UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., et al., Plaintiffs, v. LUPIN LIMITED, et al., Defendants.	**OPINION** Civ. No. 2:10-cv-05954 (WHW) **FILED UNDER SEAL**

Walls, Senior District Judge

Plaintiffs Janssen Products, L.P. and Janssen R&D Ireland (collectively, "Janssen" or "Janssen Plaintiffs") move for summary judgment of infringement of U.S. Patent No. 7,772,411 B2 (the "'411 Patent"). Defendants Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively, "Mylan") oppose. Janssen also moves for summary judgment on the validity of U.S. Patent No. 7,700,645 B2 (the "'645 Patent"). Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") and Mylan (all collectively, "Defendants") oppose, and Defendants Teva and Mylan also move for summary judgment of non-infringement of the claims of the '645 Patent, which Janssen opposes. Janssen further moves for summary judgment of infringement of U.S. Patent Nos. 7,126,015 B2 (the "'015 Patent") and 7,595,408 B2 (the "'408 Patent"). Defendants oppose, and Defendants Lupin and Teva also move for summary judgment of non-infringement of the claims of the '015 Patent and the '408 Patent, which Janssen opposes. The motions have been decided from the written submissions of the parties under Federal Rule of Civil Procedure 78. Janssen's

motion for summary judgment of infringement of the '411 Patent is granted. Janssen's motion for summary judgment on the validity of the '645 Patent is denied. Janssen's motion for summary judgment of infringement of the '015 and '408 Patents is granted in part and denied in part. Teva's motion for summary judgment of non-infringement of the '645 Patent is denied. Mylan's motion for summary judgment of non-infringement of the '645 Patent is denied. Lupin and Teva's motion for summary judgment of non-infringement of the '015 and '408 Patents is denied.

FACTUAL AND PROCEDURAL BACKGROUND

This consolidated action arises out of Defendants having filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration (the "FDA") seeking approval to sell generic versions of Janssen's highly successful HIV drug PREZISTA® (also known by its compound name, darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg products. *Markman* Op. at 1-2 (ECF No. 477). Janssen sued the various Defendants after receiving notice that they had submitted these ANDAs to the FDA.

The '411 Patent is directed to a process for manufacturing the compound (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[(4-aminophenyl)sulfonyl](isobutyl)amino-1-benzyl-2-hydroxypropyl-carbamate, also known as darunavir, the drug in both PREZISTA® and Mylan's generic version of PREZISTA®. Mylan's Opp'n to Janssen's Mot. for Summ. J. on '411 Patent at 3-4 (ECF No. 588). The '645 Patent claims the ethanolate form of the drug that Janssen developed and sells as PREZISTA®. Janssen's Br. in Support of Summ. J. on '645 Patent at 2 (ECF No. 528). Both the '015 Patent and the '408 Patent claim processes for manufacturing bis-THF, a chemical structure or moiety that is part of the darunavir molecule. Janssen's Br. in Support of Summ. J. on '015, '408 Patents at 2 (ECF No. 535).

On September 15, 2011, this Court consolidated the patent infringement actions brought by the Janssen Plaintiffs for the purposes of pretrial proceedings and trial. ECF No. 71. The Court held its *Markman* claim construction hearing on October 1, 2013, and on October 9, 2013, issued its *Markman* opinion construing the claim terms and phrases needing construction as identified by the parties. ECF No. 477. On November 22, 2013, Janssen filed three separate motions for summary judgment: one for infringement of the claims of the '411 Patent, ECF No. 524, one for the validity of the '645 Patent, ECF No. 528, and one for the infringement of the '015 Patent and the '408 Patent, ECF No. 535. That same day, Defendants Teva and Mylan filed separate motions for summary judgment of non-infringement of the '645 Patent, ECF Nos. 525, 540, and Defendants Lupin and Teva jointly filed a motion for summary judgment of non-infringement of the claims of the '015 Patent and the '408 Patent, ECF No. 533. Oppositions to all of those motions were filed on December 23, 2013, ECF Nos. 579, 588, 595, 600, 608, 609, and replies were filed on January 15, 2014, ECF Nos. 655, 656, 657, 659, 662, 664.

STANDARD OF REVIEW

The same summary judgment standard applies to motions involving patent claims as applies to motions involving other types of claims. *See, e.g.*, *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 795-96 (Fed. Cir. 1990); *Avia Group Int'l, Inc. v. L.A. Gear Calif., Inc.*, 853 F.2d 1557, 1560-61 (Fed. Cir. 1988), *abrogated on other grounds by Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008).

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute between the parties must be both genuine and material to defeat a motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A

disputed fact is material where it would affect the outcome of the suit under the relevant substantive law. *Scott v. Harris*, 550 U.S. 372, 380 (2007). A dispute as to a material fact is genuine where a rational trier of fact could return a verdict for the non-movant. *Id.* The movant bears the initial burden of demonstrating the absence of a genuine issue of material fact for trial. *Beard v. Banks*, 548 U.S. 521, 529 (2006). If the movant carries this burden, the non-movant "must do more than simply show that there is some metaphysical doubt as to the material facts." *Scott*, 550 U.S. at 380 (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986)). At this stage, "the judge's function is not himself to weigh the evidence and determine the truth of the matter." *Anderson*, 477 U.S. at 249. Each party must support its position by "citing to particular parts of materials in the record . . . or showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1).

The determination of patent infringement is a two-step process: "first, the scope of the claims are determined as a matter of law, and second, the properly construed claims are compared to the allegedly infringing device to determine, as a matter of fact, whether all of the limitations of at least one claim are present, either literally or by a substantial equivalent, in the accused device." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002); *accord, e.g.*, *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1365 (Fed. Cir. 2002). "[S]ummary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

DISCUSSION

I. The '411 Patent: Janssen's Motion for Summary Judgment of Infringement

The '411 Patent provides "a new process for the synthesis of compound of forumula (6) [*i.e.*, darunavir]." Janssen's Br. in Support of Summ. J. on '411 Patent at 2 (ECF No. 524). More specifically, the '411 Patent "provides a convenient process for the production of compound of formula (6) and intermediates . . . thereof at industrial scale." *Id.* The '411 Patent is made up of eighteen claims, and Janssen accuses Mylan of infringing claims 1, 2, 4, 6-10, 13, 15 and 18. Claim 1, which is the only independent claim, reads:

> 1. A process for preparing compound of formula (6), [graphic depiction of darunavir]
> Or an addition salt, thereof; comprising:
> (i) introducing an isobutylamino group in compound of formula (1), [graphic depiction of formula 1]
> wherein
> PG represents an amino-protecting group;
> R(sub 1) is hydrogen or C(sub 1-6)alkyl;
> (ii) introducing a p-nitrophenylsulfonyl group in the resultant compound step(i);
> (iii) reducing the nitro moiety of the resultant compound of step (ii);
> (iv) deprotecting the resulting compound of step (iii); and
> (v) coupling the resultant compound of step (iv) with a (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl derivative.

Decl. of Eugene M. Gelernter ("Gelernter Decl.") Ex. 1 at col. 23:10-51 ('411 Patent). The other asserted claims are dependent claims that depend from claim 1, directly or indirectly. Janssen's Br. in Support of Summ. J. on '411 Patent at 4 (ECF No. 524). As a result, they "incorporate by reference all the limitations" of claim 1 and "specify . . . further limitation[s] of the subject matter claimed." 35 U.S.C. § 112(d), (e).

Janssen and Mylan disagreed about how the term "compound of formula (6)" was to be construed. At the *Markman* hearing, Janssen proposed a construction of "compound of formula (6)" as meaning darunavir, while Mylan argued that "compound of formula (6)" should be

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