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GENENTECH, INC. and CITY OF HOPE

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

SANOFI-AVENTIS U.S. LLC and REGENERON PHARMACEUTICALS, INC.,

Plaintiffs,

v.

GENENTECH, INC., and CITY OF HOPE

Defendants.

GENENTECH, INC., and CITY OF HOPE,

Counterclaim Plaintiffs,

v.

SANOFI-AVENTIS U.S. LLC and REGENERON PHARMACEUTICALS, INC.,

Counterclaim Defendants.

Case No. 2:15-CV-05685-GW-AGR

**DEFENDANTS' REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION TO PARTIALLY DISMISS SANOFI AND REGENERON'S CLAIMS**

Date: August 18, 2016
Time: 8:30 a.m.
Ctrm: 10, Spring Street Floor
Judge: George H. Wu

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## I. INTRODUCTION

Sanofi and Regeneron do not contest that a covenant not to sue can divest the Court of subject matter jurisdiction. Instead, Sanofi and Regeneron principally take issue with the scope of the covenant provided by Genentech and City of Hope. Notably, Sanofi and Regeneron have never before raised any concern regarding that scope: not when Genentech and City of Hope originally said that they were withdrawing certain claims, not when Genentech and City of Hope proposed language notifying the Court of the same and asked for Sanofi and Regeneron to provide comments, not when Genentech and City of Hope provided Sanofi and Regeneron with the language of the covenant, and not at any point in the meet-and-confer process leading to this motion. If Sanofi and Regeneron had a good faith concern regarding the scope of the covenant, they would have raised that concern before now.

## II. THE COVENANT IS TIMELY

Sanofi and Regeneron complain that Genentech and City of Hope's covenant came "at the eleventh hour," Opp'n at 1, although Sanofi and Regeneron do not directly argue that the timing of the covenant casts doubt on its effectiveness to eliminate subject matter jurisdiction. The covenant is unquestionably timely. In *Dow Jones*, the Federal Circuit confirmed that a covenant not to sue is timely so long as it is given "prior to resolution or consideration of the underlying infringement claim." *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1346 (Fed. Cir. 2010) (citation omitted). In *MedImmune II*, Judge Pfaelzer concluded that the covenant was timely because it had been made prior the court's ruling on infringement or validity, notwithstanding that the court had ruled on claim construction (unlike the case here, where Sanofi and Regeneron merely stipulated to Judge Pfaelzer's constructions from prior cases). *MedImmune, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1000, 1005-06 (C.D. Cal. 2008) ("*MedImmune II*"). The covenant is thus

timely as a matter of law.[1]

## III. SANOFI AND REGENERON HAVE REFUSED TO PLACE THE PIPELINE PRODUCTS AT ISSUE IN THIS CASE

In their Opposition, Sanofi and Regeneron request the Court to order that Genentech and City of Hope's covenant encompass "all future products that Defendants' [sic] allege fall within the Cabilly III claims covered by the covenant." Opp'n at 14. That request is readily met, because Genentech and City of Hope have not alleged that any product made by Sanofi and Regeneron falls within the Cabilly III claims other than Praluent, the subject of this lawsuit. Sanofi and Regeneron made the decision to limit their declaratory relief complaint to Praluent when they filed this case and did not place their pipeline products at issue. Genentech and City of Hope's counterclaims are likewise limited to Praluent. Sanofi and Regeneron never sought to file a declaratory judgment regarding the pipeline products, nor have they sought to add their pipeline products to this case notwithstanding their assertion that such a declaratory judgment would be ripe. Indeed, as set forth in the Motion, Sanofi and Regeneron expressly blocked discovery into their pipeline products, affirmatively contending that those products are not implicated in this case. Mot. at 2-3. Genentech and City of Hope's covenant thus satisfies Sanofi and Regeneron's request by eliminating subject matter jurisdiction as to the only product at issue in this case and the only product as to which Genentech and City of Hope have made any allegation of infringement.

[1] In *Dow Jones*, the court explained that because the case or controversy requirement is a question of subject matter jurisdiction, the covenant eliminated the court's power to exercise jurisdiction notwithstanding "well-taken" prudential considerations. 606 F.3d at 1348. Even if such considerations were relevant (which they are not), Genentech and City of Hope acted properly here. As set forth in the opening papers, Genentech and City of Hope notified Sanofi and Regeneron of their intent to limit the case to claim 34 in order to streamline the issues for summary judgment before those motions were filed. Defs.' Mem. P. & A. Supp. Mot. Partially Dismiss Pls.' Cls. ("Mot.") at 1. Sanofi and Regeneron did not object at that time to Genentech and City of Hope's effort to streamline the case, nor did they ask for additional time to file their motions (a request to which Genentech and City of Hope readily would have assented). Instead, Sanofi and Regeneron simply proceeded to file motions addressing the withdrawn claims. Genentech and City of Hope then immediately filed a formal covenant not to sue on all claims other than claim 34.

In *MedImmune II*, the court rejected MedImmune's challenge to a covenant not to sue based on a pipeline product that MedImmune had similarly refused to place at issue in the case. The *MedImmune II* court observed that MedImmune had always directed its pleadings exclusively to the product at issue in the litigation, had never sought to amend its pleadings to reference its pipeline products, and had refused to provide discovery into the pipeline products. 535 F. Supp. 2d at 1009. In that situation, the court concluded that "[i]t would be inconsistent at this stage to find subject matter jurisdiction based upon a product which MedImmune, until very recently, refused to even discuss in connection with this litigation." *Id.* The same is true here. Sanofi and Regeneron have not cited any case in which a court found that a suit could proceed, notwithstanding an unconditional covenant not to sue, in order to address products that the challenging party had affirmatively refused to make a part of the case.

To be sure, a covenant not to sue must extend to future sales of existing products in order to eliminate any case or controversy. Many of the cases cited by Sanofi and Regeneron simply reflect this straightforward requirement, and the covenant given by Genentech and City of Hope unambiguously extends to present and future sales of Praluent. *See Revolution Eyewear, Inc. v. Aspex EyeWear, Inc.*, 556 F.3d 1294, 1299-1300 (Fed. Cir. 2009) (covenant insufficient where it did not preclude future infringement actions if the accused infringer offered for sale the allegedly infringing articles in the future); *Astrazeneca LP v Breath Ltd.*, No. 09-1518, 2013 WL 2404167, at *4 (D.N.J. May 31, 2013) (rejecting a covenant limited to defendant's ANDA as originally filed with the FDA that did not extend to defendant's current ANDA, which had been amended since the original filing date).[2]

[2] *Caraco Pharmaceuticals Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278, 1296-97 (Fed. Cir. 2008) presented an unusual situation in which the listing of a patent in the Orange Book precluded the declaratory judgment plaintiff from launching its product by reason of the statutory and regulatory framework, notwithstanding the existence of a covenant not to sue. In that context, the court found that the covenant did not divest the court of jurisdiction, because the defendant was blocking the launch of the product by maintaining the listing of the patent, and that block would be removed by a judgment of invalidity.

Sanofi and Regeneron argue that the covenant must extend not merely to future sales of Praluent, but also to sales of pipeline products that are awaiting FDA approval. Sanofi and Regeneron rely on *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721 (2013), in which the Supreme Court *affirmed* the effectiveness of a covenant not to sue to enforce trademarks against "existing footwear designs, or any future Already designs that constituted a 'colorable imitation' of Already's current products." *Id.* at 725. Genentech and City of Hope's covenant tracks this language. Sanofi and Regeneron should not be heard to complain that they need certainty regarding the pipeline products that they have refused to place at issue in the case.

Moreover, Genentech and City of Hope's covenant extends not merely to Praluent but also to products that are insubstantially different from it. Genentech and City of Hope have reason to believe that the pipeline products are insubstantially different from Praluent for purposes of assessing infringement of the Cabilly III claims: Based on publicly available information, it appears that both pipeline products referenced in Sanofi and Regeneron's Opposition (Sarilumab and Dupilumab) are made by coexpressing antibody heavy and light chains with variable domains and human constant domains in a CHO cell, just as is the case with Praluent. In that circumstance, the covenant extends (and, to the extent that there is any doubt, Genentech and City of Hope hereby confirm that it extends) to those products. Sanofi and Regeneron have not identified any other products that are potentially implicated by Cabilly III and that could give rise to a case or controversy. *See Already*, 133 S. Ct. at 728-29 ("[I]nformation about Already's business activities and plans is uniquely within its possession."). There is thus no subject matter jurisdiction here.

## IV. A PARTIAL COVENANT IS EFFECTIVE

Sanofi and Regeneron argue that Genentech and City of Hope's covenant is ineffective to divest the court of jurisdiction because it is addressed to some but not all of the patent's claims. However, Sanofi and Regeneron do not and cannot dispute that "the existence of a case or controversy must be evaluated on a claim-by-claim basis." *Jervis B.*

*Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984). Thus, in *Webb*, the Federal Circuit concluded that "[s]ince Webb only asserted and litigated the infringement of claims 1, 3, 4, 8, 9, and 11, and the evidence in the record is insufficient to indicate the existence of a case or controversy regarding the remaining claims in the invalidity declaratory judgment counterclaim, we vacate that portion of the district court's holding regarding the invalidity of claims 2, 5-7, 10 and 12." *Id.* (footnote omitted). The *Webb* court was addressing the limited scope of subject matter jurisdiction in view of the limited scope of the patent owner's allegations of infringement in the lawsuit, and explained that there might be jurisdiction as to all claims where the initial complaint put at issue infringement of all claims. The *Webb* decision thus makes clear that subject matter jurisdiction is indeed a claim-by-claim question. The *Webb* court did not address the effect of a covenant not to sue—in *Webb*, the patent holder had failed to assert and litigate certain claims, such that the court did not have jurisdiction to resolve them. The patent holder had not made any covenant not to sue, and so the court did not suggest that a covenant not to sue as to particular claim could be ineffective to deprive the court of jurisdiction as to that claim simply because ***other*** claims of the patent remain in play. *See also Hoffman-Laroche, Inc. v. Mylan Inc.*, No. 2:09-01692, 2009 WL 4796736, at *5 (D.N.J. Dec. 9, 2009) (jurisdiction must be evaluated on a claim-by-claim basis); *Mike's Train House, Inc. v. Broadway Ltd. Imports, LLC*, 708 F. Supp. 2d 527, 538 (D. Md. 2010) (citing cases and concluding a partial covenant is effective because jurisdiction must be assessed on a claim by claim basis); *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1348 (Fed. Cir. 2010) ("each of the claims over which a district court exercises its supplemental jurisdiction must have standing on its own.")

In *MedImmune II*, Judge Pfaelzer considered the effect of a covenant not to sue applicable to some but not all the claims of the Cabilly patent and rejected the argument that "Genentech's covenant does not act to extinguish subject matter jurisdiction because it covers only some, not all of the claims." 535 F. Supp. 2d at 1006. In reaching that conclusion, Judge Pfaelzer carefully surveyed the applicable cases, including *Lear*

*Automotive Dearborn, Inc. v. Johnson Controls, Inc*., 528 F. Supp. 2d 654 (E.D. Mich. 2007), and correctly concluded that the *Lear* rule (to the extent that it has any ongoing viability) is limited to situations in which the patent owner placed all the claims of its patent at issue.[3] Judge Pfaelzer also rejected MedImmune's policy arguments, concluding that "Federal Circuit law remains clear regarding the effect of Genentech's unilateral covenant: the invalidity claim can be heard only as to claim 33." 535 F. Supp. 2d at 1008.[4]

The only decision supporting Sanofi and Regeneron's position is *Enplas Display Device Corp. v. Seoul Semiconductor Co*., No. 13-cv-05038 NC, 2015 WL 1062676 (N.D. Cal. Dec. 3, 2015). In that case, the court considered a covenant that applied only to current conduct and not to future infringement. In finding the covenant insufficient, the court also noted that "the above cases speak to *causes of action*, and not patent claims." *Id.* at *4. However, the parties had not cited to the court, and the court did not discuss, cases such as *Jervis B. Webb Co.* making clear that jurisdiction must be assessed on a claim-by-claim basis, or *MedImmune II*, or *Lear* and its progeny, all of which speak to individual patent claims.

Sanofi and Regeneron also argue that, even if a partial covenant can be effective in some circumstances, a covenant not to sue on an independent claim is ineffective if a

[3] Sanofi and Regeneron try to distinguish their situation by noting that they filed their declaratory relief complaint before Genentech and City of Hope counterclaimed for infringement. That procedural posture makes no difference. The question is what Genentech and City of Hope placed at issue, for if they never asserted infringement, there would be no basis for subject matter jurisdiction in the first place. Here, Sanofi and Regeneron did not pursue the invalidation of any claims other than the specific claims that were the subject of Genentech and City of Hope's infringement counterclaim. Thus, for example, Sanofi and Regeneron's invalidity contentions and expert reports only addressed the invalidity of claims 25, 26, 28, 31-34, 38, 39, 43 and 47. *See, e.g.*, Opening Expert Report of Jefferson Foote, Ph.D. ¶¶ 25-29 (0642-63), Ex. 46 to Decl. Adam R. Brausa Supp. Defs.' Mot. Summ. Adjudication, ECF. No. 130-48.

[4] Sanofi and Regeneron also rely on *Shelcore, Inc. v. Durham Industries, Inc.*, 745 F.2d 621 (Fed. Cir. 1984) to suggest that a partial covenant is ineffective, but *Shelcore* did not involve a covenant not to sue and instead merely involved the withdrawal of a claim for infringement. *See also Syngenta Seeds, Inc. v. Monsanto Co*., No. 02-1331-SLR, 2004 WL 2790498, at *1 n.1 (D. Del. Nov. 22, 2004) (relying on *Shelcore* to decline to dismiss invalidity counterclaims upon the withdrawal of a claim for infringement without reference to a covenant not to sue).

dependent claim remains in play. In support of that counter-intuitive proposition, Sanofi and Regeneron rely on *Honeywell International, Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982 (Fed. Cir. 2007), but that case does not purport to set forth an exception to the rule that subject matter jurisdiction must be evaluated separately as to each claim and that a party must face some future injury arising from a particular claim in order to give rise to such jurisdiction. To the contrary, in *Honeywell* the district court identified the test as whether the defendant had "a reasonable apprehension that it will be sued on the non-asserted claims" and concluded that the defendant had met that standard. *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 288 F. Supp. 2d 638, 644 (D. Del. 2003). The Federal Circuit agreed. Neither the district court nor the Federal Circuit concluded that subject matter jurisdiction can exist as to claims that are the subject of an unconditional covenant not to sue. To the contrary, Honeywell had merely stated that it did not "intend" to assert certain claims—a representation that did not necessarily bar a future suit. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1376 (Fed. Cir. 2007) (declining to dismiss a declaratory relief action based solely on the representation that the patent holder "has absolutely no plan whatsoever to sue Sandisk"). Instead, the *Honeywell* court relied in part on the presence of co-pending litigation between the same parties to find that the defendant faced a reasonable threat of suit even as to the "withdrawn" claims. 488 F.3d at 995-96. Here, there is no such co-pending litigation, and Genentech and City of Hope have provided an irrevocable covenant not to sue on those claims. *See Grain Processing Corp. v. Am. Maize-Products Co.*, 840 F.3d 902, 906 (Fed. Cir. 1988) (covenant divested court of jurisdiction because the alleged infringer "ha[d] no 'reasonable apprehension' that it would face . . . suit on the [withdrawn] claims.").

## V. CONCLUSION

For the foregoing reasons, Defendants Genentech and City of Hope respectfully request the Court to dismiss Sanofi and Regeneron's counterclaims of invalidity as to all claims of the Cabilly III patent except claim 34.

Dated: August 11, 2016

DURIE TANGRI LLP

By: */s/ Daralyn J. Durie*
DARALYN J. DURIE

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## CERTIFICATE OF SERVICE

I certify that all counsel of record is being served on August 11, 2016 with a copy of this document via the Court's CM/ECF system.

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