgrastim case.

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**LEGAL STANDARD**

Federal Rule of Civil Procedure 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).

**DISCUSSION**

Sandoz proposes that a “HIGHLY CONFIDENTIAL – OUTSIDE COUNSELS’ EYES ONLY” designation should apply to

extremely sensitive “Confidential Information or Items” that consist of or relate to communications with the [Food and Drug Administration (“FDA”)] occurring on or after June 24, 2016 relating to the approval of Biologics License Application [“BLA”] No. 761045 for the Sandoz pegfilgrastim product, that constitute hyper-sensitive, competitive information that will cause irreparable harm if disclosed to another Party, including to such Party’s Designated House Counsel, or Non-Party, which harm could not be avoided by less restrictive means.

Sandoz Prop. Protective Order ¶ 2.11, Ex. B, Jt. Ltr. The Court finds Sandoz has not shown an OCO designation is appropriate at this point.

Courts may not deny access to confidential information solely on the basis of counsel’s in-house or retained status. *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1467-68 (Fed. Cir. 1984). “Denial or grant of access . . . cannot rest on a general assumption that one group of lawyers are more likely or less likely inadvertently to breach their duty under a protective order.” *Id.* at 1468. Rather, “the factual circumstances surrounding each individual counsel’s activities, association, and relationship with a party, whether counsel be in-house or retained, must govern any concern for inadvertent or accidental disclosure.” *Id.* Denial of access may be appropriate in some instances; for example, “where in-house counsel are involved in competitive decisionmaking, it may well be that a party seeking access should be forced to retain outside

1 counsel or be denied the access recognized as needed.” *Id.*

2 As Sandoz notes, “Amgen has yet to identify its Designated House Counsel for [this]  
3 matter[.]” Jt. Ltr. at 4. Sandoz presumes, however, that Amgen “would . . . identify at least  
4 counsel who have already appeared in this matter – Wendy Whiteford (Vice President, Law) and  
5 Lois Kwasigroch (Senior Counsel) – whose titles indicate that they have broad responsibilities  
6 with competitive impact.” *Id.* Given that Amgen has not named its designated in-house counsel,  
7 the Court cannot conduct the counsel-by-counsel, fact-specific analysis necessary to determine if  
8 Amgen’s in-house counsel engages in competitive decisionmaking. The *U.S. Steel* court defined  
9 “competitive decisionmaking” as “counsel’s activities, association, and relationship with a client  
10 that are such as to involve counsel’s advice and participation in any or all of the client’s decisions  
11 (pricing, product design, etc.) made in light of similar or corresponding information about a  
12 competitor.” 730 F.2d at 1468 n.3; *see also Barnes & Noble, Inc. v. LSI Corp.*, 2012 WL 601806,  
13 at \*2 (N.D. Cal. Feb. 23, 2012) (quoting *id.*). Although Sandoz identifies Ms. Whiteford and Ms.  
14 Kwasigroch, their titles alone do not provide sufficient information regarding their responsibilities  
15 toward or their relationship with Amgen such that the Court can determine if these attorneys are  
16 involved in any competitive decisionmaking. That Ms. Whiteford and Ms. Kwasigroch are  
17 involved in such activity is, at this point, speculation.

18 In *Brown Bag Software v. Symantec Corp.*, the Ninth Circuit reviewed a protective order  
19 that shielded the plaintiff’s in-house counsel from viewing documents that contained the  
20 defendant’s trade secrets, but allowed an independent consultant access to them to advise the  
21 plaintiff as to the documents’ relevancy. 960 F.2d 1465, 1469-72 (9th Cir. 1992). The *Brown Bag*  
22 Court noted that “proper review of protective orders in cases such as this requires the district court  
23 to examine factually all the risks and safeguards surrounding inadvertent disclosure by any  
24 counsel, whether in-house or retained.” *Id.* at 1470. The Ninth Circuit found the district court did  
25 just that: it issued the protective order after conducting “a comprehensive evidentiary hearing.” *Id.*  
26 at 1470. At the hearing, the district court heard testimony regarding both parties’ interest in the  
27 confidential information. *Id.* at 1470-71. The district court also questioned the plaintiff’s in-house  
28 counsel about his responsibilities. *Id.* at 1741. In-house counsel testified that “he was responsible

1 for advising his employer on a gamut of legal issues, including contracts, marketing, and  
2 employment.” *Id.* The district court thus “reasonably concluded that [in-house] counsel’s  
3 employment would necessarily entail advising his employer in areas relating to [the defendant’s]  
4 trade secrets.” *Id.* This “would place in-house counsel in the ‘untenable position’ of having to  
5 refuse his employer legal advice on a host of contract, employment, and competitive marketing  
6 decisions lest he improperly or indirectly reveal [the defendant’s] trade secrets.” *Id.* After  
7 weighing the hardship a protective order may have on the plaintiff’s prosecutions of its claims, the  
8 district court issued a protective order that the Ninth Circuit held “str[uck] a reasonable balance  
9 between those interests by shielding [the plaintiff’s] in-house counsel from personal knowledge of  
10 a competitor’s trade secrets, but allowing access to information through an independent  
11 consultant.” *Id.* “The order did not arbitrarily distinguish [between] outside and in-house counsel.  
12 Rather, in reaching its decision, the court considered the particular circumstances of [the  
13 plaintiff’s] counsel then before it. The same considerations could have applied equally to outside  
14 counsel.” *Id.*

15 In contrast, Amgen’s in-house counsel’s identities in this matter are still unknown. The  
16 Court is therefore unable to consider the specific responsibilities of those attorneys, and is unable  
17 to evaluate whether they are engaged in competitive decisionmaking for their client. *Cf. Pinterest,*  
18 *Inc. v. Pintrips, Inc.*, 2014 WL 5364263, at \*2 (N.D. Cal. Oct. 21, 2014) (relying on in-house  
19 counsel’s declarations stating they do not engage in competitive decisionmaking and describing  
20 counsel’s responsibilities); *Barnes & Noble, Inc.*, 2012 WL 601806, at \*2 (same). Adopting  
21 Sandoz’s OCO provision at this point would be to arbitrarily distinguish between counsel solely  
22 on the basis of their in-house and retained status.

### 23 CONCLUSION

24 At this time, the Court will not adopt Sandoz’s OCO designation. Sandoz may move to  
25 modify the protective order once Amgen identifies its designated in-house counsel, provided  
26 Sandoz can point to factual circumstances of each counsel that suggest the risk of inadvertent  
27 disclosure of confidential information.

28 **IT IS SO ORDERED.**

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Dated: January 3, 2017



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MARIA-ELENA JAMES  
United States Magistrate Judge