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 **Public Version** **Released May 3, 2019**
AMGEN INC., and TEVA PHARMACEUTICALS USA, INC., Counterclaim-Plaintiffs v. CIPLA LTD. and CIPLA USA, INC., Counterclaim-Defendants.	

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MEMORANDUM OPINION

May 2, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

This highly contentious case is not yet four months old. In its short life, the Court has held four hearings (two telephonically and two in-person) (*see* D.I. 24, 109, 173, 181, 182), resolved at least nine motions (*see, e.g.*, D.I. 1, 8, 37, 47, 61, 86, 105, 114, 115), reviewed hundreds of pages of briefing (*see* D.I. 7, 9, 11, 12, 17, 18, 21, 22, 23, 25, 34, 36, 38, 40, 41, 42, 44, 48, 67, 71, 74, 77, 79, 81, 83, 97, 98, 100, 101, 103, 110, 111, 112, 122, 131, 143, 163, 170, 178), and approved hundreds of pages of redacted filings. Both sides have sought expedited relief (*see* D.I. 34, 121) and pressed upon the Court the urgency and high-stakes nature of their dispute. (*See, e.g.*, D.I. 24 at 18 (Plaintiffs: "[W]e think this factual scenario cries out for expedition."); D.I. 181 ("Tr.") at 11 (Defendant: "[T]his case is a particularly strong one for the existence of irreparable harm to Amgen."))[1]

Most simply stated (a more detailed recitation appears below), Plaintiffs Cipla Ltd. and Cipla USA, Inc. ("Cipla") have undertaken an "at-risk" launch of their generic cinacalcet drug product ("Cipla Product"), prior to the expiration of United States Patent No. 9,375,405 (the "'405 patent"), which is owned by Defendant Amgen, Inc. ("Amgen"). In earlier litigation, Amgen alleged that the Cipla Product infringes Amgen's '405 patent. (C.A. No. 16-880-MSG D.I. 1) The parties settled the prior case by executing an agreement (*see* D.I. 73-1 Ex. 1) (the "Amgen-Cipla Agreement"), by which, among other things, Cipla agreed that: (i) the Cipla Product infringes the '405 patent, (ii) the claims of the '405 patent are valid and enforceable, (iii) Cipla will not (except under limited circumstances) begin to market the Cipla Product until 97

[1] References to the docket index ("D.I.") are to the instant case (C.A. No. 19-44-LPS), unless otherwise noted.

days before expiration of the '405 patent, and (iv) the Cipla Product will be licensed from on and after that agreed-upon launch date.

Thereafter, four other manufacturers of proposed pharmaceutical products that also would allegedly infringe the '405 patent went to trial in this Court. The Honorable Mitchell S. Goldberg, United States District Judge for the Eastern District of Pennsylvania sitting by designation in this District, issued a detailed opinion finding that the products proposed to be marketed by three of those entities – Watson Laboratories, Inc., a wholly-owned subsidiary of Teva, and hereinafter referred to as "Teva";[2] Piramal Healthcare UK Ltd. ("Piramal"); and Amneal Pharmaceuticals LLC ("Amneal") – do not infringe the '405 patent (*see* C.A. No. 16-853 D.I. 375), while a fourth product – that of Zydus Pharmaceuticals (USA) Inc. (the "Zydus Product") – would infringe that patent. Subsequently, Teva began to sell its product (the "Teva Product"), although several days later Teva entered into a settlement agreement with Amgen, by which it purportedly agreed to stop selling the Teva Product.[3] (*See* D.I. 73-1 Ex. 3) (the "Amgen-Teva Agreement")

Shortly after Teva's brief entry and exit from the market, Cipla filed the instant suit, seeking a declaratory judgment that, under the terms of the Amgen-Cipla Agreement, and due to circumstances arising from the launch of the Teva Product, Cipla now had the right to launch the Cipla Product. (D.I. 2) When, soon thereafter, Cipla did begin to sell and offer for sale its Cipla Product, Amgen filed a motion for a preliminary injunction (D.I. 121), which is pending before the Court.

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[2] *See* D.I. 73-1 Ex. 3, Amgen-Teva Agreement Ex. B) ("Watson Laboratories is an indirect wholly-owned subsidiary of Teva Pharmaceutical USA, Inc.").

[3] As will be seen, the parties disagree as to whether the Amgen-Teva Agreement requires Teva to cease selling the Teva Product.

Having considered the parties' extensive filings (*see, e.g.*, D.I. 122, 163, 170), and having heard lengthy oral argument on April 2 (*see* D.I. 181 ("Tr."); D.I. 182 ("Sealed Tr.")), the Court will deny Amgen's preliminary injunction motion.

I. BACKGROUND

Amgen owns the '405 patent, which claims pharmaceutical compositions of cinacalcet. Cinacalcet can be used to treat hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium-phosphorus product. ('405 patent 4:15-25) Amgen markets a branded drug, SENSIPAR®, that practices the '405 patent. (D.I. 73 ¶ 46; D.I. 120 ¶ 10)

Several other drug companies, including Cipla, Teva, and Piramal, filed Abbreviated New Drug Applications ("ANDAs") seeking to market generic bioequivalents to SENISPAR® before the expiration of the '405 patent. (*See, e.g.*, C.A. No. 16-880 D.I. 1; C.A. No. 16-855 D.I. 1; C.A. No. 17-713 D.I. 1) In turn, Amgen sued these companies for infringement of the '405 patent. (*See id.*) These lawsuits were consolidated into Civil Action No. 16-853 (the "16-853 Action") and assigned to Judge Goldberg.

In particular, Amgen sued Cipla for infringement of the '405 patent on September 29, 2016. (C.A. No. 16-880 D.I. 1) On February 26, 2018, before any trial, these parties executed the Amgen-Cipla Agreement. In doing so, "Cipla conceded that, among other things, the '405 patent is 'valid and enforceable in this and in any other or future causes of action, litigation or proceeding relating to [the Cipla] Product.'" (D.I. 122 at 3) (quoting Amgen-Cipla Agreement § 4.1) In exchange, Amgen licensed Cipla to launch its generic product no later than 97 days before expiration of the '405 patent – and earlier in certain specified circumstances. (Amgen-Cipla Agreement §§ 5.2, 5.3, 5.6) On March 5, 2018, Judge Goldberg entered the Amgen and Cipla's jointly-proposed consent judgment. (C.A. No. 16-853 D.I. 320; D.I. 122 at 3)

Teva and Piramal continued to challenge Amgen's assertions of patent infringement, so those parties (along with Zydus and Amneal) proceeded to trial. On August 24, 2018, following a bench trial, Judge Goldberg entered judgment finding that Teva and Piramal did not infringe any of the asserted claims of the '405 patent. (C.A. No. 16-853 D.I. 386) Amgen appealed these final judgments of non-infringement to the Federal Circuit, where the appeals remain pending. (C.A. No. 16-853 D.I. 397)

On December 28, 2018, Teva launched its generic cinacalcet product by shipping 409,128 bottles to wholesalers. (D.I. 164 ¶ 5) An internal Teva email estimates this quantity of cinacalcet constitutes 1.6 to 3.6 months of supply for the United States, depending on the dosage form. (D.I. 171-1 Ex. A, Baeder[4] Dep. at 15; D.I. 171-1 Ex. 3) In an internal email, Brendan O'Grady, Teva's Executive Vice President and Head of North America Commercial, estimated that Teva would realize about $200 million in revenue from this shipment, assuming that no other company launched a competing generic drug – and noting that Teva's revenue would "drastically decreas[e]" if other generics entered the cinacalcet market. (D.I. 171-1 Ex. 4; D.I. 171-1 Ex. A, Baeder Dep. at 24-32) Robert G. Cunard, Cipla's expert on the pharmaceutical industry, provided opinions consistent with Mr. O'Grady's email. (D.I. 164 ¶ 8) Mr. Cunard estimated Teva's revenue from its launch at $212 million, a number which might be reduced due to "shelf stock adjustments" if other generic companies launched their products before Teva's wholesalers resold the Teva Product. (*Id.*)

On January 2, 2019, just five days after Teva launched its generic product, Amgen and Teva entered into the Amgen-Teva Agreement. Under this Agreement, and despite having

[4] Ms. Christine Baeder, who is Teva's chief operations officer for U.S. generics (D.I. 171-1 Ex. 1, Baeder Dep. at 9), was designated as Teva's 30(b)(6) witness.

prevailed at trial and obtained a final judgment of non-infringement, Teva stipulated that the Teva Product ***does infringe*** the '405 patent, which Teva further stipulated was valid and enforceable. (Amgen-Teva Agreement § 4.1) Teva also agreed to pay Amgen up to $40 million dollars, depending (in part) on how long the cinacalcet market remains free of non-Amgen and non-Teva generic products, and appears to have agreed to stop selling the Teva Product. (*See id.* §§ 3.1, 7.1, 7.3) For its part, Amgen agreed to withdraw its appeal of this Court's judgment of non-infringement by the Teva Product. (*Id.* § 2.2) Amgen further agreed to release any claims that could be made in connection with the Teva Product that had been sold to that point.[5] (*Id.* § 3.2)

On January 9, 2019, Amgen and Teva jointly moved this Court for an indicative ruling.[6] (C.A. No. 16-853 D.I. 412) Specifically, Amgen and Teva requested that Judge Goldberg enter a ruling "stating that, in the event that the Federal Circuit grants a limited remand under Appellate Rule 12.1, the Court would grant Amgen's and [Teva]'s joint motion under Federal Rule of Civil Procedure 60(b) to vacate the portions of the Orders as to [Teva] and enter" a consent judgment consistent with the Amgen-Teva Agreement, i.e., a judgment of infringement by the Teva Product. (*Id.*) On March 26, 2019, Judge Goldberg denied the motion, concluding that Amgen

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[5] More particularly, the Amgen-Teva Agreement defines "Previously Sold Defendants' Product" as "that quantity of units by SKU of Defendants' Products sold to, or the title to which was otherwise irrevocably transferred to, a Third Party in the United States prior to the Signing Date as set out on Annex A hereto." (Amgen-Teva Agreement § 1.7; *see also id.* Annex A (listing 409,128 bottles of cinacalcet))

[6] A district court lacks jurisdiction to vacate a judgment that is on appeal. *See Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982) ("The filing of a notice of appeal . . . divests the district court of its control over those aspects of the case involved in the appeal."). An indicative ruling is essentially a statement by a district court that "it would grant [a] motion if the court of appeals remands for that purpose." Fed. R. Civ. P. 62.1. Once a district court makes an indicative ruling, the Court of Appeals "may remand for further proceedings." Fed. R. App. P. 12.1.

and Teva had provided no basis that "would amount to exceptional circumstances permitting grant of vacatur under Federal Rule of Civil Procedure 60(b)." (C.A. No. 16-853 D.I. 439)

Meanwhile, Cipla had filed the instant lawsuit on January 8, 2019. (D.I. 1) In its original complaint, Cipla sought (among other things) a declaratory judgment that it is entitled to launch its generic product, claiming that the Amgen-Teva Agreement violates the Sherman Act and the California Business and Professions Code. (D.I. 2) After the Court granted Cipla's request for expedited discovery (*see* D.I. 24 at 50), by which Cipla obtained a copy of the Amgen-Teva Agreement, Cipla amended its complaint to join Teva as a defendant, add a new claim of fraud, and provide greater factual specificity to its allegations. (D.I. 73) ("First Amended Complaint")

On March 8, at an in-person status conference, Cipla announced that it had launched its generic cinacalcet product. (D.I. 173 at 13-14) The parties appear to agree, and the Court finds, that Cipla's launch of its Cipla Product was an "At Risk Launch" within the meaning of the Amgen-Cipla Agreement. (*See* D.I. 122 at 5; D.I. 163 at 13; *see also* Sealed Tr. at 5) That is, Cipla began selling and offering to sell its generic product "without authorization from Amgen (whether directly or indirectly, by way of license, sub license, covenant not to sue, release or by any other means)" and without a "Final Court Decision[7] of non-infringement, unenforceability and/or invalidity of the '405 patent with respect to" the Cipla Product. (Amgen-Cipla Agreement § 5.5)

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[7] "The term 'Final Court Decision' shall refer to (i) a final judgment on the merits of a U.S. District Court or a final written decision on the merits of the United States Patent and Trademark Office Patent Trial and Appeal Board from which no appeal has been taken and the time for appeal has expired; (ii) a mandate of the United States Court of Appeals for the Federal Circuit with respect to an appeal of a final judgment from a U.S. District Court; or (iii) a mandate of the United States Court of Appeals for the Federal Circuit with respect to an appeal of a final written decision on the merits of the United States Patent and Trademark Office Patent Trial and Appeal Board." (Amgen-Cipla Agreement § 1.10)

Subsequently, on March 11, pursuant to a process the Court had discussed with the parties and expressly approved on March 8, Amgen filed a Partial Answer (D.I. 120) to Cipla's First Amended Complaint, and concurrently moved for a preliminary injunction to stop Cipla from continuing to sell the Cipla Product. (D.I. 121) In its motion, Amgen contends that the launch of the Cipla Product is a breach of Cipla's obligations under the Amgen-Cipla Agreement. (*See* D.I. 122 at 6-15; *see also* D.I. 120 ¶¶ 24-48) Amgen further contends that it is being irreparably harmed by sales of the Cipla Product and will continue to be so harmed prior to trial in this matter unless the Court grants preliminary injunctive relief. (*See, e.g.*, D.I. 121)

II. LEGAL STANDARDS

As Amgen's preliminary injunction motion is based on its breach of contract counterclaim, the Court must apply the law of the Third Circuit. *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 290 F.3d 578 (3d Cir. 2002). A preliminary injunction is "extraordinary" relief. *Id.* at 586. It may be awarded only after the Court considers whether the moving party is likely to succeed on the merits of its claim, whether the moving party is likely to suffer irreparable harm in the absence of preliminary relief, the balance of equities between the parties, and the public interest. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

As the moving party, Amgen must demonstrate both a likelihood of success on the merits of its breach of contract counterclaim and that it will likely suffer irreparable harm (of a type that would be prevented by an immediate grant of relief it could be awarded after prevailing on the merits of its claims at trial). *See Bennington Foods LLC v. St. Croix Renaissance, Grp., LLP*, 528 F.3d 176, 180 (3d Cir. 2008); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (noting that standing to assert claim requires that "it must be likely, as opposed to merely speculative, that [the alleged] injury will be redressed by a favorable decision") (internal

quotation marks omitted); *Macom Tech. Sols. Holdings, Inc. v. Infineon Techs. AG*, 881 F.3d 1323, 1330 (Fed. Cir. 2018). A party that does not meet its burden on either of these first two prongs of the preliminary injunction standard cannot be granted preliminary relief. *See Reilly v. City of Harrisburg*, 858 F.3d 173, 179-80 (3d Cir. 2017). Provided the first two prongs are satisfied, a preliminary injunction may issue even if the balance of harms and/or the public interest do not favor the moving party. *See id.* at 177-80.

A preliminary injunction is an equitable remedy. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311 (1982). Therefore, a party with unclean hands, or which has otherwise acted inequitably, should not be granted such relief. *See Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933) (stating movant for equitable relief must show "not only has he a good and meritorious cause of action, but he must come into court with clean hands"). Pertinent here is that patent misuse – which Cipla contends Amgen engaged in – is a type of inequitable conduct, and a party engaging in patent misuse should not be rewarded with a preliminary injunction. *See, e.g.*, *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 193 (1980) (stating that doctrine of patent misuse is "explicitly linked" to "unclean hands" doctrine); *U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179, 1184 (Fed. Cir. 2005) ("Patent misuse is an equitable defense to patent infringement."); *see also generally Hennessey v. Woolworth*, 128 U.S. 438, 442 (1888) (noting court always has discretion to deny preliminary injunction).

The elements of a breach of contract claim under Delaware[8] law are: (1) the existence of a contract; (2) the breach of an obligation imposed by the contract; and (3) resulting damage to the plaintiff. *See VLIW Tech., LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 612 (Del. 2003).

[8] The parties agree that Delaware law governs the Amgen-Cipla Agreement. (D.I. 122 at 6-7; D.I. 163 at 20)

"When the claim is based on a breach of contract, irreparable injury may be found in two situations: (1) where the subject matter of the contract is of such a special nature or peculiar value that damages would be inadequate; or (2) where because of some special and practical features of the contract, it is impossible to ascertain the legal measure of loss so that money damages are impracticable." *ECRI v. McGraw-Hill, Inc.*, 809 F.2d 223, 226 (3d Cir. 1987).

III. DISCUSSION

As set forth below, Amgen has not met its burden to establish a likelihood of success on the merits of its breach of contract claim. Amgen has met its burden to show that it will likely suffer irreparable harm in the absence of preliminary injunctive relief. The balance of the harms somewhat favors Amgen, even accounting for Cipla's equitable defense of patent misuse. The public interest also somewhat favors granting the requested relief. However, because Amgen has not met its burden to show a likelihood of success, the Court will deny Amgen's motion for a preliminary injunction.

A. Likelihood of Success on the Merits

Amgen seeks a preliminary injunction based on its claim that Cipla's launch of the Cipla Product constitutes a breach of the Amgen-Cipla Agreement. (*See* D.I. 122 at 1) (Amgen contending Cipla's launch is "flagrant breach" of contract) Amgen has failed to show a likelihood of success on the merits of this claim. In order to explain how the Court has reached this conclusion, it will be necessary to discuss and dissect multiple provisions of the Amgen-Cipla Agreement.

1. Unless otherwise provided, Cipla may not launch prior to the "Entry Date"

Section 7.1 of the Amgen-Cipla Agreement provides, in relevant part, that "unless otherwise permitted under this Settlement Agreement," Cipla will not market any generic

cinacalcet product between the "Effective Date of this Settlement Agreement" and the "Entry Date." (Amgen-Cipla Agreement § 7.1) The "Effective Date" of the Amgen-Cipla Agreement is March 5, 2018. (C.A. No. 16-853 D.I. 320) ("Consent Judgment") The "Entry Date" is defined as the earliest of three events, which are identified Sections 5.2(a), (b), and (c), reproduced below:

> 5.2 For the purposes of this Settlement Agreement, the "Entry Date" shall mean the earliest to occur of:
>
> a) ninety seven (97) days before the date of expiration or lapse of the last to expire claim of the '405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled,
>
> b) the Launch of a Generic Cinacalcet Product by a Third Party, Amgen or an Amgen Affiliate, except as provided in Section 5.5, and
>
> c) the date of a Final Court Decision finding all of claims 1-6 and 8-20 of the '405 patent invalid or unenforceable.

(Amgen-Cipla Agreement § 5.2)

It is undisputed that neither 5.2(a) or (c) have occurred. Thus, the parties' dispute is whether Cipla has obtained the right to launch its generic product pursuant to Section 5.2(b), or some other provision of the Agreement allows Cipla to launch before the Entry Date (i.e., "unless otherwise permitted"). Resolving this dispute requires consideration of Sections 5.6, 5.3, and 5.5, to which the Court now turns.

a. Section 5.6

Section 5.6 of the Amgen-Cipla Agreement reads as follows (with emphasis, bracketed numbers, and spacing added for ease of explanation):

> 5.6 [1] Nothing in Section 5.5 or in this Settlement Agreement shall be construed to prevent Amgen from seeking any relief it is legally entitled to, including but not limited to damages and/or a permanent injunction, provided that Amgen can only seek such

relief against the Defendants if Defendants launch Defendants' Product following a Third Party At Risk Launch, and if each Third Party with respect to its respective Third Party At Risk Launch (which At Risk Launch is either before or after an at risk launch by Defendants) is later found to infringe, or admits infringing, a valid and enforceable claim of the '405 patent and each such Third Party is required to pay, or agrees to pay, damages relating to its At Risk Launch.

[2] ***Notwithstanding*** anything to the contrary in this Settlement Agreement, ***if*** [i] any Third Party that has made an At Risk Launch of a Generic Cinacalcet Product (where such At Risk Launch is before or after an at risk launch by Defendants) ***is not found to have infringed*** one or more valid and enforceable claims of the '405 patent ***or*** [ii] ***has not ceased or agreed to cease selling*** such Generic Cinacalcet Product following an At Risk Launch, ***then Amgen shall not be entitled to seek or recover any relief*** from Defendants for Defendants' at risk sales, offers for sale, distribution, or importation of Defendants' Product.

[3] Moreover, notwithstanding anything to the contrary in this Settlement Agreement, if any Third Party that has made an At Risk Launch o[f] a Generic Cinacalcet Product (where such At Risk Launch is before or after an at risk launch by Defendants) has agreed to cease selling such Generic Cinacalcet Product, but has not agreed to pay Amgen any damages (or has agreed to pay only nominal damages) pursuant to such agreement, then Amgen shall not be entitled to seek or recover any relief from Defendants for Defendants' at risk sales, offers for sale, distribution, or importation of Defendants' Product.

[4] Finally, Amgen shall only be permitted to seek enhanced damages, increased damages, or any other damages relating to willful infringement against the Defendants if each Third Party with respect to its respective Third Party At Risk Launch (regardless of whether such Third Party's At Risk Launch is before or after Defendants' at risk launch) is later found to infringe a valid and enforceable claim of the '405 patent and each such Third Party is required to pay increased damages, enhanced damages, or any other damages relating to willful infringement.

(Amgen-Cipla Agreement § 5.6) (emphasis, bracketed numbering, and spacing added)

Amgen, largely relying on the first sentence (marked [1] by the Court) of Section 5.6, contends that "[n]othing" in the Amgen-Cipla Agreement prevents it from seeking "any relief"

against Cipla, including a preliminary injunction, except that Amgen can seek such relief against Cipla only if a third-party which launched its own product – here, the Teva Product – "is later found to infringe, or admits infringing, a valid and enforceable claim of the '405 patent and . . . is required to pay, or agrees to pay, damages relating to its At Risk Launch." (*See* D.I. 122 at 14-15) To Amgen, this first sentence of Section 5.6 is operative here because Teva, pursuant to the Amgen-Teva Agreement, has admitted infringing the '405 patent, which Teva has further admitted is valid and enforceable, and Teva has agreed to pay Amgen damages associated with its launch of the Teva Product. (*Id.*)

Cipla, by contrast, relies almost entirely on the second sentence (marked [2] by the Court) of Section 5.6. Because sentence [2] begins "[n]otwithstanding anything to the contrary in this Settlement Agreement," Cipla insists that if its launch is authorized by this single sentence, then the Court need not be concerned with any other provision in the Amgen-Cipla Agreement, as this one sentence unambiguously authorizes the launch of the Cipla Product. (D.I. 163 at 9) Cipla further contends that this sentence [2] prohibits Amgen from seeking any relief – including a preliminary injunction, as well as damages following final judgment – for two independently sufficient reasons: (1) because Teva has been "not found to have infringed" the '405 patent (*id.* at 19); and (2) because Teva "has not ceased or agreed to cease selling" the Teva Product (*id.* at 19-20).

Amgen responds that Cipla is misreading the word "or" that appears between clauses [i] and [ii] in sentence [2]. (D.I. 122 at 14-15) To Amgen, Section 5.6's prohibition on Amgen's ability to seek relief concerning Cipla's at-risk launch of the Cipla Product is triggered if and only if it is proven that [i] Teva "is not found to have infringed" ***and if it is also proven that***

[ii] Teva "has not ceased or agreed to cease selling" the Teva Product. (*Id.*) To Amgen, if just one of these conditions is satisfied – for instance, if Teva is not found to have infringed but Teva has ceased selling or at least agreed to cease selling its generic product – then Amgen's ability to seek relief against Cipla is unrestricted. (*Id.*) Amgen also contends, in any event, that the record establishes that neither of the conditions of sentence [2] is satisfied, as there is no final and non-appealable judgment that the Teva Product does not infringe ***and*** Teva has both ceased and agreed to cease selling the Teva Product. (*Id.*)

The Court ultimately agrees with Cipla's reading of Section 5.6, although not with every aspect of Cipla's characterization of the record. Hence, it is necessary to address each of the subparts of the parties' dispute with respect to Section 5.6.

i. Sentence [2] has essentially dispositive effect

Cipla contends that "the court need not go beyond the second sentence of § 5.6 of the Amgen-Cipla Agreement to conclude that Amgen is not likely to succeed on the merits of its claims for breach of that agreement." (D.I. 163 at 14) The Court is persuaded that, based on the record before it, this one sentence does have the effect of precluding Amgen from obtaining the relief it is seeking with respect to Cipla's launch of the Cipla Product.

Sentence [2] begins "[n]otwithstanding anything to the contrary in this Settlement Agreement." The clear and unambiguous meaning of this phrase is that regardless of whatever else one might find in any other provision or sentence of the Amgen-Cipla Agreement, the consequences of sentence [2] must be enforced. *See Cisneros v. Alpine Ridge Grp.*, 508 U.S. 10, 18 (1993) ("[T]he use of such a 'notwithstanding' clause clearly signals the drafter's intention that the provisions of the 'notwithstanding' section override conflicting provisions of any other section.").

Amgen argues against this conclusion on two grounds, both of which lack merit. First, Amgen points to sentence [1] of Section 5.6, claiming that this "first sentence of section 5.6 affirmatively grants Amgen a right to seek relief against Cipla: Teva admitted infringing the '405 patent, admitted the patent is valid and enforceable, and agreed to pay damages relating to its at-risk launch." (D.I. 170 at 3) The Court disagrees. Sentence [1] establishes that "[n]othing in Section 5.5" or any other part of the Amgen-Cipla Agreement "shall be construed to prevent Amgen from seeking any relief it is legally entitled to" – but, to the extent this conflicts with sentence [2], the "***[n]otwithstanding anything to the contrary in this Settlement Agreement***" introductory clause of sentence [2] makes plain that sentence [2] takes precedence over sentence [1].

Moreover, the Court does not find a conflict between sentences [1] and [2]. Instead, the two sentences contain different restrictions on rights Amgen would otherwise have to seek relief from Cipla. It is ***necessary*** for Amgen to survive the restrictions of sentence [1] (and of Section 5.5) in order to obtain the relief it is seeking – but surviving those restrictions is not a ***sufficient*** condition for obtaining such relief (where, as here, such relief is independently precluded by sentence [2]).

Sentence [1] permits Amgen to "seek[] any relief it is legally entitled to . . . provided that Amgen can only seek such relief . . . if" each third party which has launched at risk (i.e., here Teva) "is later found to infringe, or admits infringing, a valid and enforceable claim of the '405 patent" and "is required to pay, or agrees to pay, damages relating to its At Risk Launch." This sentence does not affirmatively grant Amgen any entitlement to relief but rather imposes conditions on when Amgen can obtain relief. *See generally Twp. of Tinicum v. U.S. Dep't of Transp.*, 582 F.3d 482, 488 (3d Cir. 2009) ("The phrase 'only if' describes a necessary condition,

not a sufficient condition."). Here, Teva has, by executing the Amgen-Teva Agreement, admitted infringement and agreed to pay damages relating to its December 2018 launch of the Teva Product. Had Teva not agreed to these conditions, Amgen's motion would falter at sentence [1] of Section 5.6. Because these conditions are, in fact, satisfied, sentence [1] does not bar Amgen's requested relief – but neither does this sentence entitle Amgen to relief. Instead, again, sentence [1] states necessary, but not sufficient, conditions that Amgen must satisfy in order to obtain relief directed to Cipla's At Risk Launch.

Amgen also argues that Cipla's reliance on the second sentence of Section 5.6, and treatment of it as essentially dispositive, erroneously renders other provisions of the Amgen-Cipla Agreement superfluous, including Section 5.5(a).[9] (D.I. 170 at 3) Again, the Court disagrees. Instead, Section 5.5 – like sentence [1] of Section 5.6 – sets out other conditions that ***could*** limit Amgen's ability to seek certain types of relief; in that respect, Section 5.5 sets out necessary but not sufficient conditions for Amgen to prevail on the pending motion for a preliminary injunction. (*See* Amgen-Cipla Agreement § 5.5(a)) (stating that if certain conditions are not satisfied, "then Amgen ***will not seek a temporary restraining order or preliminary injunction*** against Defendants") (emphasis added) As such, Section 5.5 – just like sentence [1] of Section 5.6 – cannot save Amgen if it loses on sentence [2] of Section 5.6. Therefore, even assuming that Amgen has satisfied the conditions of Section 5.5,[10] Amgen has still failed to show a likelihood of success on the merits of its breach of contract counterclaim if (as the Court has found) Amgen has not overcome the restrictions of sentence [2] of Section 5.6.

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[9] The pertinent portions of Section 5.5 are reproduced later in this Opinion.

[10] As will be discussed below, *see infra* Section III.A.1.b, the Court finds that Amgen has not met its burden to show that it has satisfied the conditions of Section 5.5.

In sum, then, the Court agrees with Cipla that if the conditions of sentence [2] are met, triggering the restrictions in Section 5.6 on Amgen's ability to seek relief, then Amgen's preliminary injunction motion fails based on sentence [2] of Section 5.6 alone, "[n]otwithstanding" any other provision of the Amgen-Cipla Agreement.

ii. Sentence [2] restricts Amgen if either condition [i] or [ii] is satisfied

The parties' next dispute involves how to read the conditions set out in sentence [2]. Amgen contends that the sentence [2] restriction on its entitlement to seek or recover relief relating to Cipla's At Risk Launch applies ***only if both of the conditions*** set out in sentence [2] are satisfied. Cipla, by contrast, asserts that Amgen is restricted by sentence [2] ***if even just one of the conditions*** of sentence [2] is met. On this issue, the Court again agrees with Cipla.

It is helpful to set out sentence [2] once more:

> ***Notwithstanding*** anything to the contrary in this Settlement Agreement, ***if*** [i] any Third Party that has made an At Risk Launch of a Generic Cinacalcet Product (where such At Risk Launch is before or after an at risk launch by Defendants) ***is not found to have infringed*** one or more valid and enforceable claims of the '405 patent ***or*** [ii] ***has not ceased or agreed to cease selling*** such Generic Cinacalcet Product following an At Risk Launch, ***then Amgen shall not be entitled to seek or recover any relief*** from Defendants for Defendants' at risk sales, offers for sale, distribution, or importation of Defendants' Product.

(Amgen-Cipla Agreement § 5.6) (emphasis added)

In the Court's view, this sentence clearly and unambiguously sets out two separate conditions, [i] and [ii], either of which, if satisfied, render applicable the restriction on Amgen contained in this provision. Sentence [2] uses the word "or" and so expresses two conditions, each of which is sufficient to bar Amgen from obtaining relief: (1) if a third party was "not found to have infringed;" ***or*** (2) if a third party "has not ceased or agreed to cease selling" its generic

product. *See generally Loughrin v. United States*, 573 U.S. 351, 357 (2014) (stating that "ordinary use" of word "or" "is almost always disjunctive").

The pertinent portion of sentence [2] can fairly be read as "if [i] or [ii], then Amgen shall not be entitled to seek or recover any relief for Cipla's At Risk Sales of the Cipla Product." That is, the "if" portion of the sentence sets out the conditions under which the "then" consequence will apply. It clearly directs that the "then" consequence will apply "if" [i] ***or*** [ii] occur.

Amgen's reading would, instead, effectively change the "***or***" to "***and***," requiring that the "then" consequence apply (and restrict Amgen) ***only if*** [i] ***and*** [ii] occur. But the Court is not permitted to rewrite the parties' clear and unambiguous contractual language. *See Pac. Employers Ins. Co. v. Glob. Reinsurance Corp. of Am.*, 693 F.3d 417, 426 (3d Cir. 2012) ("The parties have a right to make their own contract, and it is not the function of the court to rewrite it or give it a construction in conflict with the accepted and plain meaning of the language used.").

iii. Condition [i] has been satisfied: Teva has been "not found to have infringed"[11]

The Court further agrees with Cipla that condition [i] of sentence [2] of Section 5.6 has been satisfied: Teva has been "not found to have infringed" the '405 patent. (*See* D.I. 163 at 19) In the earlier litigation, after trial and post-trial briefing, Judge Goldberg entered final judgment that "Watson [Teva] does not infringe any of the claims asserted against it." (C.A. No. 16-853 D.I. 376 at 1)

Section 5.6's reference to "not found to have infringed" does ***not*** require the finding of non-infringement to be a "Final Court Decision," as that term is defined in the Amgen-Cipla

[11] The Court agrees with Cipla (*see* Sealed Tr. at 18-19, 21) that Amgen's briefing did not fairly raise a dispute on this point. Nevertheless, for the sake of completeness, the Court will consider it.

Agreement. The Amgen-Cipla Agreement requires exhaustion of appellate rights in order for there to be a Final Court Decision. (*See* Amgen-Cipla Agreement § 1.10) But the term "Final Court Decision" does not appear in Section 5.6. Instead, the parties (presumably deliberately) here used the undefined term "not found to have infringed," which is exactly what occurred in the District Court patent litigation (i.e., C.A. No. 16-853). *See Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010) (noting that contractual terms are to be interpreted according to their plain meaning). The numerous uses of the term "Final Court Decision" throughout other portions of the Amgen-Cipla Agreement (*see, e.g.*, §§ 5.2, 5.5) underscore the significance of that term's absence from Section 5.6. *See Republic of Sudan v. Harrison*, 139 S. Ct. 1048, 1058 (2019) (noting presumption that omission of language used elsewhere in document is intentional). Moreover, reading the phrase "not found to have infringed" to imply, in itself, a requirement that appellate rights be exhausted would render the defined term "Final Court Decision" redundant. *See United States v. Jicarilla Apache Nation*, 564 U.S. 162, 185 (2011) (noting canon against superfluous usage of words). When "sophisticated business entities enter into a settlement agreement, they rely upon and have a right to expect a fairly literal interpretation of the bargain that was struck." *AccuSoft Corp. v. Palo*, 237 F.3d 31, 41 (1st Cir. 2001) (internal quotation marks omitted).

Amgen also argues that condition [i] is not satisfied because Judge Goldberg's finding of non-infringement did not occur "following [the] At Risk Launch." (*See, e.g.*, Sealed Tr. at 15) Instead, the Court's finding of non-infringement by the Teva Product predated the launches of both the Teva Product or the Cipla Product. The Court rejects Amgen's contention. Nothing in Section 5.6 dictates the relative timing of the finding of non-infringement and the At Risk Launch. To the contrary, sentence [2] indifferently refers to "if any Third Party that ***has made***

an At Risk Launch . . . ***is not found to have infringed***" (emphasis added). Nothing in the Amgen-Cipla Agreement suggests the Court should read this language from any perspective other than as of the date of the filing of the preliminary injunction motion. As of that date (March 11, 2019), it was true that Teva "has made an At Risk Launch" and it was also true that Teva "is not found to have infringed." Thus, condition [i] of sentence [2] of Section 5.6 is satisfied.

For its contrary conclusion, Amgen points out that Section 5.6 bars Amgen from relief if, in relevant part, a third party "is not found to have infringed one or more valid and enforceable claims of the '405 patent or has not ceased or agreed to cease selling such Generic Cinacalcet Product ***following an At Risk Launch***." (Amgen-Cipla Agreement § 5.6) (emphasis added) Amgen reads the phrase "following an At Risk Launch" to qualify both the phrase "ceased or agreed to cease selling such Generic Cinacalcet Products" ***and*** the phrase "is not found to have infringed." (Sealed Tr. at 45) Amgen's construction lacks merit. A limiting clause should ordinarily be read as modifying only the noun or phrase that it immediately follows, particularly where, as here, each of the phrases is complex. *See generally Lockhart v. United States*, 136 S. Ct. 958, 962 (2016); *see also* Rule of the Last Antecedent, *Black's Law Dictionary* (10th ed. 2014) ("[Q]ualifying words or phrases modify the words or phrases immediately preceding them and not words or phrases more remote, unless the extension is necessary from the context or the spirit of the entire writing."). As such, here, the phrase "following an At Risk Launch" modifies only its last antecedent: namely, "has not agreed to cease selling."

iv. Amgen is not entitled to "seek or recover any relief" for Cipla's At-Risk Launch

Yet another effort by Amgen to evade the restriction of sentence [2] of Section 5.6 is to argue that this provision restricts Amgen only from seeking ***permanent*** injunctive relief and does

not also bar Amgen from prevailing on its preliminary injunction motion. (*See* D.I. 122 at 14) The Court disagrees.

The plain language of sentence [2] precludes Amgen from seeking "***any*** relief" (emphasis added) if the conditions of the provision are satisfied. As the Court has already explained, condition [i] is satisfied. Preliminary injunctive relief is indisputably a type of relief and, therefore, is within the scope of "any relief." Therefore, Amgen is precluded from seeking (and precluded from recovering) preliminary and permanent relief in relation to Cipla's At Risk Launch of the Cipla Product.

v. Condition [ii] will be treated as satisfied: uncertainty as to whether Teva has "not ceased or agreed to cease selling" must be construed as Teva *not* ceasing or agreeing to cease selling

Given the Court's analysis to this point, the Court must deny the preliminary injunction motion because Amgen is unlikely to succeed on the merits of its breach of contract counterclaim, since condition [i] of sentence [2] of Section 5.6 – that Teva "is not found to have infringed" – is satisfied, triggering the restriction on Amgen's ability to seek relief for Cipla's At Risk Launch of its Cipla Product. Nevertheless, given the urgency of the parties' disputes, and the resources they and the Court have invested in them, the Court now also addresses condition [ii], satisfaction of which would be an independent and adequate ground for triggering the same restriction on Amgen.

In pertinent part, Section 5.6 provides that if a third party that has made an at-risk launch "has not ceased or agreed to cease selling" its generic product, then Amgen is barred from seeking relief against Cipla for Cipla's At Risk Launch. (Amgen-Cipla Agreement § 5.6) Hence, for condition [ii] to be satisfied – making applicable the restriction on Amgen's ability to seek relief against Cipla – Teva must ***not*** have ceased nor have agreed to cease selling the Teva

Product. While it may be that Teva has, in fact, ceased and/or agreed to have ceased selling its generic product, the record is not sufficiently clear, and at this stage doubts must be resolved against Amgen. Therefore, the Court will treat condition [ii] as being satisfied, presenting another basis for a finding of no likelihood of success on the merits.

Amgen insists that the language of the Amgen-Teva Agreement "can only fairly be read as a commitment by Teva not to sell its generic product between the Signing Date and the Effective Date." (D.I. 170 at 4) For this contention Amgen relies principally on Section 7.3 of that Agreement (*see, e.g.*, D.I. 122 at 10 n.5), by which Teva "represent[s] and warrant[s]" that it has not "sold or otherwise transferred" any Teva Product "prior to the Effective Date other than the Previously Sold" Teva Product (Amgen-Teva Agreement § 7.3). Teva further agreed that if it is "found to be in breach of this Section 7.3, Amgen shall be entitled to seek relief including but not limited to damages and/or a permanent injunction." (*Id.*) Because "Previously Sold Defendants' Products" is defined (in § 1.7) as Teva Product sold "prior to the Signing Date" of the Amgen-Teva Agreement, it follows that any additional sales of the Teva Product after execution of that Agreement would be a breach of contract. Therefore, in Amgen's view, the Amgen-Teva Agreement imposes current restrictions on Teva's conduct.

The Court agrees. The plain language of Section 7.3 covers Teva's conduct both before signing the Amgen-Teva Agreement and after signing it and up until the Effective Date of the Agreement. (*See* Amgen-Teva Agreement § 7.3) (stating that warranty and representation is for product sold "prior to the Effective Date") The Amgen-Teva Agreement defines the term "Signing Date" (Amgen-Teva Agreement § 2.1) and yet does not use it in Section 7.3, which suggests a conscious choice not to limit Section 7.3's warranty and representation to past sales. This construction is supported by the context of the Agreement; it would make little sense for the

Agreement to include a representation of sales before the signing date and to bar all sales after the Effective Date, but not govern whatsoever sales between the signing date and the Effective Date. Therefore, since the Effective Date has not yet occurred, Teva remains bound by Section 7.3 not to "[sell] or otherwise transfer[]" its generic product.

But this conclusion does not answer whether condition [ii] of sentence [2] of Section 5.6 of the Amgen-Cipla Agreement is satisfied. There is uncertainty in the record as to the meaning of "sold or transferred" in Section 7.3 of the Amgen-Teva Agreement and as to the meaning of "selling" as that term is used in Section 5.6 the Amgen-Cipla Agreement – including ambiguity as to whether the respective terms in the two agreements have precisely the same meaning and scope. In particular, it is unclear whether Section 5.6 requires that Teva have agreed to cease (or to have ceased) both ***direct*** and ***indirect*** sales – and if both are required, whether the Amgen-Teva Agreement constitutes an agreement by Teva to cease both types of sales.

It is undisputed that neither Teva nor any of its affiliates has transferred title to any Teva Product since January 2, 2019. (D.I. 125, Ragan[12] Decl. ¶ 7; *see also* D.I. 171-1 Ex. 1, Baeder Dep. at 125 (stating that by January 2 Teva had "shipped every bottle [it] had in the U.S."); Sealed Tr. at 27 (Cipla agreeing there is no record evidence that Teva or its affiliates has directly sold Teva Product since January 2)) The record does establish, then, that Teva has ceased ***direct*** sales of the Teva Product, meaning that no additional dosages of the Teva Product have been injected into the market since January 2. (*See* Sealed Tr. at 27-28) However, that does not necessarily mean that ***indirect*** sales – in the form of those same dosages originally directly sold by Teva on or before January 2 moving through the drug "pipeline" (e.g., to wholesalers,

[12] Mr. Coleman Ragan is Teva's Vice President & General Counsel, North America Intellectual Property Litigation. (D.I. 125, Ragan Decl. ¶ 1)

pharmacies, and end users) – have also ceased. In fact, it is undisputed that (at least as of the April 2 hearing) many bottles of Teva Product sold by Teva to wholesalers are still moving through the marketplace. (*See, e.g.*, Sealed Tr. at 8, 24-29, 39-40) There is evidence that Teva considers these transactions to be "indirect sales" by Teva. (*See* D.I. 171-1 Ex. 1, Baeder Dep. at 53-54 (Teva characterizing sale of product from Teva wholesaler to pharmacy as "indirect sale"); *id.* Ex. 7 (Teva spreadsheet titled "Indirect Sales" recording sales by Teva wholesalers); *but see* D.I. 125 ¶ 7 (Teva's General Counsel stating that Teva does not consider these indirect sales to be Teva sales))

The Amgen-Cipla Agreement is silent (and ambiguous) as to whether "selling" includes indirect sales or is limited to direct sales. If, as Amgen contends (Sealed Tr. at 8-9), "selling" only covers direct sales, then Teva's undisputed lack of direct sales since January 2 means that Teva actually ceased selling its product. If, however, as Cipla contends (Sealed Tr. at 25-26), "selling" covers both direct and indirect sales, then Teva's undisputed ongoing indirect sales mean that Teva has not actually ceased selling its product. Without more evidentiary development – as to, for instance, whether "selling" has an accepted meaning in the pharmaceutical industry, whether Teva does or does not consider transactions other than its direct sales to be "indirect sales" by Teva, whether and to what extent the transactions that occur after Teva's direct sales impact the amount of revenues Teva ultimately realizes for its sales of Teva Product – the Court is unable to determine whether Teva has ceased or agreed to cease "selling" the Teva Product within the meaning of the Amgen-Cipla Agreement.[13]

[13] Among the issues that are unclear and may impact the construction of "selling" are: (1) who bears the risk of loss if prices go down after Teva's direct sales but before the Teva Product is consumed by an end-customer; (2) when money actually changes hands, e.g., from a wholesaler to Teva; (3) who decides what end-customers pay; and (4) the extent to which the "buyer" can

At this stage of the proceedings, the uncertainty as to the meaning of "selling" must be resolved against Amgen. Amgen is the moving party on the motion for a preliminary injunction and, consequently, must demonstrate a likelihood of success on the merits. *See Spencer Companies, Inc. v. Armonk Indus., Inc.*, 489 F.2d 704, 707 (1st Cir. 1973) (affirming denial of preliminary injunction where there was "uncertainty" as to whether movant "would ever prevail on the merits"). Moreover, Amgen will have the burden of proof on its breach of contract counterclaim when this case proceeds toward final judgment on the merits. Therefore, because Amgen has failed to show that condition [ii] is not satisfied, the Court will for purposes of this motion deem it to be satisfied, giving rise to a further basis (in addition to satisfaction of condition [i]) for precluding Amgen from seeking relief with respect to Cipla's At Risk Launch. It is, then, another basis for denying Amgen's motion.

b. Sections 5.2(b) and 5.5

Because the Court has held that Section 5.6 defeats Amgen's ability to prove it is likely to succeed on the merits of its breach of contract claim, it is not strictly necessary to consider the other provisions of the Amgen-Cipla Agreement the parties have put in dispute. The Court will proceed to consider other such provisions, however, in the interests of completeness, and also because Amgen contends that certain other provisions allow it to prevail on its motion, independent of any ruling the Court makes as to Section 5.6.

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return the product without consequence. There are indications in the record that a number of mechanisms – for example, shelf stock adjustment – require Teva to reimburse a wholesaler if the wholesaler sells product at a lower price than it paid Teva for it. (*See* D.I. 171-1 Ex. 1 at 28-29) There are also indications that wholesalers can choose not to sell Teva's product and then return it to Teva for a full reimbursement. (*See id.* at 46) (Teva agreeing that wholesaler "if it wanted to, could just hold [Teva product] until its expiration and then return it to [Teva] if it felt like [doing so]")

Section 5.2(b) of the Amgen-Cipla Agreement provides that Cipla may launch its generic upon "the Launch of a Generic Cinacalcet Product by a Third Party . . . except as provided in Section 5.5." (Amgen-Cipla Agreement § 5.2(b)) Therefore, as Amgen correctly explains, "[i]n section 5.2(b), the [Amgen-Cipla] [A]greement provides that a launch by another generic manufacturer will ***not*** trigger Cipla's entry date if the launch falls under the exception set out in section 5.5." (D.I. 122 at 4)

Section 5.5 provides, in pertinent part:

> If one or more [1] Third Parties Launches a Generic Cinacalcet Product without authorization from Amgen . . . and [2] there has not been a Final Court Decision of non-infringement, unenforceability and/or invalidity of the '405 patent with respect to the Generic Cinacalcet Product that was the subject of each respective Third Party Launch (an "At Risk Launch") ***then*** [3] . . . [i]f within ten (10) business days from . . . the date on which Amgen's General Counsel obtains knowledge of an At Risk Launch . . . Amgen does not . . . enter into an agreement with each such Third Party selling such Generic Cinacalcet Product requiring each such Third Party to cease and desist from the sale of such Generic Cinacalcet Product within thirty (30) calendar days of such agreement ***then*** Amgen will not seek a temporary restraining order or preliminary injunction against Defendants selling, offering to sell, or distributing the Defendants' Product at risk . . . [4] provided that Defendants' at risk sales, offers for sale, distribution, and importation, cease on the date the last such Third Party ceases or agrees to cease selling such Generic Cinacalcet Product, whether by mutual agreement or otherwise . . . .

(Amgen-Cipla Agreement § 5.5(a)) (bracketed numbering and emphasis added)

The circumstances here satisfy conditions [1] and [2]: [1] a third party, Teva, launched a generic product, the Teva Product, without authorization from Amgen;[14] and [2] there has not

[14] As will be discussed in connection with Cipla's patent misuse contentions, Cipla seems to argue that it will prove that Amgen gave express or tacit "authorization" to Teva for the launch of the Teva Product. At this stage of the proceedings, Cipla has not proven these allegations, and Amgen has met whatever burden it confronts to show that it is unlikely Cipla will ever be able to do so.

been a "Final Court Decision" of non-infringement, as Amgen's appeal from Judge Goldberg's final judgment of non-infringement by Teva remains pending. It is unclear whether conditions [3] or [4] have been met. Within 10 business days of obtaining knowledge of Teva's At Risk Launch, Amgen entered into the Amgen-Teva Agreement. As explained above, the Amgen-Teva Agreement currently governs Teva's conduct (and has done so since January 2, 2019, which is within 30 calendar days of the Agreement). However, as also already explained, there is ambiguity as to whether the "sale" and "selling" terms in these Agreements relate just to direct sales or also include indirect sales, leaving it unclear whether Teva has "ceased or agreed to cease ***selling***" the Teva Product or whether Teva is "requir[ed] . . . to cease and desist from the ***sale***" of the Teva Product. Here, just as was true in relation to Section 5.6, these uncertainties must be resolved against Amgen at this stage. Therefore, the Court deems Section 5.5's restriction on Amgen to be operative, providing yet another basis for denying the preliminary injunction.

In addition, Section 5.5 (in combination with Section 5.2(b)) does not allow Amgen to demonstrate a likelihood of success on the merits because it is, at best (from Amgen's perspective), in conflict with Section 5.6. For the reasons already given in connection with analysis of Section 5.6, Cipla's rights under the clear and unambiguous sentence [2] of Section 5.6 trump any conflicting provision in the Amgen-Cipla Agreement, including (if viewed as a conflict) Section 5.5. In other words, not being barred by Section 5.5 is a necessary but not sufficient condition for Amgen to prevail on its preliminary injunction motion.[15]

[15] Amgen insists that the present circumstances were contemplated by the parties and are unambiguously addressed in (and only in) Section 5.5 of the Amgen-Cipla Agreement. (*See* Sealed Tr. at 5 ("[W]e're in the land of Section 5.5."); *see also* D.I. 122 at 14 ("Section 5.5 specifically addresses what Cipla's rights are in the event of a third party's at-risk launch, and

c. Section 5.3

Section 5.3 of the Amgen-Cipla Agreement provides what is colloquially known as a "most favored nation" clause. It states, in pertinent part:

> [I]f Amgen has entered or enters into any agreement with a Third Party or Amgen Affiliate providing the Third Party or Amgen Affiliate with more favorable terms with respect to permitting a Launch of a Generic Cinacalcet Product prior to the Entry Date, then . . . the Entry Date terms in this Settlement Agreement, shall be deemed to be amended to provide such more favorable Entry Date terms to Defendants.

(Amgen-Cipla Agreement § 5.3)

The Court disagrees with Cipla's contention that Section 5.3 is applicable and (on its own) authorizes Cipla's launch of the Cipla Product. Even assuming that Amgen retroactively permitted a Teva "Launch"[16] on "more favorable terms" than Cipla enjoys – on the view that execution of the Amgen-Teva Agreement releases Teva from liability for sales of the Teva Product between December 28, 2018 and January 2, 2019 and caps Teva's damages for such sales at $40 million and, thereby, "permitted" Teva to launch – Amgen has ***not*** provided Teva "more favorable ***Entry Date*** terms" (emphasis added) than it has already provided Cipla (emphasis added).

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expressly does not grant Cipla a license to enter.")) It is true that Section 5.5, unlike Section 5.6, expressly refers to motions for a temporary restraining order and a preliminary injunction. Nonetheless, for reasons explained at length in this Opinion, the Court agrees with Cipla that this is not a situation in which Section 5.5 "governs." (Sealed Tr. at 55) Instead, Section 5.6, sentence [2], condition [i] governs, and Section 5.6's broad bar on Amgen seeking "any relief" in connection with Cipla's At Risk Launch includes a bar on seeking its preliminary injunction.

[16] The parties agree (and the Court finds) that Teva's sale of generic cinacalcet between December 28 and January 2 was a "Launch" as that term is used in the Amgen-Cipla Agreement. (Sealed Tr. at 12; Amgen-Cipla Agreement § 1.9 (defining "Launch" as "the first sale in the United States, with regard to a Generic Cinacalcet Product"))

Under the Amgen-Cipla Agreement, the "Entry Date" is the first date on which Cipla has a permanent, royalty-free license to practice Amgen's '405 patent. (Amgen-Cipla Agreement § 5.1) For a provision in another Amgen agreement to be an "Entry Date term," it must provide a perpetual, paid-up license to the licensee on a certain date. The Amgen-Teva Agreement's release of claims is not an ongoing license but rather (at most) an after-the-fact authorization of prior Teva sales that were unauthorized by Amgen at the time made. As such, the Amgen-Teva Agreement's release is not an Entry Date term and, so, does not create additional rights for Cipla.[17]

2. Conclusion as to likelihood of success on the merits

In sum, Amgen has not met its burden to show a likelihood of success on its claim that Cipla breached the Amgen-Cipla Agreement by selling Cipla Product. While Amgen has persuaded the Court that Section 5.3 does not entitle Cipla to sell its generic product at this time, Amgen has failed to show it is likely to succeed on the merits of its contentions that Cipla has breached Section 5.6 and/or Section 5.5. Instead, the Court is persuaded that Section 5.6, sentence [2], condition [i] bars Amgen from seeking any relief, including preliminary injunctive relief, with respect to Cipla's At Risk Launch. The Court also finds that Amgen has not met its burden to show that neither Section 5.6, sentence [2], condition [ii], nor Section 5.5, bars Amgen's requested relief. Accordingly, the Court must and will deny Amgen's motion. *See Winter*, 555 U.S. at 20 ("A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits.").

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[17] Even Cipla appears to recognize that its argument is based more on (arguable) practical realities than the plain language of the contracts. (*See, e.g.*, D.I. 163 at 19) (Cipla arguing that "Amgen ***effectively*** provided Teva with 'more favorable terms with respect to permitting a Launch of a Generic Cinacalcet Product prior to the Entry Date,' within the meaning of § 5.3 of the Amgen-Cipla Agreement") (emphasis added)

B. Irreparable Harm

Having found that Amgen has failed to show a likelihood of success on the merits, the Court must deny the preliminary injunction motion. Nonetheless, for reasons already given above with respect to other issues, the Court will proceed to address (in less depth) the other prerequisites to granting Amgen relief, beginning with irreparable harm. For the reasons to be explained, the Court finds that Amgen has demonstrated it will suffer irreparable harm in the absence of a preliminary injunction.

The Court is persuaded that in the time between now and trial Amgen will experience irreversible price erosion, long-term loss of market share, harm to its goodwill, and other non-quantifiable harms, such as potential layoffs of experienced staff. (*See, e.g.*, D.I. 122 at 16-21; *see also generally Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (affirming finding of irreparable harm to branded manufacturer where sale of generic would cause irreversible price erosion, loss of goodwill, and potential for reduction in workforce))[18] The price erosion and loss of market share are likely to be quite steep in this case. This is due to, among other reasons, the "Transitional Drug Add-On Payment Adjustment" ("TDAPA") policy. Under TDAPA, the Cipla Product is likely to be assigned to SENSIPAR®'s code, allowing healthcare providers (e.g., dialysis centers) using Cipla's generic drug to obtain reimbursements at a rate much higher than they actually pay for it (since reimbursements are based on the average price for SENSIPAR® plus a generic with the same code, even though the healthcare provider only pays the much lower generic price). (*See, e.g.*, D.I. 122 at 18-19 (citing evidence);

[18] The record supporting these findings includes the opinions of Mr. Christos Georghiou, a senior executive at Amgen and its former Executive Director of U.S. Nephrology Marketing (D.I. 123 ¶ 1), and of Dr. Jerry A. Hausman, one of Amgen's experts (D.I. 124 ¶ 2).

see also Tr. at 11-12 (Amgen stating that "once prices go all the way down, plans and wholesalers are not going to let you bring prices back up"))

The Court disagrees with Cipla's contention that all of Amgen's harms can be remedied by money damages. (*See* D.I. 163 at 20) Cipla's reliance for this point on *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324 (Fed. Cir. 2015), is unavailing. (D.I. 163 at 20) That a post-trial reasonable royalty was awarded to the branded drug company in that case does not mean that money damages are adequate relief here. Also unpersuasive is Cipla's citation to *Chemipal Ltd. v. Slim-Fast Nutritional Foods Intern., Inc.*, 350 F. Supp. 2d 582, 595 (D. Del. 2004), for the proposition that "under Delaware law, consequential damages in the form of goodwill, lost future profits, and lost customers have been consistently found to be too speculative and barred from recovery on breach of contract claims." (D.I. 163 at 20) The Court does not view *Chemipal* to sweep so broadly. The damages claim in *Chemipal* was "speculative" after the Court struck a proposed expert; here, Cipla has not sought to strike the opinions of Amgen's experts. In any event, even if it were true that Delaware law always excludes these consequential damages from final relief, if Amgen has a contractual right to preliminary injunctive relief to prevent the consequences of a breach, the Court would be able to enforce that contractual right.[19]

Nor does the Court agree with Cipla that the harms Amgen will suffer are not fairly traceable to Cipla. It is, of course, true that other players in the market have sold generic versions of Amgen's SENSIPAR®. But the quantities of generic product Cipla appears to have sold and is willing and able to sell in the absence of a preliminary injunction,[20] and the length of

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[19] In that scenario, arguably, Amgen's later inability to recover consequential damages might further support a finding that the harm being suffered is irreparable.

[20] *See* D.I. 173 at 19 (Cipla stating it has ability to make "a nine-figure sale into the market," i.e., at least $1 billion).

time Cipla will be selling (throughout the months if not years until this case reaches judgment on the merits), will mean that a substantial portion of Amgen's irreparable harm will be due to Cipla. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361 (Fed. Cir. 2008) (affirming finding that generic manufacturer's sales would cause irreparable harm even though two other generic manufacturers were already on market). Amgen has shown a "sufficient causal nexus" between the irreparable harm it will suffer and the actions of Cipla. *Macom*, 881 F.3d at 1330 (affirming grant of preliminary injunction based on breach of contract claim).

Finally, while it is undisputed that the market for cinacalcet will go completely generic by mid-2021 (*see* Tr. at 24, 39), that is still two years away. Just because the market is essentially guaranteed to be fully genericized two years from now, Amgen may still be – and indeed has shown that it will be – irreparably harmed by what occurs between now and that time, absent a preliminary injunction.

Hence, Amgen has met its burden to show irreparable harm.

C. Balance of Equities

A court considering a motion for a preliminary injunction "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Winter*, 555 U.S. at 24. Here, the Court must balance the harm to Amgen in allowing Cipla to sell its Cipla Product until the time of final judgment against the harm to Cipla in prohibiting it from making additional sales of the Cipla Product until that same time. The Court finds that this balance favors Amgen, although not by much.

As discussed above, the Court has found that Amgen will experience irreparable harm as a result of price erosion, loss of market share, harm to its goodwill, and other non-quantifiable harm. (D.I. 122 at 21-22) For its part, Cipla would also face harm if it were enjoined from further sales of its generic product until after trial. (*See* D.I. 163 at 20-21) In particular, Cipla

contends that it currently has a "unique" opportunity to be the sole (or at least the major) generic player in the market for cinacalcet, a market in which prices are still relatively high; this opportunity may very well be fleeting, given the potential entry of other generic challengers. (Tr. at 29-30) The "lost" revenue that Cipla would not be able to earn if a preliminary injunction is entered (but that it could earn in the absence of a preliminary injunction) would not seem to be recoverable from Amgen or anyone else, since it would be caused by lawful third-party developments in the marketplace. (*See, e.g.*, Tr. at 31-32 ("Somebody else will catch up, and someone else will then enter the market, and Cipla will have no recourse."); *see also* D.I. 24 at 52-54)

On balance, it appears that the magnitude of the harm to Amgen in having its market genericized by Cipla is greater than the harm to Cipla in missing out on pre-genericization sales. *See generally Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) ("Simply put, an alleged infringer's loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct."). Moreover, it is unclear whether Cipla actually has a substantially unique opportunity to be in the market for generic cinacalcet or whether, instead, other generic competitors will follow Cipla into the market very shortly (or may already have done so).[21]

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[21] The parties dispute whether Cipla has any unique contractual opportunities due to provisions in the Amgen-Cipla Agreement that are not included in the settlement agreements Amgen reached with other generic drug companies. *Compare* Tr. at 29-30 (Cipla's counsel insisting his client has rights "likely unique in the marketplace . . . allow[ing] Cipla to do things that other generic competitors could not do") *with* Tr. at 34-35 (Amgen's counsel disagreeing). The record includes a number of settlement agreements between Amgen and other generic manufacturers. (*See* D.I. 7-1 Ex. A; D.I. 73-1 Ex. 3; D.I. 178) The Court is unable at this time to resolve the parties' dispute as to whether Cipla has unique and valuable rights not shared by the other generic companies.

Two other factors relating to relative equities merit mention. First is that Cipla, by executing the Cipla-Amgen Agreement, voluntarily agreed to forego whatever opportunity it might otherwise have had to be the sole, first, or (likely) the predominant generic participant in the cinacalcet market. Cipla made its deal with Amgen – a deal which included admitting infringement of Amgen's valid patent instead of proceeding to trial (as other generic companies did) and willingly giving up its right (under almost all circumstances) to market sooner than 97 days prior to expiration of the '405 patent. As Amgen notes, "Piramal, not Cipla, took the risk and incurred the expense to position itself to be the first generic to enter the market at risk." (D.I. 122 at 23)

Second, the Court will address Cipla's contention that Amgen has engaged in patent misuse,[22] thereby rendering the '405 patent unenforceable. (*See, e.g.*, D.I. 163 at 15-18) Because Amgen's breach of contract claim is heavily intertwined with its settled claim of infringement of the '405 patent, were Amgen to have "unclean hands" in connection with its use of that '405 patent, that fact would constitute a strong equitable reason ***not*** to grant Amgen preliminary injunctive relief.[23] At this stage, however, Cipla has not persuaded the Court that it

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[22] While the parties briefed the issue of patent misuse under the "likelihood of success" prong of the preliminary injunction standard (D.I. 163 at 15-18; D.I. 170 at 4-7), the Court views it as more pertinently considered here as part of the balance of equities. Amgen's motion is not based on a claim of patent infringement, so overcoming a defense to patent misuse is not part of Amgen's burden in showing a likelihood of success on the merits. In any event, consideration of the patent misuse defense as part of the likelihood of success analysis would not bolster the strength of Amgen's (inadequate) showing on that prong of the test.

[23] In § 4.2(A) of the Amgen-Cipla Agreement, Cipla agreed not to "raise any issues of . . . enforceability . . . as a bar or defense to enforcement of this Settlement Agreement." The Court is not persuaded that this provision precludes Cipla from pressing its patent misuse defense, a defense which is based on facts and circumstances arising after execution of the Amgen-Cipla Agreement and on which, therefore, Cipla had no opportunity to conduct discovery. *Compare Lear, Inc. v. Adkins*, 395 U.S. 653, 674 (1969) (recognizing "strong federal policy favoring the full and free use of ideas in the public domain" and holding that pre-litigation patent license

is likely to prevail on the merits of its patent misuse defense (an issue on which Cipla will ultimately bear the burden of proof).[24]

Amgen has not committed patent misuse *per se*. It has not required Teva to pay royalties after the expiration of the '405 patent, nor has it improperly tied a license to its '405 patent to Teva's obligation to buy some unpatented product. *See Kimble v. Marvel Entertainment, LLC,* 135 S. Ct. 2401 (2015); *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 40 (2006); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969); *Brulotte v. Thys Co.*, 379 U.S. 29 (1964).

While Cipla may eventually demonstrate patent misuse under a rule of reason analysis, it has not done so at this stage. In order to do so, Cipla will need to show that the Amgen-Teva Agreement "imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Va. Panel Corp. v.*

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cannot waive licensee's right to challenge patent validity) *with Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1370 (Fed. Cir. 2001) (construing litigation settlement containing "clear and unambiguous" agreement not to challenge patent validity to be enforceable where challenger "had an opportunity to conduct discovery on validity issues")

[24] Cipla writes: "Amgen has not denied any of the following allegations, which are deemed admitted under Federal Rule of Civil Procedure 8(a)(6)," and then lists many of its core antitrust allegations. (D.I. 163 at 9-11) (quoting D.I. 73 at ¶¶ 52-63) On this point, the Court wholeheartedly agrees with Amgen: "Cipla's argument that Amgen admitted to the alleged misconduct by filing a Partial Answer is nonsensical because the parties agreed – and the court approved – that Amgen could delay responding to these allegations." (D.I. 170 at 1; *see also id.* at 4 ("This argument is absurd.")) At the March 8 status conference, the Court expressly approved delaying Amgen's obligation to answer Cipla's allegations that did not relate to the breach of contract claim. (*See* D.I. 170 Ex. 1 at 38, 43, 63-64; *see also* Fed. R. Civ. P. 8(b)(6) ("If a responsive pleading is not required, an allegation is considered denied or avoided.")) In any event, the Partial Answer denies all unaddressed allegations for the purpose of the preliminary injunction motion. (*See* D.I. 120 at 2 n.1)

MAC Panel Co., 133 F.3d 860, 869 (Fed. Cir. 1997) (internal quotation marks omitted). Based on the record evidence, it seems plausible that Amgen and Teva may have colluded to divide up the market for cinacalcet, in order to share supracompetitive profits and deter true generic competition.[25] This collusion, if proven, could be an antitrust violation under a rule of reason analysis. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015) (reversing dismissal of Sherman Act claims where patentee and generic manufacturer settled ANDA suit after district court ruled patent-in-suit's "main claim" was invalid, where generic manufacturer agreed to drop litigation and delay entry into market while patentee agreed not to produce authorized generic during generic's exclusivity period). However, it also seems plausible that Amgen and Teva may have reasonably assessed the risks each faced on appeal (and otherwise) and reached a rational compromise of their patent disputes. If this is what the evidence ultimately shows, then Cipla will fail to prove patent misuse. *See, e.g.*, *Hazeltine*, 395 U.S. at 100 (holding that royalty for both used and unused patents is permissible if dictated by "convenience of the parties rather than patent power"); *Princo Corp. v. ITC*, 616 F.3d 1318 (Fed. Cir. 2010) (stating that package patent license is permissible for "minimizing transaction costs"

[25] There are features of the Amgen-Teva Agreement that give rise to patent misuse concerns. The most notable are: (i) the requirement that Teva move (with Amgen) before Judge Goldberg to enter a judgment of infringement, after Judge Goldberg had entered a post-trial judgment of non-infringement; (ii) the fact that Amgen and Teva structured their agreement so that both make more money the longer the market remains free of other generic competition (*see, e.g.*, Amgen-Teva Agreement § 3.1 (requiring Teva to pay Amgen greater amounts the longer other generics remain off the market); D.I. 171-1 Ex. A, Baeder Dep. at 24-32 (Teva executive estimating it has earned "approximately $200 million" revenue from generic cinacalcet but that revenues would "drastically decreas[e]" if other generics launch); and (iii) the seemingly undisputed fact that Teva stands to make approximately $200 million from its already-shipped product if the cinacalcet market remains un-genericized (D.I. 171-1 Ex. A, Baeder Dep. at 24-32; D.I. 171-1 Ex. 4; D.I. 164, Cunard Decl. ¶ 8).

and "ensuring against the risk of post-agreement disputes"); *FTC v. Actavis, Inc.*, 570 U.S. 136, 156 (2013) (citing "avoided litigation costs" as legitimate ground for settlement).

For the reasons given above, the Court concludes that the balance of the equities narrowly favors Amgen. Amgen will be more harmed by the denial of an injunction than Cipla would be harmed were the Court to grant the injunction. Cipla's allegations of patent misuse do not appreciably change this balance.[26]

D. Public Interest

Finally, a "district court should consider the effect of the issuance of a preliminary injunction on other interested persons and the public interest." *Reilly*, 858 F.3d at 176. Here, the Court agrees with Amgen that the public interest would favor granting its motion if Amgen had succeeded in showing a likelihood of success on the merits, albeit only slightly.

No doubt there are important public interests on both sides of the scale here. The public has a strong interest in protecting valid patent rights, particularly as "the patent system provides incentive to the innovative drug companies to continue costly development efforts." *Sanofi-Synthelabo*, 470 F.3d at 1383. Yet the public also has a strong interest in enforcing contractual rights and encouraging the widespread distribution of life-saving pharmaceuticals to patients in need of them, an interest fostered by careful adherence to the laws permitting approval and marketing of less expensive generic versions of drugs. *See King Drug*, 791 F.3d at 388 (noting

[26] Cipla insists that "Amgen's deceptive and illegal conduct plainly bar[s] it from obtaining equitable relief of any kind." (D.I. 163 at 11; *see also id.* at 16) But Cipla's extravagant allegations – including that Amgen has been engaged in a "fraudulent scheme" and "a conspiracy to suppress competition" (D.I. 163 at 1); provided "misleading, if not outright false, descriptions of the January 2 Agreement" (*id.* at 8) to Cipla, the Court, and the marketplace; and, in "collus[ion]" with Teva, sought a "bogus judgment" from Judge Goldberg (*id.* at 14) – are, at this point, far from proven. Given the lack of proof, the Court can place but little weight on Cipla's allegations of patent misuse.

that Hatch-Waxman Act "attempted to balance the goal of making available more low cost generic drugs, with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement") (internal citations, alterations, and quotation marks omitted). It appears to the Court that the public interests favoring Amgen slightly exceed those favoring Cipla, under the circumstances of this case.

There is also a public interest in promoting settlement of litigation. *See Baseload Energy, Inc. v. Roberts*, 619 F.3d 1357, 1361 (Fed. Cir. 2010). The parties dispute whether this interest favors or disfavors the relief requested by Amgen. It is difficult for the Court to assess who is right on this question. For now, it is enough to say that the Court does not believe (and certainly does not intend) that its denial of the motion – which, in the Court's view, turns on honoring the clear and unambiguous settlement agreement to which Amgen and Cipla voluntarily bound themselves – will make it even more difficult to settle pharmaceutical patent litigation.

IV. CONCLUSION

An appropriate Order follows.