IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, and MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	Civil Action No. 19-2053-RGA

MEMORANDUM ORDER

Before me is Plaintiff Novartis's motion for an injunction pending appeal. (D.I. 421).[1] I have considered the parties' briefing.[2] (D.I. 422, 428). For the reasons set forth below, this motion is DENIED.

I. BACKGROUND

Novartis holds New Drug Application ("NDA") No. 207620 for Entresto® (sacubitril/valsartan) tablets. (D.I. 1 ¶ 125). Entresto® is indicated "to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart

[1] Docket citations are to Civil Action No. 19-2053 unless otherwise specified.

[2] I held oral argument on August 9th for this motion and a related motion for a preliminary injunction. (*See* C.A. No. 22-1395, D.I. 213). As I believed that I understood the rest of the issues sufficiently based on the briefing, I limited the argument to issues related to the motion for a preliminary injunction.

failure, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older." (*Id.*). Several drugmakers, including Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited (collectively, "MSN"), have filed ANDAs seeking FDA approval to launch generic sacubitril/valsartan products. (*See, e.g.*, *id.* ¶¶ 7, 21, 36, 51, 61, 70). This case is one of several patent infringement actions filed by Novartis against these generic drugmakers based on Entresto®-related patents. (*See* MDL No. 20-2930-RGA).

On October 29, 2019, Novartis filed a complaint alleging infringement of U.S. Patent Nos. 8,877,938 (the "'938 patent"), 9,388,134 (the "'134 patent"), 8,101,659 (the "'659 patent"), and 8,796,331 (the "'331 patent") by MSN and several other defendants. (D.I. 1). Only the '659 patent remains as issue. It is listed in the FDA's Orange Book for Entresto® and expires on January 15, 2025, with its pediatric exclusivity period ending on July 15, 2025. (*Id.* ¶ 127; D.I. 347 ¶ 31). The '659 patent generally relates to compositions of valsartan and sacubitril and the use of such compositions to treat hypertension and heart failure. Claim 1 of the '659 patent, from which the other asserted claims depend, recites:

> 1. A pharmaceutical composition comprising:
>
> (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof;
>
> (ii) the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-biphenyl-4-yl-4(3-carboxy-propionyl amino)-2-methyl-pentanoic acid or a pharmaceutically acceptable salt thereof; and
>
> (iii) a pharmaceutically acceptable carrier;
>
> wherein said (i) AT 1-antagonist valsartan or pharmaceutically acceptable salt thereof and said (ii) NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-biphenyl-4-yl-4(3-carboxy-propionyl amino)-2-

> methyl-pentanoic acid or pharmaceutically acceptable salt thereof, are administered in combination in about a 1:1 ratio.

('659 patent, 16:17–33).

On September 12, 2022, I held a three-day bench trial during which the parties presented argument and evidence on whether claims 1–4 of the '659 patent were invalid for obviousness, lack of written description, non-enablement, and indefiniteness.[3] (D.I. 370–373). On July 7, 2023, I issued a trial opinion finding the '659 patent invalid for lack of written description. (D.I. 402). Novartis subsequently filed an appeal, which is pending before the Federal Circuit. (D.I. 407).[4]

On July 24, 2024, MSN received final FDA approval for its ANDA product. (C.A. No. 22-1395, D.I. 210 at 1; *id.*, D.I. 211 at 1). Novartis moves under FED. R. CIV. P. 62(d) for an injunction pending appeal to prevent the prospective at-risk launch of MSN's generic sacubitril/valsartan product.[5] (D.I. 421). Should its motions be denied, Novartis moves for a short stay to allow Novartis to seek injunctive relief from the Federal Circuit. (*Id.*).

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[3] The '331 patent was also asserted in that trial. (D.I. 336-1, Ex. 1 at 11 n. 2; D.I. 350). The parties agreed that I need not reach a decision regarding the validity of that patent. (D.I. 379). By the time of trial, Novartis was no longer asserting the '938 and '134 patents against MSN. (D.I. 336-1, Ex. 1 at 11 n. 2).

[4] Novartis' appeal involves multiple defendants in addition to MSN. The lead case in the Court of Appeals appears to be No. 23-2218. Novartis filed its Reply Brief on January 10, 2024. Novartis has settled with some of the defendants. My understanding is that the date for oral argument has not yet been set. I do not see anything on the docket that suggests Novartis or MSN has done anything to expedite the appeals.

[5] Novartis also moved under FED. R. CIV. P. 65(b) for a temporary restraining order pending resolution of this motion. (D.I. 421). This motion was addressed by my order that the parties maintain the status quo pending issuance of this decision. (D.I. 432). The TRO motion is now moot.

II. LEGAL STANDARD

Rule 62(d) states, "While an appeal is pending from an interlocutory order or final judgment that grants, continues, modifies, refuses, dissolves, or refuses to dissolve or modify an injunction, the court may suspend, modify, restore, or grant in injunction on terms for bond or other terms that secure the opposing party's rights." FED. R. CIV. P. 62(d). "[T]he standard for obtaining a stay pending appeal is essentially the same as that for obtaining a preliminary injunction." *Conestoga Wood Specialities Corp. v. Sec'y of U.S. Dep't of Health & Hum. Servs.*, 2013 WL 1277419, at *1 (3d Cir. Feb. 8, 2013).

"The decision whether to enter a preliminary injunction is committed to the sound discretion of the trial court." *Duraco Prods., Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1437 (3d Cir. 1994) (quoting *Merchant & Evans, Inc. v. Roosevelt Bldg. Prods. Co.*, 963 F.2d 628, 633 (3d Cir. 1992)). The Third Circuit has cautioned that a preliminary injunction is "an extraordinary remedy" to be granted "only in limited circumstances." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002) (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989)). When seeking a preliminary injunction, a movant "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The movant must establish the first two requirements before a court considers, to the extent relevant, the remaining two prongs of the standard. *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x 135, 138 (3d Cir. 2019).

III. DISCUSSION

A. Likelihood of Success on the Merits

Novartis maintains the Federal Circuit is likely to reverse my judgment holding the '659 patent invalid for lack of written description. (D.I. 422 at 4). For the reasons stated in the trial opinion, I disagree.

"[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). It is undisputed that the '659 patent "does not disclose or suggest complexes of valsartan and sacubitril, and that, as of 2002, a POSA would not have contemplated, foreseen, or envisioned such complexes." (D.I. 402 at 27). I agreed with Novartis that "in 2002, complexes of valsartan and sacubitril, pharmaceutical complexes, and complexes, generally, were unknown to a POSA." (*Id.* at 44; *see id.* at 30–33, 41–42). Based on these findings of fact, "the Novartis scientists, by definition, could not have possession of, and disclose, the subject matter of such complexes in 2002, and therefore, axiomatically, Plaintiff cannot satisfy the written description requirement for such complexes." (*Id.* at 44 (quoting *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1249 (Fed. Cir. 2004)) (cleaned up)). Novartis has failed to convince me that it is likely to succeed on appeal.

B. Irreparable Harm

Novartis contends it will suffer irreparable harm absent an injunction. (D.I. 422 at 7–11). As an initial matter, I am skeptical about Novartis's characterization of many of its potential harms. For example, Novartis maintains "[a]n at-risk launch by MSN . . . is also likely to trigger at-risk launches by several other generic drugmakers, thereby destroying Entresto®'s market

momentum and causing Novartis to suffer immediate irreparable harm in the form of lost sales, lost market share, loss of formulary position, and price erosion." (*Id.* at 8). I do not find it reasonable to attribute harm resulting from the actions taken by other generic drug makers to MSN's decision to launch its own individual product.[6] Nor do I think it fair to attribute to MSN the harm of impaired promotion of Novartis's other cardiovascular drugs, which would result from Novartis's own profit-maximizing business decision to decrease its cardiovascular product salesforce in response to MSN's launch. (*See id.* at 10).

In any event, I believe Novartis has not shown its asserted harms cannot be remedied through monetary damages. *See Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App'x 297, 301 (Fed. Cir. 2009) ("The burden is . . . on the patentee to demonstrate that its potential losses cannot be compensated by monetary damages."). Novartis and its expert, Dr. Vellturo, offer two main arguments in support of a finding of irreparability, neither of which I find sufficient.

Novartis argues that the "full extent of [its] losses will be difficult—if not impossible—to calculate." (D.I. 422 at 10). Novartis argues that estimating damages would be difficult due to the "complicated and changing dynamics of the heart failure drug market," "uncertainty over how payers will respond to the entry and subsequent withdrawal of generic products," and the "importance of physician and patient education to Entresto®'s continued market momentum." (*Id.* (citing D.I. 423 at ¶¶ 58–62)). The section of Dr. Vellturo's report that Novartis cites in

[6] It also seems perverse to allow Novartis to establish irreparability on this basis. Novartis has entered into settlement agreements with multiple generic drugmakers, which I suspect, based on my experience in dealing with such cases, allow all generics to launch if one generic is able to launch. Such a ruling would effectively allow Novartis to maintain its monopoly by the way it has structured its settlements with other companies that threaten its monopoly.

support of this proposition, however, does not discuss these factors.[7] I am unable to find that Novartis satisfied its burden of establishing that the identified factors (even if I assume their existence) would cause significant difficulty in calculating damages. I agree with the opinion of Dr. McDuff, MSN's expert, that "all of these alleged losses are standard economic analyses that can be quantified and compensated" and that "there are no factors here that make a damages determination particularly unusual or difficult." (D.I. 429 ¶¶ 13–19; *see also Horizon Medicines, LLC v. Alkem Lab'ys, Ltd.*, 2021 WL 10874872, at *1 (D. Del. Aug. 23, 2021) ("Financial harm from launch is complicated, but that is generally true of damages issues in patent cases.")).

Novartis and Dr. Vellturo contend that the monetary damages would likely be beyond MSN's ability to pay. (D.I. 422 at 8–9; D.I. 423 ¶¶ 63–67). I find credible Dr. McDuff's opinion that Dr. Vellturo overstates Novartis's potential loss and understates MSN's potential revenue. (*See* D.I. 429 ¶¶ 21–26 (referencing D.I. 423)). I am confident that MSN, a large generic drugmaker with prior experience in conducting at-risk launches (*see, e.g.*, D.I. 430 ¶ 5 (declaration from an Executive Director of MSN noting two recent at-risk launches conducted by

[7] This section of Dr. Vellturo's report focuses on arguing that, because Novartis's internal predictions continually under-forecasted Entresto®'s annual net sales, any lost profits calculations based on these forecasted sales would also understate lost profits. (*See* D.I. 423 at ¶¶ 58–62). Novartis does not emphasize this argument in its briefing and, in any event, Dr. Vellturo has not convinced me that damages would be impossible to calculate. The '659 patent's pediatric exclusivity expires less than a year from now. As Dr. McDuff notes, the parties would have the benefit of actual sales and market data on which to base or adjust their damages models. (*See* D.I. 429 ¶ 19). Furthermore, I agree with Dr. McDuff, MSN's expert, that the data suggests that the actual sales tend to track the forecasted sales within some reasonable margin of error and that growth appears to follow a relatively stable trend. (*Id.* ¶ 18 (referencing D.I. 423, Fig. 2, at 27)). I am convinced that the parties' damages experts, to the extent that they would base their calculations on Novartis's internal reports, could make appropriate estimates and adjustments to their models to account for these documented understatements. While there would be some uncertainty inherent in these calculations, "all [damages] approximations involve some degree of uncertainty." *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015).

MSN)), would be sufficiently prepared to launch its generic sacubitril/valsartan products without being driven to financial ruin by possible litigation losses. (*See id.* ¶ 11 ("MSN's current financial condition would allow it to cover the difference between escrowed sales and Novartis' lost profits based on available cash and reserves, and anticipated profits from sales of other products."); *id.* ¶ 12 ("MSN also has the ability to control and limit the amount/volume of generic sacubitril-valsartan product it manufactures and distributes in the United States, and thereby mitigate its potential financial exposure."); *id.* ¶ 13 ("MSN has the potential to acquire insurance coverage for the profit differential should the Court award Novartis damages.")).

For the stated reasons, I find Novartis has not established irreparable harm.

C. Balance of Equities and Public Interest

My findings on the likelihood of success and irreparable harm factors call for denial of Novartis's request for injunctive relief. While I need not address the balance of equities and public interest prongs, I note that they do not support granting Novartis a Rule 62(d) injunction.

Novartis argues that the balance of hardships favors granting the injunction because MSN would likely be unable to cover all the monetary damages. (D.I. 422 at 18). As stated above, I am skeptical that MSN would be unable to compensate Novartis for its losses. I am further convinced that MSN's potential harm from the loss of its first-mover advantage would outweigh the potential harm to Novartis. That the Rule 62(d) injunction would need to last only until the Federal Circuit resolves the appeal does not affect my conclusion. I find the balance of equities does not favor enjoining MSN's launch.

Novartis argues that generic entry will cause public harm because Novartis would be forced to reduce its efforts to educate physicians and patients and to reduce its patient support programs for Entresto®. (*Id.* at 18–19). I do not believe that Novartis would be "forced" to take

any such actions. Based on the billions in annual net revenues that Novartis has earned, and continues to earn, from Entresto® sales (D.I. 423, Fig. 2, at 27), I doubt that maintaining its current level of investment for these services would cause Novartis to face financial hardship. As stated above, I find it unreasonable to attribute the harm that would result from Novartis's profit-driven actions to MSN's launch. I also agree with MSN that the possible decrease in public awareness is likely outweighed by the increased accessibility and affordability of sacubitril/valsartan drugs that would result from generic competition. (*See* D.I. 428 at 12–13). I find the public interest factor favors denying injunctive relief.

IV. CONCLUSION

For the reasons above, Novartis's motion for an injunction pending appeal (D.I. 421) is **DENIED.**

I will grant Novartis's request for a stay (*id.*) to allow Novartis to seek injunctive relief from the Federal Circuit. I expect Novartis to appeal this Memorandum Order by filing a notice of appeal today. I further expect Novartis to file emergency motions in the Court of Appeals as soon as possible. With that understanding, Novartis and MSN are hereby ordered to maintain the status quo for 72 hours from the issuance of this Memorandum Order. I expect the Court of Appeals is in the best position to decide whether to continue the stay, and, if it does, for how long.

IT IS SO ORDERED.

Entered this 12th day of August, 2024

United States District Judge