IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	:	
Plaintiff,	:	
v.	:	Civ. No. 16-853-MSG CONSOLIDATED
AMNEAL PHARMACEUTICALS LLC, et al.,	:	
Defendant.	:	

MEMORANDUM OPINION

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October 5, 2021
Wilmington, Delaware

GOLDBERG, U.S. DISTRICT JUDGE:

This Opinion should be the last step in this long running patent litigation arising under the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355, also known as the Hatch-Waxman Act. In 2018, after a four-day bench trial, I issued an opinion finding that Defendant Piramal Healthcare UK Ltd. ("Piramal") did not infringe United States Patent No. 9,375,405 (the "'405 patent"), which had been assigned to Plaintiff Amgen Inc. ("Amgen"). Thereafter, Amgen posted a $39,000,000 bond to secure an agreed-upon injunction of Piramal and Intervenor Slate Run Pharmaceuticals, LLC ("Slate Run") pending Amgen's appeal of my non-infringement judgment. Because the Federal Circuit has affirmed that judgment, Piramal and Slate Run now seek to recover damages from the bond for being wrongfully enjoined. Between March 24 and 25, 2021, I held a two-day bench trial on the issue of damages. After careful consideration of the evidence submitted during that proceeding, I will award $28,701,172 in lost damages plus pre-judgment interest to Piramal and Slate Run. This Opinion sets forth the basis for this award.

I. BACKGROUND

A. The Parties

Amgen is the assignee of the '405 patent and markets cinacalcet tablets covered by that patent under the brand-name Sensipar. (D.I. 375 at 2-3). In 2017, Piramal filed Abbreviated New Drug Application No. 210207 with the FDA, seeking approval to market a generic version of cinacalcet tablets in 30, 60, and 90 mg dosage strengths. (D.I. 293-1, Ex. 1 at ¶¶ 80-82).

The relationship between Piramal and Slate Run is primarily governed by a 2017 commercialization agreement, wherein Piramal agreed to develop, manufacture, and obtain regulatory approval of its cinacalcet tablets. (PSR-078; D.I. 554 at 1). And, Slate Run was given

the exclusive right to sell and distribute Piramal's tablets in the United States. (*Id.*). Piramal and Slate Run share the profits from those sales. (*Id.*).

B. Procedural History and Market Entries

In 2016 and 2017, Amgen sued several generic cinacalcet manufacturers for infringement of the '405 patent, including Piramal, Teva, and Cipla.[1] These cases were consolidated under the caption *Amgen, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 16-853. A four-day bench trial was held in March 2018. Cipla settled with Amgen on the eve of trial. (D.I. 320).

In July 2018, I issued an opinion concluding that neither Piramal nor Teva infringed Amgen's '405 patent and entered judgment accordingly. (D.I. 375; D.I. 376; D.I. 386). Amgen timely filed an appeal to the United States Court of Appeals for the Federal Circuit. (D.I. 397).

On December 28, 2018, while the appeal was still pending, Teva launched, becoming the first manufacturer on the market to sell generic cinacalcet. In the pharmaceutical supply chain, manufacturers can sell their drug products to wholesale distributors who can then resell those drug products to hospitals, pharmacies, and clinics (hereinafter, "retailers"). Or, the manufacturer can skip over the wholesale distributors and sell directly to the retailers. During Teva's launch, it sold generic cinacalcet to both wholesalers and retailers. (D.I. 668 at 26, 39; PSR066; PTX726 at 3; D.I. 667 at 335:1-3; PSR066).

Teva ended its launch on January 2, 2019 by settling with Amgen. (PSR093 § 7.1). The settlement required Teva to stop selling its generic cinacalcet into the market. But that settlement did not prevent wholesalers from reselling their supply of Teva product acquired during the short launch. (D.I. 667 at 267:1-6, 315:7-13). Thus, retailers who wanted Teva product after January

[1] The name "Teva" covers Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., and Actavis Pharma, Inc. collectively. The name "Cipla" covers Cipla USA, Inc. and Cipla Ltd. collectively.

2, 2019 could still obtain it indirectly from the wholesalers. In addition, the price for the sale between a wholesaler and a retailer can be set one of two ways: (1) by a negotiation between the wholesaler and the retailer, or (2) by a contract between the manufacturer and the retailer.

On March 6, 2019, both Cipla and Piramal launched their generic cinacalcet tablets. (D.I. 667 at 265:2-9). At this time, Cipla's launch was subject to the terms of its private settlement agreement with Amgen, and Piramal's launch was at-risk because Amgen's appeal was still pending in the Federal Circuit. (D.I. 418 at 2). Shortly thereafter, Amgen filed separate preliminary injunction motions against Cipla and Piramal to stop their sale of generic cinacalcet tablets.

Amgen's motion against Cipla was subject to full briefing and oral argument before the Honorable Leonard P. Stark. *See Cipla Ltd. v. Teva Pharms. USA, Inc*., No. 1:19-cv-44-LPS (D. Del.) (D.I. 121). On May 2, 2019, Judge Stark denied Amgen's preliminary injunction motion against Cipla. (*Id*. at D.I. 186).

Although Piramal and Slate Run initially opposed Amgen's preliminary injunction motion, it was not subject to full briefing and oral argument. (D.I. 447). Instead, on April 12, 2019, the parties reached an agreement and filed a proposed order stipulating to an injunction, which I entered on April 15, 2019. (D.I. 457; D.I. 462). The order expressly enjoined both Piramal and Slate Run from selling cinacalcet and further required, pursuant to Fed. R. Civ. P. 62(d), that Amgen post a $39,000,000 bond as a condition of the injunction, which Amgen did on May 22, 2019.[2] (D.I. 462; D.I. 476; D.I. 476-1).

[2] On October 14, 2020, I granted Slate Run's motion to intervene as a matter of right under Rule 24(a)(2), after Amgen tried to deny Slate Run access to discovery on the erroneous grounds that Slate Run had not been enjoined and, therefore, could not recover damages under the security bond. (D.I. 554; D.I. 555).

On January 7, 2020, the Federal Circuit affirmed my judgment of non-infringement in favor of Piramal and against Amgen. *See Amgen Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 19-1086 (Fed. Cir. Jan. 7, 2020) (D.I. 26). The Federal Circuit issued a mandate to that effect on April 22, 2020. (D.I. 491). The effect of this affirmance was that Piramal and Slate Run were wrongfully enjoined from April 15, 2019 (when I entered the stipulated injunction order) until April 22, 2020 (when the Federal Circuit issued the mandate).

C. The Damages Trial

Between March 24 and 25, 2021, I held a bench trial on the issue of damages for wrongful injunction. Testimony was presented by Piramal's Vice President of Finance Christopher Leahy, Slate Run's President Michael Plessinger, and two experts. Piramal and Slate Run offered as an expert Ivan T. Hoffman, a Vice President and Managing Director of Gleason IP, who calculated damages owed to Piramal and Slate Run based on a cinacalcet market in a but-for world. (D.I. 666 at 230:10-232:80). Amgen's expert was Michael E. Tate, a Vice President at Charles River Associates, who opined on the same topic as Mr. Hoffman. (D.I. 667 at 356:18-358:22).

II. LEGAL STANDARDS

Under Rule 65(c), "The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). The Rule "implies 'that when a party has been wrongfully enjoined it may collect some or all of the security.'" *Nat'l Collegiate Athletic Ass'n v. Governor of New Jersey*, 939 F.3d 597, 603 (3d Cir. 2019) (quoting *Global Naps, Inc. v. Verizon New England, Inc.*, 489 F.3d 13, 20 (1st Cir. 2007)). "[A] party is wrongfully enjoined when it had a right all along to do what it was enjoined from doing." *Nat'l Collegiate*, 939 F.3d at 603.

"[T]here is a rebuttable presumption that a wrongfully enjoined party is entitled to recover provable damages up to the bond amount." *Id*. at 606-08. Provable damages does not mean that the alleged damages must be proven with "mathematical certainty," only that the alleged damages cannot be speculative and must be proximately caused by the injunction. *Id*. at 609 n. 15; *see also Latuszewski v. VALIC Fin. Advisors, Inc*., 393 F. App'x 962, 966 (3d Cir. 2010) (same).

III. DISCUSSION

To determine the proper amount of damages, I must attempt to determine what would have happened in a hypothetical "but-for" world where Piramal and Slate Run were not enjoined from selling generic cinacalcet between April 15, 2019 and April 22, 2020. *See Takeda Pharms., U.S.A., Inc. v. West-Ward Pharm. Corp*., 2018 WL 6529289, *4 (D. Del. Nov. 12, 2018) (determining wrongful-injunction damages based on "what would happen in the 'but-for' world").

Piramal and Slate Run request damages totaling $37,526,323. (D.I. 668 at 2). This amount is comprised of three separate sources of damages:

- $28,701,172 based on a hypothetical sale to Fresenius Medical Care ("Fresenius");
- $8,508,330 based on a hypothetical sale to CVS; and
- $316,822 based on the costs of goods destroyed.

Piramal and Slate Run have also requested prejudgment interest. I will address each of these sources of damages and the request for prejudgment interest before turning to Amgen's broader arguments as to why any award of damages should be reduced or denied.

A. Sale to Fresenius

Piramal and Slate Run claim lost profits of $28,701,172 based upon 69,144 bottles of generic cinacalcet (hereinafter "~69,000 bottles") manufactured by Teva and purchased by Fresenius on April 17, 2019. Fresenius is one of the largest purchasers of cinacalcet in the country

due to their dialysis clinics. (D.I. 666 at 264:6-8). Piramal and Slate Run contend that, but for the injunction, Fresenius would have purchased Piramal product on April 17 instead of Teva product.

1. Background Facts

Several background facts set the stage for my conclusions on whether, but for the injunction, there would have been a sale of ~69,000 bottles of generic cinacalcet between Fresenius and Slate Run.

During Teva's launch between December 28, 2018 and January 2, 2019, it sold 14,000 bottles of generic cinacalcet directly to Fresenius and over 400,000 bottles directly to wholesalers AmeriSource Bergen and Cardinal Health. (D.I. 668 at 26, 39; PSR066; PTX726 at 3; D.I. 667 at 335:1-3; PSR066). Thus, if Fresenius wanted to buy Teva product after Teva settled with Amgen on January 2, 2019, it could still obtain the drug product indirectly from the wholesalers. In addition, the price for any Teva product purchased by Fresenius from a wholesaler would be set by a pre-existing contract between Fresenius and Teva that was still in effect after Teva settled. (*See*, *e.g.*, PSR068).

On March 6, 2019, Piramal and Cipla launched their generic cinacalcet tablets. Fresenius reacted to the market changes by purchasing a significant amount of its generic cinacalcet needs from Cipla. Specifically, in the month of March 2019, Fresenius purchased 117,000 bottles of Cipla product. (D.I. 667 at 335:13-15; PTX645). Teva reacted to the market changes by amending its contract with Fresenius on March 10, 2019 to provide a price reduction. (PSR068).

Three days after Teva's price reduction, on March 13, 2019, Fresenius arranged to purchase, and did purchase, 23,000 bottles of Piramal product, not Teva product. (PSR051; PSR064). In an email to Slate Run, Fresenius laid out its purchasing strategy, explaining that it had converted its cinacalcet purchases from brand to generic, but was interested in "de-risking our

supply chain with the addition of your [i.e., Piramal] product." (PSR064). Thus, it appears that Fresenius wanted to use Cipla as its main supplier but also wanted to avoid the risks of depending on only one supplier by using a secondary supplier. Piramal and Slate Run contend that but-for the injunction they would have been the secondary supplier.

On April 9, 2019, Fresenius emailed Slate Run to express interest in purchasing an additional 14,000 bottles of generic cinacalcet product. (PSR061). Slate Run declined the sale because it had agreed in principle to stipulate to the injunction. (D.I. 665 at 163:13-22). Piramal and Slate Run do not include this lost sale of 14,000 bottles in their claim of lost-profit damages.[3] Instead, Piramal and Slate Run rely on this potential transaction to show that Fresenius wanted its primary supplier to be Cipla, and its secondary supplier to be Piramal and Slate Run, not Teva. (D.I. 668 at 20).

On April 17, 2019, two days after the injunction was entered, Fresenius purchased 69,144 bottles of Teva product from a wholesaler. (PSR067). This is the sale upon which Piramal and Slate Run base their lost profits damages.

2. Conclusions

To reach the ultimate conclusion that in a but-for world Fresenius would have purchased ~69,000 bottles of Piramal product, not Teva product, I must first find a willing buyer, a willing seller, and a sufficient amount of available product to complete the transaction.

I conclude that Fresenius was a willing buyer, or more specifically, that Fresenius would have preferred to purchase ~69,000 bottles of Piramal product over ~69,000 bottles of some other manufacturers' product. On April 17, 2019, the day the hypothetical sale occurred, the only

[3] Knowing that the amount of lost-profit damages is capped by the bond amount, Piramal and Slate Run have chosen to be selective in the potential sales that they presented in their damages case. (D.I. 668 at 4).

generic cinacalcet on the market was made by one of three manufacturers – Cipla, Piramal, or Teva. Given the choice of purchasing Piramal or Cipla product, I conclude that Fresenius would have preferred Piramal product because Fresenius was trying to de-risk its supply chain. (D.I. 667 at 266:23-267:14). I also conclude that given a choice between Piramal and Teva product, Fresenius would have again preferred Piramal product, because Piramal's price was lower than Teva's, (PSR063, Ex. C § 1(d); PSR068; D.I. 667 at 275:2-5), and customers like Fresenius are motivated to obtain the lowest purchase price. (D.I. 667 at 312:18-20). Fresenius would have further preferred Piramal product over Teva product because Piramal could continue to directly supply the market, whereas Teva had agreed through a litigation settlement to cease making direct sales (*id*. at 266:16-21), and it is beneficial for a buyer like Fresenius to maintain a relationship with a generic supplier that could continue to provide product. (*Id*. at 269:24-270:2).

Piramal and Slate Run were also willing sellers. In other words, but-for the injunction, Piramal and Slate Run would have had the appetite to risk selling the ~69,000 bottles to Fresenius. Amgen posits that Piramal and Slate Run planned to limit their risk by launching a limited quantity of product and quickly exiting the market. (D.I. 669 at 8-21). But Amgen also admits that Piramal and Slate Run wanted and tried to sell all of the bottles it manufactured for the launch, showing an inclination for at least the risk associated with those sales. (D.I. 663 at 46:2-10; D.I. 665 at 130:5-7, 154:14-15; D.I. 667 at 412:5-7). Piramal had manufactured 395,000 bottles for the launch (*id*. at 411:23-25), and Slate Run sold approximately 300,000 of those bottles before the injunction. (*Id*. at 254:3-8). Including the hypothetical sale of ~69,000 bottles to Fresenius, Piramal and Slate Run would have sold no more than ~369,000 bottles, which is less than Piramal's initial launch quantity. Consequently, even if Amgen's theory of a limited launch is correct, Piramal and Slate Run would still have sold the ~69,000 bottles to Fresenius.

Finally, I find that Piramal and Slate Run could easily provide the quantity of product Fresenius requested. Fresenius wanted to buy ~69,000 bottles of cinacalcet. (D.I. 667 at 297:21-298:11). Slate Run had in stock all but ~6,000 bottles of 30 mg (*id.*), which means Slate Run had in inventory 86% of the product Fresenius wanted. And, Slate Run could have easily arranged to provide the remaining ~6,000 bottles. But for the injunction, Slate Run would have been able to broker an indirect deal with the wholesaler Cardinal Health to provide the additional ~6,000 bottles, because Cardinal Health had plenty of 30 mg bottles of Piramal product on hand. (*Id*. at 298:24-299:2). And Slate Run would likely have set the price for this indirect sale at price point that remained attractive to Fresenius. In the alternative, if immediate delivery was not an issue, Piramal could have manufactured the additional ~6,000 dosages, which would have taken two to three weeks, plus an additional week for shipping. (*Id*. at 298:14-23; D.I. 663 at 38:6-39:15). Thus, I find that contrary to Amgen's assertion, inventory was not an issue that would have prevented the sale of ~69,000 bottles to Fresenius.

Considering all of these facts together, I find that, but for the injunction, Fresenius would have purchased 69,144 bottles of generic cinacalcet tablets made by Piramal, not Teva. That sale would have generated $28,701,172 in profit for Piramal and Slate Run. (PSR108; D.I. 667 at 270:23-274:15).

As previously stated, "there is a rebuttable presumption that a wrongfully enjoined party is entitled to recover provable damages up to the bond amount." *Nat'l Collegiate*, 939 F.3d at 603. Amgen raises several arguments in an attempt to rebut the presumption that Piramal and Slate Run are entitled to damages based on the hypothetical sale to Fresenius. None are persuasive.

First, Amgen argues that the sale to Fresenius is speculative because there was no written record of a purchase order or an attempt to complete a purchase order for the ~69,000 bottles. (D.I.

669 at 21-22). As an initial matter, Amgen has not cited any binding precedent holding that lost profit damages are speculative unless there is a written record of an unfilled or canceled contract. At most, Amgen has cited a non-binding case from a district court in another circuit involving a small business with no track record of making sales. (*See* D.I. 669 at 22 (citing *B.G. Soft Ltd. v. BG Soft Int'l*, 2002 WL 1467744 (E.D.N.Y. Apr. 29, 2002)). Because Piramal and Slate Run are well-established companies with a history of selling pharmaceutical drug products, including to the very customer involved here, I find *B.G. Soft* unpersuasive.

In addition, it is not surprising that the written evidence Amgen seeks does not exist because Fresenius already knew from its attempt to purchase ~14,000 bottles of Piramal product the week prior that Piramal and Slate Run had agreed to an injunction. Indeed, the actual injunction order was entered two days before Fresenius purchased the ~69,000 bottles of Teva product and that order would have been public knowledge. Thus, Fresenius had no need to go back and confirm what it already knew – that Piramal and Slate Run could not sell the ~69,000 bottles of cinacalcet.

Second, Amgen argues that Fresenius would not prefer Piramal product over Teva product in the but-for world, because in the real world (under the injunction) Fresenius could have still obtained Piramal product indirectly through a wholesaler and chose not to. (D.I. 669 at 26-27). Amgen's argument ignores some realties that can make an indirect purchase of Piramal product different and, therefore, less attractive than a direct purchase. To start, Slate Run did not have a contract in place with Fresenius that would have set a price for an indirect purchase, and Slate Run believed it could not negotiate one during the injunction. (D.I. 665 at 160:3-7, 164:19-23, 216:9-13). As a result, Fresenius would have had to negotiate a price for an indirect purchase of Piramal product with the wholesaler.

An indirect price set by a negotiation with a wholesaler is normally higher than a direct price because the wholesaler operates as a middle-man who has their own profit interests. (D.I. 666 at 216:9-18, 220:4-15; D.I. 667 at 275:17-276:4). On the other hand, Fresenius already had a contract in place with Teva that set a price for an indirect purchase of Teva product. (PSR068). If the indirect price for Piramal product set by the wholesaler was higher than the indirect price already set by Teva, then Fresenius would rationally prefer an indirect purchase of Teva product over an indirect purchase of Piramal product. In short, an indirect purchase negotiated by the wholesaler is not an equivalent substitute for a direct purchase from Slate Run. Therefore, Fresenius' decision in the real world to not purchase Piramal product indirectly carries little weight regarding what Fresenius would prefer in the but-for world if it could have purchased Piramal product directly.

Finally, Amgen argues that in the but-for world Piramal and Slate Run would have, as they did, stipulate to the injunction on April 12, 2019, but then some time later I would have denied Amgen's motion for preliminary injunction, at which point Piramal and Slate Run could re-enter the market. (D.I. 669 at 19-20). This sequence of events seems implausible. Once I entered the parties' proposed stipulated injunction order, the pending motion for an injunction was resolved, leaving no motion for me to decide. For Amgen's scenario to exist, I would have had to *sua sponte* vacate the stipulated injunction order and order the parties to complete briefing on a previously-decided motion. Amgen offers no explanation for why I would take such actions. For this reason, I reject Amgen's arguments based on a hypothetical set of facts in which Piramal and Slate Run temporarily exit the market based on a stipulated injunction but then later re-enter after defeating the preliminary injunction. (*See*, *e.g.*, *id*. at 28-29).

B. Sales to CVS

Piramal and Slate Run also claim lost profits worth $8,508,330 based on 68,013 bottles of Cipla product CVS purchased between July 5, 2019 and April 22, 2020. Piramal and Slate Run claim that but for the injunction, CVS would have purchased Piramal product instead.

1. Background Facts

In order to explain what would have happened in a but-for world, I will first provide background on CVS's purchasing methods and CVS's reactions to changes in the generic cinacalcet market. CVS can purchase drug products either directly from a manufacturer or indirectly through the wholesalers Cardinal Health and McKesson. (D.I. 665 at 179:14-20; D.I. 667 at 314:13-25).

As previously stated, the first significant market change for generic cinacalcet was Teva's entry in December 2018 as the first generic manufacturer. In response, CVS shifted from buying Amgen's branded product to Teva's generic product. (PDX-5.41). Although Teva's settlement with Amgen on January 2, 2019 prevented Teva from further selling directly into the market, CVS continued to buy Teva product over the next several months indirectly through a wholesaler. (PSR001; PSR002; PTX656; D.I. 667 at 267:1-6, 284:20-285:1, 315:7-13, 350:18-22).

The next significant market change came in early March 2019, when Cipla and Piramal launched their generic cinacalcet product. (D.I. 667 at 265:2-9). Although CVS now had more options for generic cinacalcet than just Teva product, over the next two months, CVS continued to primarily purchase Teva product, and these purchases were made indirectly through Cardinal Health. (PDX-5.41; PTX 656 at 2). Nevertheless, CVS did not entirely ignore the new market entrants. Over those same two months, CVS also purchased some Piramal product indirectly

through the wholesaler McKesson. (PTX 656 at 2). But CVS did not purchase any Piramal product through the Cardinal Health. (*Id.*). And CVS purchased no Cipla product.

After May 2, 2019, the market dynamics changed again. By this point in time, Piramal and Slate Run were enjoined from further sales, but Cipla had defeated Amgen's injunction motion. (D.I. 457; D.I. 462; *Cipla Ltd. v. Teva Pharms. USA, Inc.*, No. 1:19-cv-44-LPS (D. Del.) (D.I. 186)). In this time period, CVS's purchases of cinacalcet shifted away from Teva product and toward Piramal product. For June and July of 2019, essentially 100% of CVS's cinacalcet purchases were of the Piramal product, and these purchases were made indirectly through a wholesaler. (PDX-5.41; PTX 656 at 2; D.I. 667 at 348:2-11, 349:5-10).

The last meaningful change in market dynamics occurred between July 2019 and August 2019, when CVS shifted from primarily buying Piramal product to primarily buying Cipla product. (PDX 5.41; PTX 656 at 2). Although Cipla was not under an injunction and could sell to CVS directly, CVS's purchases of Cipla product were indirect through a wholesaler. (D.I. 667 at 344:1-345:25, 346:16-19; PSR001; PTX647).

2. Conclusions

Piramal and Slate Run argue that but-for the injunction CVS would have preferred Piramal product over Cipla product, because CVS's purchasing decisions were primarily motivated by concerns with direct and continuous supply. Therefore, in a but-for world, the CVS sales that went to Cipla would have instead gone to Piramal. Piramal and Slate Run's theory, however, is completely undermined by the facts of record.

CVS repeatedly demonstrated that its purchasing decisions were not primarily motivated by concerns with a direct and continuous supply. For example, in March and April of 2019, CVS had a choice between Teva product, Piramal product, or Cipla product. CVS continued to choose

Teva product, even though Teva was the only manufacturer during this time period that could not provide a direct and continuous supply. (D.I. 667 at 344:1-345:25, 346:16-19; PSR001; PTX647). Teva was barred by a settlement from providing a direct supply, so all of the Teva product CVS obtained during this period was purchased indirectly through wholesalers.

In a second example, Piramal product became CVS's dominant choice in June and July of 2019 but significantly, this was *after* Piramal and Slate Run were enjoined from selling directly into the market. (D.I. 667 at 349:5-10). Thus, during the months that Piramal product was CVS's preferred product, CVS had to purchase Piramal product indirectly through a wholesaler. During this same time period, CVS continued to ignore Cipla, even though Cipla was the only manufacturer who could guarantee a direct and continuous supply because Amgen's motion to preliminarily enjoin Cipla had been denied.

In a final example, Cipla product finally became CVS's dominant choice around August 2019. But all of CVS's purchases of Cipla product were indirect through the wholesalers Cardinal and McKesson, even though Cipla was free to ship directly. (D.I. 667 at 344:1-345:25, 346:16-19; PTX637, Tab 2, Lines 778-786, 796-798). Based on all of these examples, I find that CVS's purchasing decisions were not primarily motivated by a concern with direct and continuous supply.

Instead, I agree and credit the opinion of Amgen's expert, Dr. Tate, who stated, "It's the lowest-priced generic that become the predominant [product] at CVS." (D.I. 667 at 399:15-17). In support of this opinion, data of CVS's real-world purchases in June 2019 show that when CVS was primarily purchasing Piramal product, Piramal had the lowest price. (PTX 656 at 5; *see also* D.I. 667 at 398:25-399:3; PDX-5.41). Then, by September 2019, when CVS was primarily purchasing Cipla product, Cipla had the lowest price. (PTX 656 at 5; *see also* D.I. 667 at 399:4-10; PDX-5.41). Dr. Tate estimates that the price CVS actually paid for Cipla product during the

injunction period was 13% lower than the price at which Piramal products were sold. (D.I. 667 at 389:24-390:2).

Piramal and Slate Run—not Amgen—have the burden to show that the injunction was the proximate cause of the lost sales to CVS. *See Nat'l Collegiate*, 939 F.3d at 609 n. 15. Given the facts before me, I conclude that Piramal and Slate Run have failed to carry their burden.

C. Cost of Goods Destroyed

Piramal and Slate Run also seek damages in the amount of $316,822 based on bottles of inventory that were destroyed because they had become short-dated, i.e., because they were close to their expiration date and therefore could not be sold. (D.I. 668 at 34). Piramal and Slate Run assert that but for the injunction, these bottles could have been sold. (D.I. 667 at 299:4-15). But this theory is unsupported by any explanation or evidence regarding to whom these products could have been sold, when, or for how much. In short, Piramal and Slate Run's claim for the costs of goods destroyed (that otherwise could have been sold) is too speculative to be recoverable. *Nat'l Collegiate*, 939 F.3d at 609 n. 15.

D. Whether the Court Should Limit or Deny the Damages Award

Slate Run has an Investor that can also act as a buyer in the generic cinacalcet market.[4] For the following two reasons, Amgen asserts that the existence of Slate Run's Investor is a reason to limit or deny any damages award.

1. Alleged Concealment of Slate Run's Investor

The Seventh Circuit has a rule stating that damages on an injunction bond may be reduced or denied if "there is a good reason for not requiring the plaintiff to pay in the particular case."

[4] I have previously ruled that the identity of Slate Run's Investor will be kept under seal but the existence of this Investor will not. (*See* D.I. 702 at 11-12).

Coyne-Delany Co., Inc. v. Cap. Dev. Bd. of State of Ill., 717 F.2d 385, 391 (7th Cir. 1983). Examples of "good reasons" recognized by the Seventh Circuit include the resources of the parties, the defendant's efforts to mitigate his damages, and the outcome of the underlying suit. *Id*. The Third Circuit has not explicitly adopted the Seventh Circuit's "good reason" rule. Indeed, the only time the Third Circuit addressed the "good reason" rule, it found that the list of good reasons recognized by the Seventh Circuit did not overcome the presumption that a wrongfully enjoined defendant was entitled to recover bond damages. *See Nat'l Collegiate*, 939 F.3d at 608.

Notably, Amgen is not asking me to adopt the "good reason" rule as applied by the Seventh Circuit or considered by the Third Circuit in *National Collegiate*. Instead, Amgen is asking me to use the Seventh Circuit's "good reason" rule as a springboard to create new law. Specifically, Amgen argues that any damages award should be reduced or denied because Piramal and Slate Run made misrepresentations and omissions to the Court during the injunction proceedings that concealed Slate Run's relationship with its Investor, thereby allowing Piramal and Slate Run to obtain an injunction that did not require a product recall. (D.I. 669 at 41-44).

Ultimately, even if Piramal and Slate Run had made misrepresentations and/or misleading omissions during the injunction proceeding, I did not and could not rely on those misrepresentations to issue the injunction. To issue the injunction pursuant to Fed. R. Civ. P. 62(d), I relied primarily on the fact that the parties presented to the Court a stipulated and negotiated proposed injunction order. If Amgen was a willing party to that stipulation and unhappy about the terms it negotiated, it should not have agreed to them.

Finally, there is no proof that Piramal and Slate Run made any misrepresentations or misleading omissions to the Court during the injunction proceeding. Amgen disagrees and contends that Piramal and Slate Run made two false statements:

- Piramal and Slate Run stated in their opposition brief that they had "no control over Piramal's cinacalcet tablets after they have been sold to customers, including [the Investor]." (D.I. 447 at 1).

- Piramal's Chief Operating Officer, John Fowler, stated in a declaration that "it would be extremely difficult, if not impossible" to conduct a recall. (D.I. 448 ¶ 14).

But Amgen has not shown that either statement was false.

The second statement pertains to Piramal's Chief Operation Officer, Mr. Fowler, and is based on the fact that "recalls in the pharmaceutical industry are regulated by the U.S. Food and Drug Administration," and involve "[n]umerous other parties … including customers, retail outlets, wholesalers, and distributors, each of whom is likely to have its own practices and processes." (D.I. 448 ¶ 13). Amgen does not argue that the facts on which Mr. Fowler based his opinion are false or that Mr. Fowler did not sincerely believe his opinion. Accordingly, I find that Piramal and Slate Run did not make any misrepresentations or omissions to the Court during the injunction proceedings that would warrant that damages be reduced.

2. Payments to Slate Run's Investor

According to Amgen, Slate Run makes "some sort of payment" to its Investor based on a percentage of its profits. (D.I. 667 at 402:21-24, 404:14-25). Amgen argues that these payments are realized as profits to the Investor and, therefore, cannot be realized as (lost) profits to Slate Run. (D.I. 669 at 39-40). Slate Run credibly explained that the payments are actually a business expense, specifically the repayment of a loan. (D.I. 668 at 40; D.I. 665 at 148:15-149:7). The evidence reflects that the Investor provided loans and notes to Slate Run for start-up capital and operations. (*Id.*). But the Investor does not own Slate Run, own any shares in Slate Run, or have control over Slate Run's business decisions. (D.I. 663 at 104:1-105:15). Accordingly, Slate Run is not sharing its profits, but using a percentage of its profits to pay a business expense.

How a company chooses to spend its profits does not determine whether or not those profits were lost. *See*, *e.g.*, *Kalman v. Berlyn Corp*., 914 F.2d 1473, 1483 (Fed. Cir. 1990) (holding that district court erred by deducting taxes that would have been paid from lost profits award). Accordingly, I will not deduct from the amount of proven lost profits any amounts used to pay business expenses.

E. Prejudgment Interest

Amgen does not dispute that Piramal and Slate Run are entitled to prejudgment interest on their lost profits, that the prejudgment interest should be calculated based on a time period that runs from the date the injunction was granted (April 15, 2019) to the date a judgment is entered on their damages claim, or that the prejudgment interest rate should be set at 5.5%, compounding yearly. (D.I. 668 at 34-35; D.I. 669).

These terms are also consistent with applicable precedent. *See Takeda*, 2018 WL 6529289, at *6 (noting that "prejudgment interest is regularly awarded to a party who has been wrongfully enjoined"); *id*. (determining that the prime interest rate as of the date the injunction issued "best compensates Defendants as it reflects the rate at which Defendants would most likely have been able to borrow money"); *Rite-Hite Corp. v. Kelley Co., Inc*., 56 F.3d 1538, 1555 (Fed. Cir. 1995) (holding that the court has discretion to award compound interest which ensures that the wronged party is fully compensated). Accordingly, I will award prejudgment interest on the terms discussed above.

IV. CONCLUSION

For the foregoing reasons, I will award $28,701,172 in lost profit damages to Piramal and Slate Run based on a hypothetical sale of ~69,000 bottles of Piramal product to Fresenius on or around April 17, 2019. I will further award prejudgment interest on these lost profits at a 5.5%

interest rate, compounded yearly. Any other requests for relief are denied for the reasons stated above. The parties shall submit a proposed final order consistent with this opinion.