FOR PUBLICATION

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

By complaints, Plaintiff patent-holders and drug-makers have sued Defendant generic drug manufacturers for alleged infringements of patents on a chemical compound used in the manufacture of Plaintiff's product, Prezista. The patents, for this opinion, are U.S. Patent No. 7,700,645 B2 (the "'645 Patent"), U.S. Patent No. 7,126,015 B2 (the "'015 Patent"), and U.S. Patent No. 7,772,411 B2 (the "'411 Patent").

Prezista is an ethanolate form of the chemical compound named darunavir. The '015 Patent claims processes for manufacturing a chemical structure or moiety, bis-THF, that is part of the darunavir molecule. The '411 Patent is directed to a process for manufacturing darunavir in Prezista and Defendant Mylan's generic version. The '645 Patent claims the ethanolate form that Plaintiff Janssen developed and sells as Prezista.

Earlier summary judgment motion practice by the parties caused the Court to determine that:

1) Janssen's motion for summary judgment of infringement of the '411 Patent against Mylan was granted.
2) Janssen's motion for summary judgment on the validity of the '645 Patent was denied.
3) Janssen's motion for summary judgment of infringement of the '015 and '408 Patents was granted in part and denied in part: the Court found that Lupin infringed certain claims of the '015 Patent, including asserted claim 1.
4) Teva's motion for summary judgment of non-infringement of the '645 Patent was denied.
5) Mylan's motion for summary judgment of non-infringement of the '645 Patent was denied.
6) Lupin's and Teva's motion for summary judgment of non-infringement of the '015 and '408 Patents was denied.

Before trial, Teva and Janssen resolved their dispute, and the '408 Patent is no longer at issue.

A bench trial has been held on the remaining matters: the validity of the patents—as to Lupin, claim 4 of the '645 Patent and claim 1 of the '015 Patent, and as to Mylan, claim 13 of the '411 Patent.

This Opinion will be based and concentrated on what the Court has found to be material and supportive facts necessary to answer the primary question: Did either Defendant prove invalidity of a patent-in-suit by clear and convincing evidence?

To find the answer(s), the Court has reviewed the relevant evidence adduced at trial, aided by recollection, notes, trial transcripts, and the parties' proposed findings of fact. The Court has evaluated the credibility of all witnesses, lay and expert, testing not only what the person said, but

how it was said and what was not said, against these criteria: Was this more likely so or not? Did what was said make sense in the totality of the circumstances? Was this, after all, clearly convincing to the fact finder?

To its chagrin, the Court has determined that expert witnesses, though not all, called by the defense were more interested in obfuscation than in helping the Court as a fact finder "seek the truth." Too often—and too repeatedly—the Court had to importune and finally direct certain defense witnesses to directly answer questions posed. The trial transcripts will identify these persons as Dr. Trevor Laird and Dr. Michael Zaworotko. *See, e.g.*, Laird Tr. 1450:20-1451:5, 1486:23-1487:10, 1488:5-22; Zaworotko Tr. 1650:16-19, 1684:5-24, 1712:18-19. Ironically, such representatives of science were more interested in evasion than intellectual candor. As to their testimony, the Court as fact finder invokes *falsus in uno, falsus in omnibus*. Each did the cause of his particular Defendant no good.

In challenging the patents' validity, Defendants face a heavy burden. By statute, issued patents are "presumed valid," 35 U.S.C. § 282 (2012), and Defendants must overcome that presumption by clear and convincing evidence. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012). "Clear and convincing evidence is such evidence that produces 'an abiding conviction that the truth of [the] factual contentions are highly probable.'" *Id.* (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

The Court finds that neither Defendant met its obligation to overcome the presumption of validity of the patents-in-suit by clear and convincing evidence.

I. Findings of Fact

To the extent any finding of fact reflects a legal conclusion, it shall be to that extent deemed a conclusion of law, and vice versa.

A. Background

i. The patents at issue

On October 24, 2006, the Patent and Trademark Office ("PTO") issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." Pre-Trial Order at 12, ¶ 34. Lupin does not contest—for the purposes of this litigation only—that the '015 Patent has a priority date of September 10, 2001, nor that Janssen R&D Ireland holds title to the '015 Patent. *Id.* at 12, ¶¶ 35, 36. Janssen is asserting claim 1 of the '015 Patent against Lupin. *Id.* at 12, ¶ 37.

On August 10, 2010, the PTO issued the '411 Patent, entitled "Process for the Preparation of (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[(4-aminophenyl) sulfonyl](isobutyl) amino]-1-benzyl-2-hydroxypropylcarbamate." *Id.* at 13, ¶ 44. Mylan does not contest—for the purposes of this litigation only—that the '411 Patent has a priority date of December 23, 2003, nor that Janssen R&D Ireland holds title to the '411 Patent. *Id.* at 13, ¶¶ 45, 46. Janssen is asserting claim 13 of the '411 Patent against Mylan. *Id.* at 13, ¶ 47.

On April 20, 2010, the PTO issued the '645 Patent, entitled "Pseudopolymorphic Forms of a HIV Protease Inhibitor." *Id.* at 11, ¶ 29. Lupin does not contest—for the purposes of this litigation only—that the '645 Patent has a priority date of May 16, 2002, nor that Janssen R&D Ireland holds title to the '645 Patent. *Id.* at 11, ¶¶ 30, 31. Janssen is asserting claim 4 of the '645 Patent against Lupin. *Id.* at 11, ¶ 32.

ii. Prezista (darunavir)

Janssen Products, L.P. is the holder of approved New Drug Application ("NDA") No. 21-976 for Prezista (darunavir). Janssen manufactures, markets and sells Prezista, a human immunodeficiency virus (HIV-1) protease inhibitor. *Id.* at 9, ¶¶ 14, 15. The FDA has approved Prezista for the treatment of HIV-1 infection in adult patients and in pediatric patients 3 years of

age and older. *Id.* at 9, ¶ 16. The active pharmaceutical ingredient in Prezista is darunavir in an ethanolate form. *Id.* at 9, ¶ 17. Prezista tablets are currently sold in the United States in 75 mg, 150 mg, 400 mg, 600 mg, and 800 mg dosage strengths. *Id.* at 9, ¶ 18. The '645 Patent is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") with respect to Prezista. *Id.* at 9, ¶ 20.

iii. The ANDAs

On June 23, 2010, Mylan filed ANDA No. 202136 with the FDA, seeking approval to sell darunavir tablets, 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg, described in the ANDA. *Id.* at 9, ¶ 21.

On June 23, 2010, Lupin filed ANDA No. 202073 with the FDA seeking approval to sell darunavir tablets, 400 mg and 600 mg, described in the ANDA. On June 3, 2011, Lupin amended its ANDA No. 202073 to incorporate additional strengths of 75 mg, 150 mg, and 300 mg. *Id.* at 10, ¶¶ 23-24.

iv. Claim construction

In its *Markman* opinion, the Court construed "solvate" in the asserted claims of the '645 Patent to mean "a crystal form that contains stoichiometric or non-stoichiometric amounts of solvent." ECF No. 477 at 5; Pre-Trial Order at 13, ¶ 48. The Court also construed the term "compound of formula (6)" in the asserted claims of the '411 Patent as "darunavir," or the graphic depiction of darunavir. *Markman* Op. at 11; Pre-Trial Order at 13-14, ¶ 49.

B. The '015 Patent

i. The invention and the claim at issue

The invention of the '015 Patent "relates to a method for the preparation of [bis-THF] . . . ." Defendants' Trial Exhibit ("DTX") 7 ('015 Patent) at col. 1:12-14. The

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