IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC and SANOFI MATURE IP, Plaintiffs, v. APOTEX CORP., *et al.*, Defendants.	Civil Action No. 20-804-RGA **CONSOLIDATED**

MEMORANDUM ORDER

The Magistrate Judge issued a Report and Recommendation (D.I. 279) recommending that I grant-in-part and deny-in-part Defendants' motion to dismiss Sanofi's Second Amended Complaint ("SAC") (D.I. 252). The Magistrate Judge recommended that I dismiss Sanofi's counts of infringement of the '592 Patent as barred under the doctrine of claim preclusion and that I deny Defendants' motion to dismiss Sanofi's counts of induced infringement under the '110 and '777 Patents. (D.I. 279). Both parties filed objections. (D.I. 284, 285). I have considered the objections and the responses (D.I. 287, 288), and I review the Magistrate Judge's recommendation *de novo*.

Sanofi's Objection

Sanofi objects to the Magistrate Judge's determination that its cause of action for infringement of the '592 Patent is barred by claim preclusion. Sanofi makes three arguments in support of its objection, which I consider in turn.

First, Sanofi argues that the Magistrate Judge's analysis is inconsistent with *Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344 (Fed. Cir. 2014) ("*Senju*") because she "automatically"

concluded that, because the amended claims are narrower than the original claims, they cannot be the basis for a new cause of action. (D.I. 284 at 2-5). I disagree with Sanofi's characterization of the Magistrate Judge's analysis and interpretation of *Senju*. In her Report, the Magistrate Judge expressly acknowledges that the Court in *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." (D.I. 279 at 14). Thus, her conclusion that the amended claims of the '592 Patent do not create a new cause of action is not based solely on the fact that they are a subset of the original claims, but also on a determination that the differences between the original and amended claims here are no more significant than the differences between the original and amended claims in *Senju*. (*Id.* & n.10).

Senju makes clear that a detailed factual analysis of the materiality of the differences between the amended and original claims is not necessary where a court can "readily ascertain that the [amended] claims [are] essentially the original claims with the addition of limitations designed to avoid prior art." 746 F.3d at 1353. That is the case here, for the reasons the Magistrate Judge explained in her Report. (D.I. 279 at 12-14 & n.10).

Second, Sanofi argues that the amended claims "are not merely a 'subset' of, but rather materially different from, the original claims" for three reasons: (1) they cover a three-component premedication "aspect" of the invention that was not previously claimed, nor considered in the New Jersey Action, (2) the new "increasing survival" limitation is material because it rendered the amended claims patentable over the prior art, and (3) the final judgment in the New Jersey Action did not include all the original claims that are the basis for the amended claims. (D.I. 284 at 5-8).

All these arguments fail.

First, the addition of a premedication routine undeniably narrows, rather than broadens, the scope of the original claims, necessarily rendering the amended claims a "subset" of the original claims. Moreover, this particular premedication routine limitation is not meaningfully different than the added limitations directed to "the amount of Gatifloxacin or its salt, the pH range, and the amount of EDTA" that the Court in *Senju* concluded did not "materially alter" the original claims that lacked such limitations. 746 F.3d at 1350.

Second, amendments directed to avoiding prior art, which necessarily narrow the scope of the claim, do not in and of themselves create a new right of enforcement. *See id.* at 1353. As explained by the Magistrate Judge, in *Senju*, "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." (D.I. 279 at 13).

Third, as the Magistrate Judge also explained, "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." (D.I. 279 at 13 (citing *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1338, 1341-42 (Fed. Cir. 2012))). Sanofi could have asserted (and Defendants say, without citation, did assert (D.I. 256 at 5)) original claims 1 and 27, which were the basis for the amended claims, in the New Jersey Action but made the strategic decision to assert at trial a subset of the claims that did not include those two claims. *See Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, 2018 WL 9364037, at *18-19 (D. N.J. 2018).

Finally, Sanofi argues "the equities here do not merit claim preclusion" because Sanofi did not instigate the IPR proceeding itself and, unlike in *Senju*, Sanofi sought the amended claims

before a decision on the validity of the original claims had issued. (D.I. 284 at 8-10). While Sanofi is correct that the circumstances here present less of a concern of gamesmanship than the circumstances in *Senju*, I agree with the Magistrate Judge's reasoned conclusion that nevertheless, the overriding equitable consideration here is the potential prejudice to Defendants who would be forced to "defend the same conduct against the same patent twice." (D.I. 279 at 16). Sanofi's argument about the equities essentially boils down to a contention that it did nothing wrong or in bad faith. That is not a sufficient equitable interest to escape the application of claim preclusion where "careful inquiry" shows all the requirements are met, as it does here. *Brown v. Felsen*, 442 U.S. 127, 132 (1979). As the Supreme Court stated, "For the sake of repose, res judicata shields the fraud and the cheat as well as the honest person." *Id.*

Defendants' Objection

Defendants object to the Magistrate Judge's conclusion that Sanofi has plausibly alleged that Defendants' proposed labels encourage physicians to prescribe the ANDA products with the intent of increasing patient survival, as required by the claims. Defendants argue the two sections of the Proposed Label relied upon by the Magistrate Judge – (1) the Indications and Usage section and (2) the TROPIC Study summary section – are insufficient to plausibly show the label "encourages" physicians to prescribe the drug with the intent to increase survival, as opposed to more broadly for "treatment." (D.I. 285 at 7). I disagree.

Section 1 of the Proposed Label, "INDICATIONS AND USAGE," states that the ANDA product "is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with docetaxel-containing treatment regimen." (D.I. 248-1 Ex. D at 3). Section 14, the Clinical Studies section of the label, describes

results of clinical trials conducted to evaluate the "efficacy and safety" of the ANDA product. (*Id.* at 25). The very first table in this section, Table 5, is entitled, "Efficacy of [the ANDA product] in [a clinical study] in the Treatment of Patients with Metastatic Castration-Resistant Prostate Cancer (intent-to-treat analysis)," and displays data showing increased survival rates for patients treated with the ANDA product. (*Id.*).

Defendants rely on *Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019), to argue that the label's encouragement of "treatment" does not specifically encourage "increasing survival." Their argument is that in *Grunenthal* a label indicating the generic's use for "moderate to severe chronic pain" did not "specifically encourage" its use for the treatment of a specific type of pain subsumed under "moderate to severe chronic pain." (D.I. 285 at 7-8). *Grunenthal*, however, is inapposite because there the defendants expressly carved out the patented indication from their label language by filing a "Section vii" statement with the FDA. *Id.* at 1339-40. Here, not only have Defendants not carved out "increased survival" from their labels, they have included results from a clinical study demonstrating that increased survival is a primary metric by which the efficacy of treatment with the ANDA product was measured. (D.I. 248-1 Ex. D § 14.1). A factfinder could plausibly conclude from the inclusion of Table 5 that the Proposed Label "encourages" physicians to use the ANDA product to increase patient survival.

Conclusion

For these reasons, the Magistrate Judge's Report and Recommendation (D.I. 279) is ADOPTED.

Defendants' motion to dismiss (D.I. 252) is GRANTED-IN-PART and DENIED-IN-PART. Sanofi's claims of infringement of the '592 Patent are DISMISSED.

IT IS SO ORDERED.

Entered this 15th day of September, 2022.

United States District Judge