

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CIPLA LTD. and CIPLA USA, INC.,

Plaintiffs,

v.

AMGEN INC., and
TEVA PHARMACEUTICALS USA, INC.,

Defendants.

C.A. No. 19-44-LPS

AMGEN INC., and
TEVA PHARMACEUTICALS USA, INC.,

Counterclaim-Plaintiffs

v.

CIPLA LTD. and CIPLA USA, INC.,

Counterclaim-Defendants.

MEMORANDUM ORDER

Pending before the Court is Amgen Inc.’s (“Amgen”) motion for an injunction pending appeal, *see* Fed. R. Civ. P. 62(d), or, in the alternative, for a 14-day injunction to enable Amgen to pursue, at the Third Circuit, an expedited motion for an injunction pending appeal, *see* Fed. R. App. P. 8(d). (D.I. 192) The relevant facts are set out in the Court’s May 2, 2019 Opinion, which denied Amgen’s motion (D.I. 121) for a preliminary injunction to stop Cipla Ltd. and Cipla USA, Inc. (together, “Cipla”) from selling its generic cinacalcet product (“Cipla Product”). (*See* D.I. 186) (“Opinion” or “Op,”) The Court found that Amgen had not demonstrated a likelihood of success on the merits of its claim that Cipla breached the parties’ settlement agreement (“Amgen-Cipla Agreement”) by selling Cipla Product. (*Id.*) After reviewing briefing

relating to the pending motion (D.I. 194, 197, 199), **IT IS HEREBY ORDERED** that Amgen's motion (D.I. 192) is **DENIED**, for the following reasons:

1. Federal Rule of Civil Procedure 62(d) provides, in relevant part, that a court may grant an injunction while an appeal is pending from an interlocutory order that refuses to grant the injunction. To succeed on its Rule 62(d) motion, Amgen must demonstrate: (1) a "strong showing" that it is likely to succeed on the merits in its appeal; (2) absent an injunction it will be irreparably harmed; (3) an injunction or stay will not substantially injure Cipla; and (4) an injunction will not harm the interests of the public. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *see also Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). An injunction pending appeal is "extraordinary" relief. *United States v. Cianfrani*, 573 F.2d 835, 846 (3d Cir. 1978). The decision of whether to grant an injunction pending appeal is one within the discretion of the district court. *See In re Revel AC, Inc.*, 802 F.3d 558, 567 (3d Cir. 2015).

2. A substantial portion of Amgen's briefing is devoted to its contention that it should obtain its requested injunction pending appeal merely by showing (on the first prong of the test) just a "reasonable chance, or probability" of success on the merits, a burden which may even be lower than the one Amgen confronted in moving for a preliminary injunction. (*See, e.g.*, D.I. 194 at 1) The Court disagrees. A "strong showing" of likelihood of success is required to prevail on a Rule 62(d) motion. *See Hilton*, 481 U.S. at 776; *see also All. for the Wild Rockies v. Kruger*, 35 F. Supp. 3d 1259, 1270 (D. Mont. 2014) ("[I]njunctive remedies are extraordinary remedies. This maxim carries particular significance when a plaintiff seeks an injunction pending

appeal.”).¹ In any event, Amgen has not shown even a reasonable chance or probability of success on the merits.²

3. Amgen also faults the Court for resolving uncertainties against it. (*See, e.g.*, D.I. 199 at 7) The Court found Section 5.6 to be clear and unambiguous and denied the preliminary injunction principally on this basis. (*See Op.* at 10-24) To the extent the Court identified material factual uncertainties in the record – e.g., whether Teva has ceased selling its product – Amgen will have the burden of proof on these disputes as this case proceeds on the merits (i.e., to prevail on its breach of contract counterclaim). Amgen also had the burden on its motion for a preliminary injunction. Amgen’s criticisms of the Court’s Opinion, thus, do not persuade the Court that Amgen has a reasonable chance of prevailing on appeal.

4. Amgen argues that the Court’s interpretation of Section 5.6 of the Amgen-Cipla Agreement renders “superfluous” the rest of the “Agreement’s licensing and acceleration structure.” (D.I. 194 at 5, 6 n.2) Amgen further faults the Court’s interpretation for “undermin[ing] the overall contractual scheme” (*id.* at 4), which intends to “place[] Cipla on equal footing with other generic manufacturers” (D.I. 199 at 4). Neither Amgen’s new arguments, nor its reiteration of already-rejected arguments, persuades the Court that Amgen is likely to succeed on the merits of its appeal. Amgen has failed to persuade the Court that the Court’s reading of sentence [2] of Section 5.6, as clearly and unambiguously requiring denial of the preliminary injunction motion, is incorrect. Nor has Amgen provided any persuasive basis

¹ Amgen’s reliance on *In re Revel AC, Inc.*, 802 F.3d at 567-69, for a lower standard, is unavailing. *In re Revel* expressly states that a movant for a stay pending appeal *must* provide “a strong showing of the likelihood of success.” *Id.* at 565.

² Amgen’s appeal is from the denial of a preliminary injunction, so the Court of Appeals will apply a “deferential” abuse of discretion standard of review. *See Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017), *as amended* (June 26, 2017).

for the Court to predict that Amgen's arguments will fare better on appeal. The Court's role is to determine Amgen's and Cipla's rights and responsibilities under the Amgen-Cipla Agreement, not to maintain "parity" (D.I. 194 at 6) among generic manufacturers or effectuate any other intent that is inconsistent with the contractual language the parties negotiated and executed.

5. For the reasons articulated in its Opinion, Court finds that Amgen has demonstrated that it will be irreparably harmed in the absence of an injunction pending appeal. (D.I. 186 at 29-31) The balance of harms also favors Amgen, narrowly. (*See id.* at 31-36)³ Finally, the public interest also slightly favors Amgen here, for the same reasons as already given in the Opinion. (*See id.* at 36-37) Nonetheless, because Amgen has not met its burden with respect to likelihood of success on appeal, the Court will deny the motion for an injunction pending appeal.

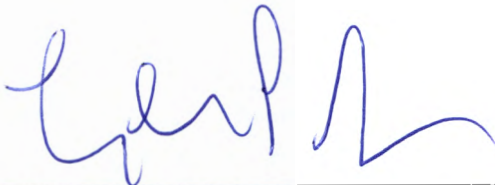
6. The Court will also deny the lesser, alternative relief sought by Amgen, which is a 14-day injunction to allow Amgen to pursue, at the Third Circuit, an expedited motion to grant an injunction pending appeal, *see* Fed. R. App. P. 8(d). (D.I. 194 at 14-15) Again, Amgen has failed to show likelihood it will succeed with its appeal. Additionally, the balance of harms and the public interest do not favor disrupting the market for generic cinacalcet over the next two weeks as Amgen seeks to obtain expedited relief from the Court of Appeals. While it is unclear how great of a benefit Amgen would obtain by prohibiting further Cipla sales during that short timeframe, the harm to Cipla from having to undertake a brief halt in its sales activities⁴ – and

³ The Court recognizes that in describing Cipla's intended "nine-figure sale" it mistakenly equated this with "at least \$1 billion" of sales, when it should have characterized it as only between \$100 million and \$999 million in sales. Correcting this error does not alter the balance of harms.

⁴ Cipla has been selling Cipla Product for about two months. (D.I. 197 at 5)

the harm to the public from temporarily (and perhaps confusingly) losing access to a generic drug it currently may purchase – seems substantial. Amgen, having lost on its motion to preliminarily enjoin Cipla’s sales, will not be rewarded with an injunction to enjoin (even for two weeks) those very same sales simply because it has filed an appeal.⁵ See generally *Ortho Pharm. Corp. v. Amgen, Inc.*, 882 F.2d 806, 813 (3d Cir. 1989) (stating that goal of preliminary injunctive relief is “preservation of the status quo”).

May 9, 2019
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT COURT

⁵ Amgen’s reliance on this Court’s decision in *Noven Pharmaceuticals, Inc. v. Mylan Technologies, Inc.*, 2018 WL 4007848 (D. Del. Aug. 22, 2018), is unavailing. As Cipla points out, the generic manufacturer in *Noven* had not already launched, due to a temporary restraining order. *Id.* at *1. In *Noven*, then, the requested temporary injunction continued the status quo, whereas here it would disrupt it.