## Northern District of California

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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. 14-cv-04741-RS

## ORDER DENYING MOTION FOR INJUNCTION PENDING APPEAL

On March 25, 2015, this Court entered final judgment under Rule 54(b) of the Federal Rules of Civil Procedure as to its March 19 order on the parties' cross motions for judgment on the pleadings, dismissing with prejudice Plaintiffs Amgen, Inc. and Amgen Manufacturing, Limited's (collectively "Amgen") first and second claims for relief; granting judgment in favor of defendant Sandoz, Inc. et al.'s first through fifth counterclaims; and denying Amgen's motion for a preliminary injunction. On March 27, 2015, Amgen filed an appeal of this order with the United States Court of Appeals for the Federal Circuit. Amgen furthermore moves this Court for an injunction secured by bond that would restrain Sandoz from launching its biosimilar product pending the outcome of its appeal, pursuant to Rule 62(c), or, in the event this Court denied an injunction pending appeal, an injunction lasting until the Federal Circuit can rule on the appeal of such an order. The parties have stipulated that, upon this Court's denial of Amgen's application,

Amgen will appeal it to the Federal Circuit within two days.<sup>1</sup>

Rule 62(c) affords a district court from which an interlocutory order or final judgment that grants, dissolves, or denies an injunction is on appeal, the discretion to "suspend, modify, restore, or grant an injunction" while the appeal is pending "on terms for bond or other terms that secure the opposing party's rights" on a finding that such relief is warranted. Courts evaluate motions for preliminary injunction and motions for injunction pending appeal using similar standards. *See Alaska Conservation Council v. U.S. Army Corps of Engineers*, 472 F.3d 1097, 1100 (9th Cir. 2006). In *Winter v. Natural Resources Defense Council*, the Supreme Court declared that in order to obtain an injunction, a plaintiff must establish that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of injunctive relief, (3) the balance of the equities tips in its favor, and (4) an injunction is in the public interest. 555 U.S. 7, 20 (2008). *See also Hilton v. Braunskill*, 481 U.S. 770, 776 (1987) (setting forth substantially the same factors in deciding whether to grant a Rule 62(c) motion).

As noted in the prior order on the parties' cross motions for judgment on the pleadings and denying Amgen's motion for a preliminary injunction, the Ninth Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a "sliding scale." *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) ("[T]he 'serious questions' version of the sliding scale test for preliminary injunctions remains viable after the Supreme Court's decision in *Winter*."). According to this test, "[a] preliminary injunction is appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," provided, of course, that "plaintiffs must also satisfy the other [*Winter*] factors" including the likelihood of irreparable harm." *Id.* at 1135; *see also Conservation Congress v. U.S. Forest Service*, 803 F. Supp. 2d 1126, 1129-30 (E.D. Cal.

Federal Circuit hear this matter in its June calendar.

<sup>25</sup> Sandoz has agreed to refrain from launching its filgrastim biosimilar product, Zarxio, until the earlier of May 11, 2015, or a decision by the Federal Circuit on Amgen's application for an injunction pending appeal. The Federal Circuit has already granted Amgen's unopposed motion to expedite briefing, ensuring its completion by April 30; and the parties have requested that the

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2011) (applying *Cottrell's* "serious questions" version of the sliding scale test on a Rule 62(c) motion).<sup>2</sup>

While Amgen raises significant and novel legal questions as to the merits of its case, as noted in the Court's prior order, its tenuous and highly contingent showing of irreparable harm forecloses injunctive relief. Indeed, Amgen repeats, to no avail, its previously considered grounds for contending it will suffer irreparable harm. Even taking into account the additional evidentiary material filed subsequent to the hearing on the parties' motions, Amgen's showing of potential price erosion, harm to Amgen's customer relations and goodwill, and diversion of Amgen's sales representatives' energy, is speculative. Moreover, even if these ramifications were certain to occur, according to this Court's interpretation of the BPCIA, any detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen patent. Amgen having made no showing as to this latter point, the likelihood of it wrongfully suffering irreparable harm appears slim and does not merit injunctive relief. Amgen's contention that Sandoz overstates the prejudice it would suffer in the face of an injunction pending appeal does not, therefore, tip the balance of equities in Amgen's favor.

Accordingly, Amgen's motion for an injunction pending appeal to the Federal Circuit of this Court's order on the parties' cross motions for judgment on the pleadings and Amgen's motion for preliminary injunction or, in the alternative, pending appeal of this order, is denied.

IT IS SO ORDERED.

Dated: April 15, 2015

RICHARD SEEBORG United States District Judge

<sup>&</sup>lt;sup>2</sup> The parties clash on which standard should apply here. In matters not unique to patent law, the Federal Circuit typically defers to the law of the regional circuit from which the case arises. Allergan, Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350, 1354 (Fed. Cir. 2013). In any case, the issue of which standard should apply to Amgen's motion need not be decided here, as Amgen fails to clear the hurdles set forth under either standard.