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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

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

Plaintiffs,

vs.

GENENTECH, INC., and CITY OF HOPE,

Defendants.

GENENTECH, INC., and CITY OF HOPE,

Counterclaim Plaintiffs,

vs.

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

Counterclaim Defendants.

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

PLAINTIFFS' OPPOSITION TO DEFENDANTS' 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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Plaintiffs sanofi-aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. (collectively, "Plaintiffs") submit this memorandum in opposition to Defendants Genentech, Inc. and City of Hope's (collectively, "Defendants" or "Genentech") motion to dismiss Plaintiffs' Declaratory Judgment Complaint as to all claims of the Cabilly III patent except dependent claim 34. Defendants argue that dismissal is "mandated" by the covenant not to sue provided by Defendants with respect to Plaintiffs' product Praluent® on any patent claim of Cabilly III other than dependent claim 34. Their motion is fatally flawed because it is contrary to the controlling Supreme Court and Federal Circuit law—which Defendants fail to even cite. A "case or controversy" continues to exist regarding the patent rights that Defendants wield (now and in the future) against Plaintiffs, and this court continues to possess declaratory judgment jurisdiction over Plaintiffs' claims. Defendants' motion should be denied.

INTRODUCTION

At the eleventh hour—after all discovery has closed, after all experts submitted their positions concerning the invalidity of the Cabilly III claims, after Plaintiffs filed their dispositive motions demonstrating the invalidity of the Cabilly III claims—Defendants unilaterally decided to change the course of this litigation. Defendants now drop all of their claims but one—dependent claim 34[1]—and demand that Plaintiffs do the same with their invalidity claims. In effect, Defendants have yanked their claims, assuring that they cannot be invalidated and saving them to assert another day. To be clear, Defendants can turn around and assert these very claims against Plaintiffs in relation to any of its other monoclonal antibody products (in particular, those products that will shortly come to market)—thereby wasting the efforts of the parties and court in this litigation and simply

[1] Claim 34 reads: "The method of claim 32 wherein the mammalian cell is a CHO cell." Claim 34 contains all of the limitations of claims 32, 31, and independent claim 25.

"resetting" the clock for Defendants.

Contrary to Defendants' assertion, this likelihood is not "hypothetical." Defendants have clearly stated that in their view the Cabilly patents broadly cover the production of any antibody through the co-expression of antibody heavy and light chains in a single host cell (and have sued numerous companies who have made and sold products that were produced using such recombinant methods). Plaintiffs' manufacture and sale of Praluent® and expected future sale of drug products sarilumab and dupilumab present a real, immediate and substantial dispute over the Cabilly III patent, including the withdrawn claims. Defendants assert that they have withdrawn all but one patent claim from their infringement allegations in order to streamline the case; however, they have also signaled their ulterior motive as well—to gut Plaintiffs' counterclaims by removing certain invalidity arguments from the case.[2] This is improper, and highlights the fact that Plaintiffs have an immediate legal interest in invalidating Defendants' claims in order to remove the threat the Cabilly III patent poses to Plaintiffs' right to develop and bring antibody treatments to the market.

As the Supreme Court has recognized, courts must be skeptical of covenants not to sue that materialize in the context of ongoing litigation and "should proceed with caution before ruling that they can be used to terminate litigation." *See Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 726 (2013) (Kennedy, J., concurring). In particular, the holders of intellectual property rights should not be permitted to enforce those rights in litigation without at "the same time assuming the risk [that their rights] will be found invalid and unenforceable." *Id.* The Supreme Court's concern is particularly true here, as Defendants have dropped only some claims but

[2] Defendants have chosen to proceed on the narrow, dependent claim 34 in hopes of shielding their broader claims from several distinct invalidity attacks from Plaintiffs and preventing the jury from hearing how the Cabilly inventors failed to achieve in vivo antibody assembly—the very claim scope Defendants now assert against Plaintiffs.

continue to wield one (the narrowest, dependent claim) against Plaintiffs and preserve the remaining claims for an imminent repeat battle. Here, a controversy still exists between the parties over infringement of the Cabilly technology.

In citing the 1995 *Super Sack* decision as the leading case on the issue before the court, Defendants are completely—and glaringly—wrong. By ignoring the ensuing 20 years of law, Defendants avoid key precedents including the U.S. Supreme Court decision in *Already, LLC v. Nike* and the Federal Circuit decision in *Honeywell v. Universal Avionics*—which are the actual leading (and controlling) decisions on the issue of whether subject matter jurisdiction over Plaintiffs' declaratory judgment claims of invalidity is now automatically extinguished in light of Defendants' partial covenant not to sue. The answer, under these precedents, is no.

STATEMENT OF RELEVANT FACTS

Plaintiffs filed their Complaint for Declaratory Judgment of Invalidity and Non-infringement of U.S. Patent No. 7,923,221 ("Cabilly III") on July 27, 2015. Specifically, Plaintiffs alleged that their Praluent® (alirocumab) product does not infringe any valid claim of the Cabilly III patent, relying upon 35 U.S.C. §§ 101, 102, 103 and 112. (Dkt. 1.) In support of declaratory jurisdiction, Plaintiffs relied upon the fact that Genentech has made clear to the biopharmaceutical industry and to Plaintiffs that it contends that the claims of the Cabilly patents effectively preclude others from commercially manufacturing any recombinant monoclonal antibody without Genentech's permission. Genentech's General Counsel, Sean Johnston, stated in 2002: "The recently issued patent broadly covers the co-expression of immunoglobulin heavy and light chain genes in a single host cell… [w]e do not believe that the claims are limited by type of antibody (murine, humanized, or human) or by host cell type." (*Id.*) Plaintiffs also relied upon the fact that Defendants have alleged infringement of the Cabilly III patent (and Cabilly II) against other manufacturers of monoclonal antibodies, including Bristol-Myers

Squibb Co., Eli Lilly and Co., GlaxoSmithKline, Human Genome Sciences, Centocor Ortho Biotech Inc. and MedImmune, Inc. (*Id.*)

Defendants answered Plaintiffs' Complaint by alleging infringement of the Cabilly III patent claims by manufacturing, marketing distributing, offering for sale and/or selling Praluent® in the U.S., and/or importing Praluent® into the U.S. (Dkt. 30.) Over the past year, the parties have conducted and completed fact and expert discovery. Dispositive motions were filed on July 1, 2016. Just three days before the briefs were due Genentech filed a notice with the court of its intention to drop all claims except dependent claim 34, purportedly in order to "narrow and focus infringement and validity issues before the court at summary judgment and limit the number of issues that need to be considered by the jury at trial." (Dkt. 123.) This notice was subsequently found to be deficient by the clerk's office. (Dkt. 124.) On July 8, 2016, Genentech filed its Covenant Regarding Praluent®, as to all claims other than 34 (and only as to Praluent® and products that are not more than insubstantially different from Praluent®), in an effort to "streamline and simplify the issues for resolution." (Dkt. 147.) Plaintiffs filed a notice on July 11, 2016 objecting to Genentech's unilateral determination that the covenant automatically divests the court of jurisdiction as to Plaintiff's counterclaims of invalidity. (Dkt. 148.) This motion practice followed.

ARGUMENT

I. The Court Retains Jurisdiction to Address Plaintiffs' Challenges to the Validity of the Withdrawn Cabilly III Patent Claims

A. Defendants' Withdrawal of Only Selected Claims leaves the "Entire Subject Matter" of The Cabilly III Patent Claims At Issue

"Whether a covenant not to sue will divest the trial court of jurisdiction depends on what is covered by the covenant." *Revolution Eyewear, Inc. v. Aspex EyeWear, Inc.*, 556, F.3d 1294, 1297 (Fed. Cir. 2009). Where a covenant encompasses less than all of the parties' disputes, subject matter jurisdiction remains. *Id.* Because Genentech's partial covenant withdraws only selected claims

of the Cabilly III patent, this Court retains subject matter jurisdiction over Plaintiffs' invalidity action for the remaining challenged claims.

Defendants argue that *Super Sack* and its progeny "mandate" dismissal of Plaintiffs' invalidity action for the claims covered by its partial covenant. This reading of *Super Sack* is without merit and fails to address the issue at hand—whether a partial covenant, covering only a subset of a patent's claims (and in particular, leaving just one dependant claim), divests a court's subject matter jurisdiction as to patent claims dropped by the Defendants. The relevant precedents demonstrate that the answer is no. Defendants cite no Federal Circuit authority in support of their position that subject matter jurisdiction is automatically divested for those claims; nor can they. The Federal Circuit has allowed declaratory judgment claims of invalidity even after a patentee removes a subset of claims from the case. *See Shelcore, Inc. v. Durham, Indus., Inc.*, 745 F.2d 621, 624(Fed. Cir. 1984) ("By voluntarily dismissing with prejudice claim 13 of the '831 utility patent, Shelcore removed the issue of infringement of claim 13 from the trial court's consideration. But Shelcore could not unilaterally remove the validity issue because Durham's counterclaim put validity of all claims [1-13] in issue."). This is especially true where, as here, the withdrawn claims are directed to the same subject matter as the asserted claims. *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 995-96 (Fed. Cir. 2007).

In *Honeywell* the Federal Circuit affirmed a district court's finding of subject matter jurisdiction over invalidity of withdrawn claims where a patentee promised not to sue on only a subset of the asserted claims.[3] 488 F.3d at 995-96. The Federal Circuit held that where a party "withdrew some independent claims from the litigation" and "chose to maintain causes of action based on certain dependent

[3] To be sure, the patentee "represented to defendants in writing of its present and future intent not to pursue infringement of certain previously asserted claims of the [patents-in-suit]." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 288 F. Supp. 2d 638, 644 (D. Del. 2003).

claims relating to its display technology" it thus "left the ***entire subject matter*** of the display claims at issue." *Id* at 995. (emphasis added). This is because "infringement of a dependent claim also entails infringement of its associated independent claim[s]." *Id.* Applying the Supreme Court's *MedImmune* standard, the Federal Circuit affirmed the district court's decision to retain subject matter jurisdiction over the withdrawn claims (as well as the district court's finding of invalidity) because ***corresponding dependent claims*** remained asserted in the case, and thus the subject matter of the related claims remained in dispute.[4]

Like the patentee in *Honeywell*, Genentech continues to assert dependent claim 34, despite its withdrawal of other related claims. In the Cabilly III patent, claim 34 depends from claim 32, which depends from claim 31, which depends from independent claim 25.[5] All of these claims are previously asserted, and they all relate to methods for making antibodies by co-expression of heavy and light chains. By continuing to assert claim 34, Genentech necessarily keeps the subject matter of these claims at issue in the parties' dispute.[6] Accordingly, under *Honeywell*, subject matter jurisdiction of invalidity remains over the withdrawn

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[4] Defendants fail to acknowledge this distinction in citing *Mike's Train House, Inc. v. Broadway Ltd. Imports, LLC*, 708 F. Supp. 2d 527, 539 (D. Md. 2010) (covenant for "stand-alone claims" which do not depend from any withdrawn claims). The court noted that the "effect of a promise not to sue depends upon the nature of the claim withdrawn" and explained that pursuant to *Honeywell* a "patentee that withdraws an independent claim but continues to assert infringement of claims dependent on the withdrawn claims leaves the entire subject matter of [those] claims at issue." *Id*. at 539, n. 28.

[5] In *Honeywell*, the Federal Circuit affirmed the district court's invalidation of the independent claims that the patentee had withdrawn. *See*, 488 F.3d at 996 affirming 288 F.Supp.2d 638, 662 (D. Del. 2003)

[6] The Court in *MedImmune, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1000 (C.D. Cal. 2008), did not address *Honeywell* or the relationship between the subject matter of withdrawn versus asserted claims in reaching its decision. Importantly, *MedImmune* is distinguishable as Genentech did not continue to pursue infringement of a dependent claim after withdrawing the independent claim from which it depends.

Cabilly III patent claims, and at a minimum the claims from which claim 34 depends. This is particularly true here, because in assessing the validity of claim 34 the elements of the independent claim from which it depends (claim 25) must also be considered.

Importantly, the cases relied upon by Defendants do not address the specific facts of our case, and each is distinguishable. For example, in *Super Sack*, the patentee warranted not to assert ***the entire patent*** against the accused infringer. *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1056 (Fed. Cir. 1995)The Federal Circuit held that this divested the court of jurisdiction over the counterclaim, because there was no longer a controversy between the parties. *Id.* at 1058 ("[A] patentee defending against an action for a declaratory judgment of invalidity can divest the trial court of jurisdiction over the case by filing a covenant not to assert ***the patent at issue*** against the putative infringer…." (emphasis added)). Likewise, Genentech's other Federal Circuit citations address only covenants over entire patents. *See, e.g., Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1348 (Fed. Cir. 2010) ("In the case at bar, Ablaise's covenant not to sue avowed that Ablaise would not sue Dow Jones for ***any acts of infringement of its '530 patent***." (emphasis added)).

Neither *Super Sack* nor its progeny apply here because Genentech has not offered a complete covenant to the Cabilly III patent, and continues to assert infringement of at least one of its claims.[7] This distinction is significant—Genentech's partial covenant fails to completely extinguish the parties' dispute

[7] Furthermore, the Federal Circuit, in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346 (Fed. Cir. 2007), noted that *Super Sack* applied the "disapproved" "reasonable apprehension of imminent suit" test. Therefore, although the holding in *Benitec* is not dependent on the "reasonable apprehension of imminent suit" requirement, the Court based its analysis of whether jurisdiction existed over the alleged infringer's declaratory judgment counterclaims solely on the framework of *MedImmune*.

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regarding infringement of the subject matter covered by the Cabilly III patent. *See Enplas Display Device Corp. v. Seoul Semiconductor, Co. Ltd.*, No. 13-cv-05038, 2015 WL 7874323 at *3-4 (N.D. Cal. Dec. 3, 2015) (denying patentee's motion to dismiss invalidity counterclaims after a partial covenant not to sue on some, but not all, claims because the accused infringer "has an immediate legal interest in protecting its right to continue producing its [product] without a license," and "[t]he parties remain adverse as to whether [accused infringer] is infringing the [asserted] patents"). Indeed, in the District of Delaware, Judge Robinson relied on this very reasoning to distinguish *Super Sack*, and denied a patentee's motion to dismiss invalidity counterclaims where the patentee had removed some, but not all, of the asserted patent's claims. *Syngenta Seeds, Inc. v. Monsanto Co.*, Civ. 02-1331-SLR, 2004 WL 2790498, at * 1, n. 1 (D. Del. Nov. 22, 2004) ("[I]n *Super Sack* . . . the patentee withdrew the entire patent from controversy, not just discrete claims. The court finds the distinction substantial."). The same reasoning applies here.

Defendants also rely on *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984), to argue that the impact of a covenant not to sue must be evaluated "on a claim by claim basis." (*See* Br. at 6.) This is a misapplication of *Jervis*. Although *Jervis* allowed a Plaintiff patentee to limit the scope of a Defendant's invalidity counterclaims by asserting a subset of the patent's claims, it explicitly issued a narrow holding that excluded Defendants' present situation:

> This holding is applicable ***only*** to those instances where the declaratory judgment plaintiff, ***responding to an initial complaint by the declaratory defendant that asserted the infringement of less than all of his claims***, counterclaimed for an invalidity declaration but failed to meet the case or controversy requirement regarding the invalidity of all claims. ***This holding does not preclude the issuance of a declaratory judgment that all claims are valid or invalid in response to, inter alia (1) the filing of a declaratory judgment complaint asserting the invalidity of all of a patentee's claims in***

> ***response to general accusations of infringement by the patentee*** . . .

Jervis, 742 F.2d at 1399, n. 8 (emphasis added). Genentech did not file an "initial complaint" for patent infringement. Instead, as explicitly carved out by *Jervis*, Plaintiffs filed the initial declaratory judgment complaint asserting invalidity of the ***entire*** Cabilly III patent in response to a long history of infringement threats and charges against the industry by Genentech. Accordingly, contrary to Genentech's argument, nothing in *Jervis* expands the ruling in *Super Sack* to cover partial covenants under these facts.

Indeed, other courts have properly followed *Jervis'* exceptions when addressing this issue, and upheld subject matter jurisdiction of invalidity over withdrawn claims. *See Lear Auto. Dearborn, Inc. v. Johnson Controls, Inc.*,[8] 528 F.Supp.2d 654, 674 (E.D. Mich. Nov. 2, 2007) (upholding subject matter jurisdiction over invalidity of withdrawn claims, and citing *Jervis*, 742 F.2d at 1399, n.8); *see also F.B. Leopold Co., Inc. v. Roberts Filter Mfg. Co., Inc.*, Civ. No. 92-2427, 1995 WL 776945, at *3 (W.D. Pa. Aug. 2, 1995) (finding patentee's removal of some, but not all, claims of the asserted patent "insufficient" to divest the Court's subject matter jurisdiction based in part on *Jervis*' explicit exceptions).

Clearly, to preclude declaratory judgment jurisdiction, the covenant must be sufficiently broad to eliminate the controversy with respect to the withdrawn claims. In essence, it must negate the underlying injury. Here, the covenant is limited and subject matter jurisdiction regarding invalidity remains over the withdrawn Cabilly III patent claims (and at a minimum the claims from which

[8] The facts of *Lear* are quite similar to the present case, where a patentee responded to a motion for summary judgment of invalidity by selectively offering a covenant not to sue on some, but not all, claims. The *Lear* court properly noted that "it is difficult to view [patentee's] tactics in this case as anything other than ***an eleventh-hour attempt to pull the jurisdictional rug out from under a counterclaim that it could not defend against on the merits***." *Lear*, 528 F.Supp.2d at 674. Such is the case here.

claim 34 depends) as a controversy remains as to whether Defendants will continue to assert its patent rights (over the Cabilly technology) against Plaintiffs' antibody drugs. Declaratory relief is available when the patentee "puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).

B. Defendants' Limited Covenant Does Not Divest the Court of Jurisdiction As to the Withdrawn Cabilly III Patent Claims

Jurisdiction over Plaintiffs' invalidity claims aimed at the withdrawn Cabilly III claims remains with the court, as Defendants have chosen to maintain infringement "causes of action" relating to its recombinant antibody technology, thus leaving this subject matter at issue. *See Honeywell*, 488 F.3d at 995-96. The limited covenant provided by Defendants is also insufficient to divest the court of jurisdiction regarding those claims, because Defendants are free in the future to assert the Cabilly III claims against Plaintiffs' other antibody products.

The Supreme Court has made clear that a covenant not to sue must be broad enough to demonstrate that the alleged infringer has "no reasonable risk of [being] sued again" and that the burden of demonstrating this lies with the party providing the covenant (*i.e.*, Defendants). *Already*, 133 S. Ct. at 724. The Supreme Court, in *Already*, stated:

> "our cases have explained that 'a defendant claiming that its voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur.'"

Id. at 727 (quoting *Friends of the Earth, Inc. v. Laidlaw Environmental Services, Inc.*, 528 U.S. 167, 190 (2000).

In the *Already* case, in response to a trademark infringement suit, Already

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filed a counterclaim challenging the validity of Nike's trademark.[9] While the case was pending, Nike issued a covenant not to sue promising not to raise any trademark or unfair competition claim against Already or its affiliates based on Already's existing and future designs that constituted a "colorable imitation" of its existing products. 133 S. Ct. at 725. Nike then moved to dismiss the counterclaims on the ground the covenant extinguished the case or controversy, and Already opposed the motion. *Id.* The district court dismissed the counterclaim and the Second Circuit affirmed, stating that the covenant was drafted broadly enough that the threat of future litigation was "nonexistent" as there were no shoes that would infringe Nike's trademark yet not fall within the covenant. *Id.* at 726, 733. In the District Court's view from "Already's perspective, there was 'little difference' between invalidating the trademark and the scope of protection already afforded by the covenant.'" *Id.* at 732.

On appeal, the Supreme Court held that it was Nike's (the party offering the covenant) "burden to show" that the covenant was broad enough to end the continuing case or controversy—that it could not reasonably be expected to resume its enforcement actions against Already, in light of Already's "anticipated future activities". *Id.* at 727-29. This is a "formidable burden" and must take into consideration whether or not Already has "sufficiently concrete plans to engage in activities not covered by the covenant". *Id.* The Supreme Court held that "given the breadth of the covenant," Nike's enforcement of its trademark against Already

[9] While *Already* relates to trademark rights "the Court's analysis was clearly framed as applicable to intellectual property rights generally, including patents. Indeed, in some respects, the Court's language is more appropriate to patent litigation than it is to trademarks." Donald S. Chisum, *Chisum Patent Law Reference Guide 0081*, http://www.chisum.com/cplrg-guides/0081-2. (Ex. 1); *e.g., Arkema Inc. v. Honeywell Int'l Inc.*, 706 F.3d 1351, 1358 (Fed. Cir. 2013); *AstraZeneca LP v. Breath Ltd.*, No. 09-1518, 2013 WL 2404167 at *3 (D.N.J. May 31, 2013); *PerfectVision Mfg., Inc. v. PPC Boadband, Inc.*, 951 F. Supp. 2d 1083, 1087-90(E.D. Ark. 2013) (applying *Already* to patent cases).

"cannot reasonably be expected to recur" and affirmed the Second Circuit's dismissal. *Id* at 729. Thus, the Supreme Court made clear that if Already had identified products that infringe the Nike rights, but fell outside the covenant—the controversy would not be moot.[10] Id. at 729-732.

Here, we have very different facts, as Defendants have not met their burden of demonstrating that enforcement of the Cabilly III patent will not recur against Plaintiffs. First of all, Defendants can assert all of the dropped claims against any and all future products, in addition to the remaining claim 34. The parties could be in front of the court within months regarding the very same claims that the parties have litigated for the past year, because Genentech has made clear that it believes all recombinant therapeutic antibodies entering the market fall within the Cabilly patent claims.

Citing *Already*, courts have required broad covenants extending to future products in order to remedy this very situation. *See, e.g., Sonix Technology v. Kenji Yoshida*, 12-cv-380-CAB(DHB), Slip Op. at 3 (S.D. Ca. Dec. 30, 2015) (Ex. 2) (citing *Already*, the court found that a covenant that "unconditionally and irrevocably affords Sonix and its customers . . . complete freedom from allegations that any product embedded with Sonix's [optical identification] technology infringes any claim of any of the patents . . . whether they are produced and/or sold before or after the covenant" was broad enough to cover the allegedly infringing "optical identification technology" regardless of the product that it was incorporated into). Thus, under *Already*, ***a covenant must include future products that would infringe a previously asserted claim***, in order to make it "absolutely clear that [the patent holder] could not reasonably be expected to resume its enforcement efforts." *Id*. at 6.

[10] It has been questioned whether *Super Sack* is "still good law" in the wake of *Already* to the extent it allows "a covenant not to sue to moot an invalidity counterclaim when the covenant does not extend to future modified products." Chisum, *Chisum Patent Law Reference Guide 0081* (Ex. 1).

The Federal Circuit has made clear, following the *MedImmune* test, that declaratory judgment jurisdiction is met when the patentee "puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk*, 480 F.3d at 1381. It is not necessary for the party to actually infringe before seeking a declaration of rights. *Id.* In the context of a drug product, the Federal Circuit has ruled that a case or controversy exists when the alleged infringer has applied to the FDA seeking marketing approval. *See Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014); *see also Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir.1997) (finding a justiciable controversy where the party has filed an Abbreviated New Drug Application for FDA approval); *Caraco Pharm. v. Forest Labs.*, 527 F.3d 1278, 1295-97 (Fed. Cir. 2008) (filing of ANDA supplies declaratory judgment jurisdiction); *Amgen, Inc. v. Hoffman-LaRoche Ltd.*, 456 F.Supp. 2d 267, 278-79 (D. Mass. 2006) (court found that an approval date that is 20 to 24 months away can be considered sufficiently imminent for jurisdictional purposes).

The cases cited by Genentech to the contrary are distinguishable. For instance, in *Benitec*, 495 F.3d at 1349, the declaratory judgment plaintiff had not submitted any filing with the FDA, including any New Drug Application and it was still years away (if ever) from approval.[11] Here Plaintiffs have filed various applications with the FDA and await approval—*i.e.*, the plans are concrete, definite and imminent. Indeed, the Prescription Drug User Fee Act action date is October 30, 2016 for sarilumab. (Sarilumab Press Release,Ex. 3.) Furthermore, dupilumab has been granted "Breakthrough Therapy" designation by the FDA. (Dupilumab Press Release, Ex. 4.) Thus, these products will be marketed and sold in the near future—and consequently—Sanofi and Regeneron will face additional litigation

[11] *Amana Refrigeration v. Quadlux, Inc.*, 172 F.3d 852 (Fed. Cir. 1999) did not involve a drug product. Furthermore, the future "pipeline" products were not identified by Amana in any definite or concrete manner—contrary to the facts of *Already*, and contrary to facts in the instant case.

under Defendants' partial covenant.

CONCLUSION

For the foregoing reasons, Plaintiffs request that the Court deny Defendants' motion to dismiss Plaintiff's Declaratory Judgment Complaint regarding the invalidity of the withdrawn claims (but at a minimum claims 25, 31 and 32, which claim 34 depends from). Plaintiffs also request that the Court order that, to the extent a covenant not to sue is provided for any of the claims of the Cabilly III patent, the covenant meets the requirements of *Already v. Nike* and thus, encompasses all future products that Defendants' allege fall within the Cabilly III claims covered by the covenant.

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