IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, *Plaintiffs*, v. ELI LILLY AND COMPANY, *Defendant*.	)	C.A. No. 14-113-RGA-MPT

PRETRIAL ORDER EXHIBIT 4:

SANOFI'S STATEMENT OF ISSUES OF LAW

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Pursuant to L.R. 16.3(c)(5), Plaintiffs provide the following statement of issues of law that remain to be litigated.

I. INFRINGEMENT

1. Under the Hatch-Waxman Act, it is a statutory act of patent infringement to file a New Drug Application ("NDA") under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2), for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a patented drug or method of use. 35 U.S.C. § 271(e)(2)(A). "When a patentee seeks to block FDA approval of an NDA under 35 U.S.C. § 271(e)(2)(A), the infringement inquiry focuses on the hypothetical infringement that would occur if the defendant's NDA were approved and the defendant began to make and sell the drug." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1047 (Fed. Cir. 2001) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed.Cir.1997)); *accord Novartis Pharms. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733, at 738 (D. Del. 2014) (Andrews, J.,) ("Under 35 U.S.C. § 271(e)(2)(A), a court must determine whether, if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." (internal annotations omitted)). The patentee "has the burden of proving infringement by a preponderance of the evidence." *Novartis Pharms.*, 48 F. Supp. 3d at 738. The infringement inquiry is "based on consideration of all the relevant evidence, including the [NDA] filing, other materials submitted by the accused infringer to the FDA, and other evidence provided by the parties." *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002).

2. The first step in determining infringement is to construe the asserted claims, a matter of law decided by courts. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389-91 (1996). "When construing the claims of a patent, a court considers the literal language of a

claim, the specification and the prosecution history." *Wyeth v. Impax Labs., Inc.*, 526 F. Supp. 2d 474, 477 (D. Del. 2007) (citing *Markman*, 52 F.3d 967, 979 (Fed. Cir. 1995) aff'd, 517 U.S. 370 (1996). It is a "well-established principle that a court may not import limitations from the written description into the claims." Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1347 (Fed. Cir. 1998); accord, *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006) (refusing to limit a claimed class of pharmaceutical compounds to the specific chemical structure depicted in the specification); *Wyeth*, 526 F. Supp. 2d at 479-80 (refusing to limit the general claim term, "extended release formulation," to the specific ingredients listed in the specification). Also, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005)

3. Furthermore, "expert testimony inconsistent with the Court's claim construction is unreliable and unhelpful to the finder of fact." *Personalized User Model, L.L.P. v. Google Inc.*, No. CV 09-525-LPS, 2014 WL 807736, at *2 (D. Del. Feb. 27, 2014); *see also LP Matthews LLC v. Bath & Body Works, Inc.*, 458 F. Supp. 2d 198, 210 (D. Del. 2006).

A. <u>Literal Infringement</u>

4. "The application of a patent claim to an accused product is a fact-specific inquiry. Literal infringement is present only when each and every element set forth in the patent claims is found in the accused product. . . . Infringement can be shown by any method of analysis that is probative of the fact of infringement, and, in some cases, circumstantial evidence may be sufficient." *Novartis Pharms.*, 48 F. Supp. 3d at 738-39 (internal citations omitted).

5. A product infringes a claim when it meets each claim element during normal operation. *See, e.g., CIF Licensing, LLC v. Agere Sys. Inc.*, 727 F. Supp. 2d 337, 347 (D. Del. 2010) ("For purposes of conducting an infringement analysis, the Federal Circuit distinguishes

between usual or reasonable uses of a device on one hand, and uses which are unusual, or merely possible, on the other hand."). "[I]nfringement is not avoided merely because a non-infringing mode of operation is possible." *Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1350 (Fed. Cir. 2007). A product can meet a claim element for the presence of a specific compound even when a very small quantity of the compound is present in the product. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1339–41 (Fed. Cir. 2005) (finding that the asserted claim was not limited to commercially significant amounts of paroxetine hydrochloride hemihydrate and affirming the district court's finding of infringement based on the trace amounts of paroxetine hydrochloride hemihydrate in the accused product). "[T]he statute leaves no leeway to excuse infringement because the infringer only infringed a little." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352–53 (Fed. Cir. 2000) (Rader, J., concurring); *accord Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1356 (Fed. Cir. 2013) (summarizing Judge Rader's concurrence in *Embrex* and other cases "reject[ing] the proposition that patent claims should be construed to avoid reading on 'trace amounts' of a patented compound").

6. Because direct patent infringement is a strict liability offense, the defendant's alleged desire to avoid infringing is irrelevant. *See Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920, 1926 (2015). Accordingly, an accused product that meets every limitation of an asserted claim infringes even if the defendant did not intend for every limitation to be present. *See, e.g., Novartis Pharm. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733, 740 (D. Del. 2014) (Andrews, J.) (finding that an ANDA product infringed where the infringing element entered the product in small amounts as an impurity introduced by an upstream supplier).

B. Infringement under the Doctrine of Equivalents

7. The doctrine of equivalents prohibits one from "avoiding infringement liability by making only 'insubstantial changes and substitutions . . . which, though adding nothing, would

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