IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, *et al.*, Plaintiffs, v. APOTEX CORP., *et al.*, Defendants.	C.A. No. 20-cv-804-RGA (Consolidated)

REPORT AND RECOMMENDATION

This dispute puts the race into *res judicata*. Despite Sanofi's[1] speed to protect its market exclusivity—or perhaps because of it—I conclude that it cannot maintain its claims against Defendants for infringement of U.S. Patent No. 8,927,592 ("'592 patent"). Sanofi already sued Defendants once for infringement of the '592 patent and lost. But Sanofi obtained some substitute patent claims during an *inter partes* review, and now it wants to sue Defendants again on the '592 patent and assert those substitute claims. Having carefully considered the relevant Federal Circuit precedent, I conclude that Sanofi's new allegations of infringement of the '592 patent are barred by the doctrine of claim preclusion. Accordingly, I recommend that the Court GRANT Defendants' motion to dismiss those counts.

Defendants also argue that the Court should dismiss Sanofi's claims for infringement of two other patents, U.S. Patent Nos. 10,583,110 ("'110 patent) and 10,716,777 ("'777 patent"). The parties have been litigating those patents in this case for two years, the Court has construed the

[1] Plaintiffs Sanofi-Aventis U.S. LLC and Sanofi Mature IP are collectively referred to as Sanofi.

claims, and fact and expert discovery is largely complete. Sanofi has plausibly alleged that Defendants' proposed labels will encourage patented uses, so I recommend that the Court DENY Defendants' motion to dismiss Sanofi's allegations of infringement of the '110 and '777 patents.

I. BACKGROUND

The procedural history is tortuous, but a recitation is important to understanding the present dispute.

Sanofi sells the drug JEVTANA® (cabazitaxel), which is approved by the FDA for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. (D.I. 248 ("SAC") ¶ 80.) Between 2014 and 2016, several drug manufacturers, including Defendants Apotex Corp., Apotex Inc. (collectively "Apotex"), and Sandoz, Inc. ("Sandoz"), filed regulatory submissions—Abbreviated New Drug Applications ("ANDAs") and New Drug Applications pursuant to 21 U.S.C. § 355(b)(2) ("(b)(2) NDAs")—seeking FDA approval to market cabazitaxel products. (SAC ¶¶ 10–11.) At that time, Sanofi had three patents listed in the Orange Book for cabazitaxel, including the '592 patent and U.S. Patent No. 5,847,170 ("'170 patent"). The filers sought to market their products prior to the expiration of Sanofi's patents, so Sanofi promptly sued them for infringement in district court in the District of New Jersey.

While the New Jersey cases were ongoing, one of the New Jersey defendants, Mylan Laboratories Limited ("Mylan"), filed for *inter partes* review (IPR) of the '592 patent, which claimed methods of using cabazitaxel. (D.I. 255 at 2.) The Patent Trial and Appeal Board (PTAB) instituted an IPR for claims 1–5 and 7–30 in September 2016, which meant that the final written decision would issue by September 2017, when trial in the New Jersey cases was scheduled. In its institution decision, the PTAB held that the preambles of independent claims 1 ("method for

treating a patient . . .") and 27 ("method of increasing the survival of a patient . . .") were "non-limiting," which meant the only claim limitations were administering the specified drugs to the specified patients.[2] *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, No. IPR2016-00712, 2016 WL 5753968, at 3–5 (P.T.A.B. Sept. 22, 2016). The PTAB's institution decision led Sanofi to file a contingent motion to replace independent claim 27 and dependent claims 28–30 with new independent claim 31 and new dependent claims 32–34 to make "increasing survival" in claim 27's preamble a claim limitation and to add a three-component premedication regimen that Sanofi contended was not disclosed in the prior art.[3] *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, 2017 WL 4221400, at *1, *27–29 (P.T.A.B. Sept. 21, 2017); *see also* D.I. 255 at 2.

Meanwhile, Sanofi moved to stay the New Jersey cases to await the outcome of the IPR. (C.A. No. 14-7869, D.I. 136-1 (D.N.J.).) The New Jersey court denied the motion to stay and presided over a consolidated bench trial from September 8–29, 2017. The New Jersey court found

[2] Original claim 1 provided: "1. A method for treating a patient with prostate cancer that has progressed during or after treatment with docetaxel, comprising administering to said patient a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, in combination with a corticoid."

Original claim 27 provided: "27. A method of increasing the survival of a patient with a castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel, comprising administering a dose of 20 to 25 mg/m^2 of cabazitaxel, or hydrate or solvate thereof, to the patient in combination with prednisone or prednisolone."

[3] Claim 31 provides: "31. (substitute for claim 27) A method of increasing survival comprising administering to a patient in need thereof (i) an antihistamine, (ii) a corticoid, (iii) an H_2 antagonist, and (iv) a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof wherein said antihistamine, said corticoid, and said H_2 antagonist are administered prior to said dose of 20 to 25 mg/m^2 of cabazitaxel, or hydrate or solvate thereof in combination with prednisone or prednisolone, wherein said patient has castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel."

Sanofi took the position before the PTAB that "the proposed substitute claims add elements to claims 27–30 of the '592 patent and do not remove any limitations." *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, 2017 WL 4221400, at *29.

that Sanofi's '170 patent was valid and infringed, and the court issued an injunction against approval of the defendants' regulatory applications until the '170 patent expired on September 26, 2021. *See Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC* (*Sanofi I*), No. 14-7869, 2018 WL 9364037, at *4 (D.N.J. Apr. 25, 2018). As for the '592 patent, the New Jersey court ultimately found that dependent claims 21 and 30[4] had non-limiting preambles and were obvious.[5] *Id.* at *5, *18, *35. Sanofi did not appeal the district court's finding that claims 21 and 30 were obvious. *See Sanofi-Aventis U.S. LLC v. Dr. Reddy's Labs., Inc.*, 933 F.3d 1367, 1372 (Fed. Cir. 2019).

While the New Jersey trial was occurring, the PTAB issued a final written decision finding that original claims 1–5 and 7–30 of the '592 patent were obvious and denying Sanofi's contingent motion to amend. *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, 2017 WL 4221400, at *2. Sanofi appealed the denial of its contingent motion to amend. On appeal, the Federal Circuit ruled that the PTAB had erred by construing the preamble of proposed substitute claim 31 ("method of increasing survival . . .") as non-limiting and by putting the burden on Sanofi to prove that the proposed substitute claims were valid. *Sanofi Mature IP v. Mylan Labs. Ltd.*, 757 F. App'x 988, 992 (Fed. Cir. 2019). On remand, the PTAB concluded that Mylan had not shown substitute claims 31–34 were obvious. *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, 2019 WL 5430242, at *13

[4] Claim 21 depended on claim 20, which depended on claim 1 ("method of treating a patient . . ."). Claim 30 depended on claim 27 ("method of increasing the survival of a patient . . .").

[5] Sanofi actually asserted at trial claims 7, 11, 14–16, 21, 26, and 30. No. 14-7869, 2018 WL 9364037, at *35. However, the IPR led Sanofi to disclaim claims 7, 11, 14–16, and 26 before the New Jersey court's judgment, and that court's finding that those claims were obvious was later vacated by the Federal Circuit as moot. *Sanofi-Aventis U.S. LLC v. Dr. Reddy's Labs.*, Inc., 933 F.3d 1367, 1372 (Fed. Cir. 2019). Hence, the claims ultimately held invalid in the New Jersey action were 21 and 30.

(P.T.A.B. Oct. 22, 2019). The Federal Circuit summarily affirmed,[6] and the amended claims issued on August 23, 2021. (SAC, Ex. A at 23.)

Meanwhile, in June and July 2020, Sanofi filed complaints in this Court against Defendants Apotex, Sandoz, and others, alleging that the sale of the products described in their 2014 regulatory submissions would infringe Sanofi's more recently issued '110 patent (issued March 10, 2020) and '777 patent (issued July 21, 2020). The Court held a Markman hearing on December 17, 2020, and issued a claim construction order on January 11, 2021. (D.I. 215.) Fact and expert discovery on those patents is largely (if not totally) complete. (*See* D.I. 267.)

On August 30, 2021, a few days after the Patent and Trademark Office (PTO) issued the certificate of amendment for the '592 patent, Sanofi filed a Second Amended Complaint against Defendants that added allegations of infringement of the substitute claims of the '592 patent. On September 13, 2021, Defendants Apotex and Sandoz filed their motion to dismiss the SAC. Defendants argue that the doctrine of claim preclusion bars Sanofi from asserting the '592 patent against Defendants a second time. Defendants also argue that the SAC fails to plausibly allege that the sale of their products will induce infringement of the '110 and '777 patents.

The trial is currently scheduled to begin on January 11, 2023. (D.I. 267.)

II. LEGAL STANDARDS

A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim on which relief can be granted. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when the complaint contains

[6] *See* Fed. Cir. R. 36.

"factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). A possibility of relief is not enough. *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

In determining the sufficiency of the complaint, I must assume all "well-pleaded facts" are true but need not assume the truth of legal conclusions. *Id.* at 679. "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (quotation omitted).

III. DISCUSSION

A. '592 patent

Defendants argue that claim preclusion bars Sanofi from asserting the '592 patent because Sanofi previously sued Defendants for infringement of that patent in a case that went to final judgment. The doctrine of claim preclusion says that "a judgment on the merits in a prior suit bars a second suit involving the same parties or their privies based on the same cause of action." *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 327 n.5 (1979); *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1165 (Fed. Cir. 2018). The Federal Circuit applies regional circuit law with respect to the general principles of claim preclusion. *Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344, 1348 (Fed. Cir. 2014). In the Third Circuit, claim preclusion requires (1) a final judgment on the merits in a prior suit involving (2) the same parties (or their privies) and (3) a subsequent suit based on "the same cause of action." *Id.* (quoting *CoreStates Bank, N.A. v. Huls Am., Inc.*, 176 F.3d 187, 194 (3d Cir. 1999)). The parties do not dispute that the first two elements are satisfied here:

Sanofi's current case involves the same Apotex and Sandoz regulatory filings as the prior New Jersey cases that went to final judgment.

The parties vigorously dispute whether the final element is satisfied: is Sanofi's current assertion that Defendants' regulatory filings infringe the amended '592 patent claims "the same cause of action" as Sanofi's previous assertion that those same filings infringed the original claims of the '592 patent?[7] Whether a second suit for patent infringement is based on "the same cause of action" as an earlier suit is a question of Federal Circuit law. *Id.* The Federal Circuit "generally follow[s] the Restatement (Second) of Judgments ([Am. Law Inst.] 1982) (hereinafter Restatement), which defines a cause of action based on the transactional facts from which it arises"—including the accused activity and the asserted patent claims. *SimpleAir,* 884 F.3d at 1165 (citing Restatement § 24 cmt. b); *Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1323–24 (Fed. Cir. 2008).

The question here is this: under what circumstances is a patentee's assertion of amended claims that issued out of an IPR proceeding considered the same cause of action as a prior suit involving original claims in the same patent? The parties did not cite, and the Court is not aware of, any Federal Circuit case addressing how claim preclusion applies to these precise circumstances. As explained below, however, the Federal Circuit has had occasion to address how claim preclusion applies to multiple suits on the same patent when the patentee obtained amended claims through other administrative proceedings.

[7] The word "claim" as it is used when discussing the doctrine of claim preclusion refers to a cause of action, not a patent claim. Following the Federal Circuit's practice, I will avoid ambiguity wherever possible by reserving the term "claim" for patent claims and referring to "cause of action" when discussing claim preclusion.

1. *Aspex* and *Senju*

In *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1339–41 (Fed. Cir. 2012), the Federal Circuit held that claim preclusion can bar a patentee from asserting the same patent in a second suit against the same defendant, even if the claims asserted in the second suit did not exist in the same form when the patentee filed the prior suit. In that case, the patentee had asserted the same patent against the defendants in prior actions that resulted in final judgments. *Id.* at 1338–39. The patentee subsequently obtained amended claims as the result of an *inter partes* reexamination initiated by a third party, and the patentee then sued the defendants a second time for infringing the new claims. *Id.* at 1339–40. The defendants argued that the second suit was barred by claim preclusion, but the patentee contended that, because the new claims did not exist when the prior actions were filed, those new claims created new causes of action.

The Federal Circuit agreed with the defendants. It held that even though the new claims could not have been asserted in the original actions, they did not qualify as a new cause of action because they were "not materially different" from other claims that were previously available. *Id.* at 1341–42; *see also id.* at 1341 ("We agree with the district court that the changes made to claim 23 in reexamination were insubstantial."). The Federal Circuit observed that, while the amended claims contained additional limitations not in the original claims, two of those additional limitations were already implicit in the original claims and another was "insignificant" because it "narrow[ed] the scope of the claim in a way that d[id] not affect the products . . . at issue." *Id.* The court further pointed out that, because the new claims that emerged from the reexamination were, by statute, required to be narrower than the original claims, they "did not create a new legal right against infringement that [the patentee] lacked under the original version of the patent" and, thus, "d[id] not create a new cause of action that did not exist before." *Id.*

The *Aspex* case left some open questions. For example, was the court's holding that claim preclusion bars assertion of claims that hadn't issued at the time of the original action limited to cases where the new claims are "not materially different" from claims that could have been asserted in the original action? That question was answered two years later in *Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344, 1347 (Fed. Cir. 2014). Like this case, *Senju* was an ANDA case. After the defendant (Apotex) filed an ANDA for approval to market a generic version of the patentee's branded ophthalmic solution, the patentee sued the defendant for patent infringement in district court. The court held a bench trial and concluded that the defendant's product infringed some of the asserted claims but that all the asserted claims were invalid as obvious over the prior art. *Id.* at 1347. After the district court issued its findings of fact and conclusions of law, but before it entered final judgment, the patentee filed a request with the PTO for reexamination of its own patent. The PTO granted reexamination, and the patentee amended one of the claims that the district court had previously found obvious. The patentee amended the claim to add several limitations that presumably avoided the prior art that rendered the original claims invalid, including limitations directed to the pH and the amounts of two ingredients. *Id.* at 1347, 1350. The patentee also cancelled several claims and obtained several other new claims. After the issuance of the new claims, but still prior to the district court's final judgment in the first action, the patentee filed a new case asserting the new claims against the defendant. Then, when the district court entered final judgment in the first case, the defendant sought to have the second case dismissed on the basis of claim preclusion. The district court agreed and dismissed the second suit.

A split panel of the Federal Circuit affirmed. For starters, the majority reiterated *Aspex*'s holding that "claims that emerge from reexamination do not in and of themselves create a new

cause of action that did not exist before." *Id.* at 1352. The court next addressed the patentee's attempt to distinguish *Aspex* on the basis that the amended claims in that case "were not materially different" from original claims that could have been asserted in the first suit. *Id.* at 1353. The *Senju* patentee argued that claim preclusion does not bar a second suit unless the district court compares the new claims with the original claims and makes a "detail[ed]" factual determination that they are not materially different. *Id*. at 1352. According to the patentee, because the question of whether claims are "materially different" is a factual determination, the district court erred by dismissing the second suit at the motion to dismiss stage.

The Federal Circuit panel rejected that argument. It observed that, pursuant to the statutes governing reexamination, 35 U.S.C. §§ 132(a), 305, a reexamined patent claim cannot be broader than the original claim, so it "cannot contain within its scope any product or process which would not have infringed the original claims." *Id*. at 1352. In other words, if the defendant infringes the reexamined claims asserted in the second suit, the defendant's same acts would have also infringed the patentee's original claims. *Id.* at 1352–53 ("[B]ecause the patent right is a right to exclude whose outer boundary is defined by the scope of the patent's claims, . . . reexamination does not provide larger claim scope to the patentee than the patentee had under the original patent claims.").

The court further observed that, "[b]oth in *Aspex* and in [*Senju*] the district court could readily ascertain that the reexamined claims were essentially the original claims with the addition of limitations designed to avoid prior art. In *Aspex*, the appellate court noted that fact; in [*Senju*] the trial court noted that the amended and new claims were essentially the original claims with limiting words added." *Id.* at 1354. Because the reexamined claims asserted in the second suit fell strictly within the scope of original claims that the patentee could have asserted in the first suit,

the reexamined claims did not "create a new cause of action" for purposes of claim preclusion. *Id.* at 1353.

Perhaps because it recognized that it had never opined on the precise scope of what reexamination amendments are forbidden by 35 U.S.C. § 305, the *Senju* majority stopped short of pronouncing a bright line rule that claims issued during reexamination can never create a new cause of action. It stated:

> Whether it is possible that a reexamination could ever result in the issuance of new patent claims that were so materially different from the original patent claims as to create a new cause of action, but at the same time were sufficiently narrow so as not to violate the rule against reexamined claims being broader than the original claims, is a question about which we need not opine—that is not the case before us. We hold that, in the absence of a clear showing that such a material difference in fact exists in a disputed patentable reexamination claim, it can be assumed that the reexamined claims will be a subset of the original claims and that no new cause of action will be created. This applies whether the judgment in the original suit was based on invalidity of the claims or simply on non-infringement.

Id. at 1354. Because the reexamined claims at issue in *Senju* were a "subset" of original claims that could have been asserted in the first suit, the Federal Circuit affirmed the district court's dismissal of the patentee's second suit. It did so notwithstanding that the added limitations might have changed the outcome—the patentee's first suit found that the defendant infringed some of the original claims but all the original asserted claims were obvious; the reexamined claims asserted in the second suit contained additional limitations that might have made them nonobvious.

Judge O'Malley dissented. Among other things, she argued that "[i]f reexamination did, in fact, create rights that did not exist in time for [the patentee] to assert them in the first action against [the defendant], claim preclusion should not prevent [the patentee] from asserting its new rights" and that "[t]o rule otherwise would fault [the patentee] for failing to raise claims that did

not exist." *Id.* at 1354 (O'Malley, J., dissenting). Judge O'Malley also responded to the majority's suggestion that claim preclusion bars a second suit asserting reexamination claims absent "a clear showing that . . . a material difference in fact exists" between the original and reexamined claims, stating,

> [t]he basis for requiring this heightened showing or placing the burden on the patentee is unclear. Because the majority has determined that Senju has not shown such a material difference here, moreover—where Senju's reexamined claims are presumptively valid and its original claims have been ruled invalid—it is difficult to imagine how a party could meet the heightened requirement that the majority imposes today.

Id. at 1356 n.2 (O'Malley, J., dissenting).

2. Application of *Aspex* and *Senju* to this case

Applying the principles set forth in *Aspex* and *Senju*, I conclude that the doctrine of claim preclusion bars Sanofi from asserting the '592 patent in this case. There is no dispute that the new '592 patent claims Sanofi obtained from the IPR proceeding are essentially original patent claims with at least two additional limitations—limitations the PTAB did not find proven to be in the prior art. *Mylan Labs. Ltd.*, 2017 WL 4221400, at *29; D.I. 255 at 2, 9. If Defendants infringe the new claims, they would also have infringed the original claims. Because the new claims are a "subset" of original claims, "no new cause of action [was] created" by their issuance. *Senju*, 746 F.3d at 1353.

Sanofi does not dispute that the amended claims asserted in this case are subsets of some of the original claims of the '592 patent. (D.I. 255 at 9.) However, Sanofi argues that the amended claims are not barred by claim preclusion because they are broader in some ways than the claims addressed in the New Jersey court's prior opinion. *See Sanofi I*, 2018 WL 9364037, at *35. That

is because the broadest original claims, such as independent claim 1, were not asserted at trial.[8] *See id.* I reject that argument. The application of claim preclusion does not turn on what claims were actually asserted in the prior case. What matters is what could have been asserted in the prior case. *Aspex*, 672 F.3d at 1338, 1341–42. There is no dispute that Sanofi could have tried original claims 27–29, from which its new asserted claims derive, in the previous case.

Sanofi next argues that dismissal is inappropriate because it has plausibly alleged that "the amended claims are materially different from the original claims." (D.I. 255 at 9–10.) Sanofi points out, for example, that the PTAB has found that Sanofi's addition of the new limitations resulted in a finding of patentability over the prior art. (*Id.*) In *Senju*, however, the Federal Circuit affirmed the district court's dismissal notwithstanding the patentee's contention that the amended claims were materially different than the original claims because the amended claims contained limitations that avoided the prior art. *Senju* says if the new claims are a subset of the original claims, they are the same cause of action. The *Senju* majority was also clear that claim preclusion applies even when "the judgment in the original suit was based on invalidity of the claims." 746 F.3d at 1353.[9]

[8] The claims subject to the final judgement had more precise dosage limitations than the amended claims—for example original claim 21 requires doses of exactly 20 mg/m^2 whereas original claim 1, and two of the amended claims, allow a range of doses from 20 to 25 mg/m^2. (D.I. 248, Ex. A at 20–23.)

[9] Sanofi attempts to distinguish *Senju* on the basis that the new claims obtained by the patentee in that case were in fact obvious, as demonstrated by the fact that a district court so concluded in a different action. According to Sanofi, this case is different because the PTAB found in the IPR that Mylan failed to prove Sanofi's amended claims were obvious, and the Federal Circuit affirmed. The main problem with Sanofi's argument is that the Federal Circuit's majority decision in *Senju* did not turn on the question of whether the new claims were in fact obvious. It turned on whether the new claims were a subset of the original claims.

It is true, as Sanofi points out, that *Senju* declined to adopt a bright line rule that all "narrower" claims issuing out of reexamination proceedings are the same cause of action as the original claims. But I agree with defendants that the Federal Circuit's theoretical observation in *Senju* that it may be possible to obtain a claim in reexamination that creates a new cause of action does not prevent dismissal here. In *Senju*, the court held that the new claims were the same cause of action when they were essentially the original claims with additional limitations. That is the situation here.[10]

Sanofi is correct that *Senju* concerned new claims obtained through reexamination, while Sanofi obtained its new claims from an IPR proceeding. But Sanofi has not persuasively explained why any differences between reexamination and IPR proceedings are relevant to the claim preclusion analysis. Sanofi points out, for example, that depositions are available for an IPR but not for a reexamination. But what difference does that make to the question of whether the new claims are a subset of the original claims? The Federal Circuit's decision in *Senju* did not turn on the availability of discovery. It turned on the circumstance that reexamination proceedings do not

[10] Sanofi tries to distinguish *Senju* and *Aspex* on the basis that "the three-component premedication required by [Sanofi's] amended claims does not represent the mere addition of words that narrow existing aspects of the claims or make implicit limitations explicit. Rather, the three-component premedication is a distinct aspect of the invention disclosed in the '592 patent that was not previously claimed." (D.I. 255 at 10.) I reject that argument. For one thing, I am unaware of any doctrine of patent law that distinguishes between "claim limitations" and "claim aspects," and Sanofi does not cite any cases making that distinction. Moreover, I don't read *Senju* to be restricted to situations in which "words" were added to existing limitations. Rather, *Senju* says that claim preclusion should apply when the amended claims cover a subset of the scope covered by an original claim.

In support of its position that dismissal is inappropriate, Sanofi also quotes dictum from *Cardpool, Inc. v. Plastic Jungle, Inc.*, 817 F.3d 1316, 1323–24 (Fed. Cir. 2016), but that case merely held that a district court properly declined to advise on the future application of *res judicata* to reexamined claims in the context of "a case that the parties agreed was moot" because the defendant had stopped the accused conduct.

result in a new patent, and that the claims in that case were, consistent with the rules governing amendments, a subset of the original claims. Like reexamination proceedings, amendments during IPR proceedings do not result in the issue of a new patent, nor may IPR claim amendments enlarge the scope of the claims or introduce new matter. 35 U.S.C. §§ 316(d)(3), 318(b). I also reject Sanofi's argument that dismissal is inappropriate because the precise question of how claim preclusion applies to claims issued during IPR proceedings is "one of first impression." (D.I. 255 at 6.) *Senju* was resolved at the motion to dismiss stage, and similarly in this case discovery would not affect the conclusion that the new claims are subsets of the original claims.[11]

Sanofi contends that preventing a patent holder from suing on a previously litigated patent with new claims it obtained in a IPR "would undermine the IPR framework" and would be "particularly prejudicial to owners of Orange Book-listed patents." (D.I. 255 at 12–13.) It points out that if a defendant who filed an ANDA initiates an IPR, if the district court hearing the first ANDA cases declines to stay pending that IPR, and if the district court case reaches final judgment

[11] Sanofi cites cases discussing how the doctrine of claim preclusion applies to subsequent suits involving continuation patents. *See, e.g., SimpleAir,* 884 F.3d at 1164; *Purdue Pharma L.P. v. Mylan Pharms. Inc.*, No. 15-1155, 2017 WL 784989, at *9 (D. Del. Mar. 1, 2017), *adopted*, 2017 WL 2569604 (June 13, 2017). Those cases are distinguishable because, among other reasons, continuation patents are distinct patents that may include claims with broader or different scope. *See SimpleAir*, 884 F.3d at 1166–69.

Sanofi cites *Target Training Int'l, Ltd. v. Extended Disc N. Am., Inc.*, 645 F. App'x 1018, 1025–26 (Fed. Cir. 2016), but that case is distinguishable because there was no prior judgment on the merits. *Id.* at 1025.

Sanofi also cites *Gillig v. Nike, Inc.*, 602 F.3d 1354, 1363 (Fed. Cir. 2010), and *Lawlor v. Nat'l Screen Serv. Corp.*, 349 U.S. 322, 328 (1955), for the proposition that claim preclusion does not bar the assertion of rights that did not exist when the original suit was filed. Both cases involved new causes of action that arose from factual events that occurred after earlier suits were filed. Neither of those cases involved the infringement of the same patent by the same acts litigated in a prior suit. *Senju* says that claim preclusion can bar a later suit even if the asserted patent claims did not exist at the time of the first suit.

before amended claims issue out of the IPR, then the patentee's amended claims can only be asserted against ANDA filers who did not participate in the first round of litigation. (*Id.*) Sanofi is correct that this may be the result in some cases and that an ANDA filer named in the first suit will be free to sell its generic version even though it might be infringing valid amended claims. Importantly, however, that will only be the result if the ANDA filer wins a final judgment in the first case. Any prejudice to the patentee in that situation is counterbalanced by prejudice to the ANDA filer from having to defend the same conduct against the same patent twice. And any prejudice to the patentee is of its own making, as it could have filed for the amended claims during the original prosecution of the patent or sought reexamination before filing the first litigation.

Sanofi says that applying the doctrine of claim preclusion to bar assertion of amended claims obtained during an IPR is not necessary to prevent gamesmanship by patentees because IPR proceedings cannot be initiated by a patentee. It also points out that it sought to avoid this situation by requesting a stay of the New Jersey cases pending the IPR. If Sanofi's contention is that claim preclusion should be restricted to cases where the patentee put its own patent into administrative proceedings to attempt a "do-over" after an adverse judgment, I reject that argument. In *Aspex*, the Federal Circuit held that claim preclusion barred the assertion of claims issued from a reexamination in a subsequent litigation, even though the reexamination was initiated by a third party. 672 F.3d at 1339.

Sanofi's arguments are not without force. Before *Senju*, they might have had a chance of winning. But the *Senju* majority rejected similar arguments, and I see no principled basis on which to distinguish this case. Accordingly, I recommend that the Court dismiss Sanofi's '592 patent causes of action against Apotex and Sandoz (Counts V and VI).

B. ’110 and ’777 patents

Defendants also argue that the Court should dismiss Sanofi’s allegations of infringement of the ’110 and ’777 patents. As noted above, the parties have already been litigating those patents in this case for two years. The parties have already proceeded through discovery, and the Court has already construed the asserted claims. The allegations in Sanofi’s pleadings regarding those two patents have not materially changed. But when Sanofi amended its pleadings to include claims for infringement of the ’592 patent, Defendants seized on an opportunity to try to get the counts involving the ’110 and ’777 patents dismissed. I recommend that the Court deny Defendants’ request.

The SAC alleges that Defendants’ ANDA and (b)(2) NDA products will induce infringement of the ’110 and ’777 patents. Section 271(b) of Title 35 provides that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” To state a claim of induced infringement under § 271(b), the complaint must plausibly allege that (1) there has been direct infringement, (2) the defendant knowingly induced infringement, and (3) the defendant possessed the intent to encourage another’s infringement. *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005). Under 35 U.S.C. § 271(e)(2), an ANDA or (b)(2) NDA applicant is liable for inducing infringement of a method patent if its label would actively encourage a patented use. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319, 1321–22 (Fed. Cir. 2012); *see also GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021).

Defendants contend that their proposed labels will not encourage infringement of asserted claims of the ’110 and ’777 patents, which cover “method[s] of increasing survival” in patients with castration-resistant metastatic prostate cancer that has progressed during or after treatment

with docetaxel.[12] In particular, Defendants point out that Judge Andrews has already construed the "method of increasing survival" preamble of the asserted claims to require "the intentional purpose of increasing . . . survival in an individual patient in need of . . . increasing survival." (D.I. 215.) Defendants argue that their proposed labels do not encourage doctors to form the intent to administer the products with the purpose of increasing survival.

I agree with Sanofi that it has plausibly alleged that Defendants' proposed labels encourage physicians to prescribe their products with the intent of increasing survival. Defendants' proposed labels tell physicians that their products are indicated "for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (SAC ¶ 92, Ex. D § 1.) The proposed labels also describe the results of a clinical study that found a decrease in the number of deaths and an increase in the median survival time when such patients were treated with cabazitaxel as opposed to another treatment regimen. (SAC ¶ 92, Ex. D § 14.) At this stage of the case, it is plausible that a physician reading those labels will be encouraged to administer Defendants' proposed products to a patient with the intent of increasing

[12] Independent claim 1 of the '110 patent recites: "1. A method of increasing survival comprising administering to a patient in need thereof (1) cabazitaxel, or a hydrate of solvate thereof, as a new cycle every three weeks and (2) dexchlorpheniramine administered at a dose of 5 mg, dexamethasone administered at a dose of 8 mg, and an H2 antagonist, each administered prior to the administration of said cabazitaxel, or hydrate of solvate thereof, wherein said patient has castration resistant metastatic prostate cancer that has progressed during or after treatment with docetaxel."

Independent claim 1 of the '777 patent recites: "1. A method of increasing survival comprising administering to a patient in need thereof a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, in combination with an H_2 antagonist, wherein the H_2 antagonist is administered to the patient prior to administering the dose of cabazitaxel, and wherein said patient has castration resistant metastatic prostate cancer that has progressed during or after treatment with docetaxel."

the patient's survival. Defendants are free at a later stage of the case to make whatever arguments they want about how physicians will interpret their proposed labels.

IV. CONCLUSION

For the reasons stated above, Defendants' motion should be GRANTED-IN-PART and DENIED-IN-PART:

1. Defendants' motion should be GRANTED as to Sanofi's claims involving the '592 patent. Counts V and VI should be dismissed.

2. Defendants' motion should be DENIED as to Sanofi's claims involving the '110 and '777 patents.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated March 7, 2022, a copy of which can be found on the Court's website.

Dated: July 8, 2022

The Honorable Jennifer L. Hall
United States Magistrate Judge