UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA, INC. and POZEN INC.,	:	Case No. 11-2317 (MLC) (DEA)
	:	**REDACTED**
Plaintiffs,	:	**AMENDED MEMORANDUM OPINION** :
v.	:	
	:	
DR. REDDY'S LABORATORIES, INC., *et al.*,	:	
	:	
Defendants.	:	
	:	

COOPER, District Judge

I. Background

This is a patent dispute between Plaintiffs Horizon Pharma, Inc. and Pozen Inc. (together, "Horizon") and two groups of generic drug manufacturers: (1) Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. ("DRL"); and (2) Mylan, Inc.; Mylan Pharmaceuticals Inc.; and Mylan Laboratories Ltd. ("Mylan," and together with DRL, "Defendants"). Horizon holds New Drug Application ("NDA") No. 022511 for Vimovo, a branded drug product whose active pharmaceutical ingredients are naproxen and esomeprazole magnesium. (Dkt. 421 at 6.)[1]

This case arises out of Defendants' submission of Abbreviated New Drug Applications ("ANDAs") to the FDA pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j), for the purpose of obtaining FDA approval for the commercial manufacture, use, import, offer for sale, and sale of a generic version of Vimovo. Specifically, DRL filed ANDA No. 202461 ("DRL ANDA I") and ANDA No. 204206 (DRL ANDA II"). Mylan filed ANDA No. 204920 ("Mylan ANDA"). Based on submissions by the parties in the pre-trial order, all three ANDAs relate to tablets containing 375 mg or 500 mg of naproxen and 20 mg esomeprazole magnesium. (Dkt. 421 at 7–8.)[2] All three ANDAs included so-called "Paragraph IV" certifications that the products would not infringe Horizon's patents and/or that those patents are invalid or unenforceable. (Id.) The Paragraph IV certifications covered U.S. Patent No. 6,926,907 ("the '907 patent") and No. 8,557,285 ("the '285 patent")

[1] The Court will cite documents filed on the Electronic Case Filing System ("ECF") by referring to the docket entry numbers as "dkt." Pincites reference ECF pagination.

[2] Lupin Pharmaceuticals, Inc. and Lupin Ltd. ("Lupin") submitted an ANDA filing (No. 202654). Horizon's case against Lupin (Case No. 11-4275) has been stayed pending the outcome of this case. (Dkt. 455.)

(together, the "Asserted Patents"). In response to those Paragraph IV certifications, Horizon asserted infringement of claims 5, 15, 52, and 53 of the '907 patent.[3] Horizon has also asserted claims 1 through 4 of the '285 patent.[4]

Mylan has stipulated that its ANDA product would infringe the Asserted Patents. (Dkt. 421 at 8.) DRL has admitted that its DRL ANDA I Product would infringe the Asserted Patents. (Id.) We previously granted summary judgment in DRL's favor that its ANDA II

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[3] The asserted claims of the '907 patent (together with claim 1 for context) are:

1. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:

(a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;

(b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms; and wherein said unit dosage form provides for coordinated release such that:

i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher;

ii) at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5.

5. The pharmaceutical composition of claim 1, wherein said acid inhibitor is a proton pump inhibitor selected from the group consisting of: omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole.

15. The pharmaceutical composition of . . . claim[] 1 . . . wherein said acid inhibitor is a proton pump inhibitor.

51. A method of treating a patient for pain or inflammation, comprising administering to said patient the pharmaceutical composition of claim 15.

52. The method of claim 51, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.

53. The pharmaceutical composition of any one of claims 5-11 wherein said unit dosage form is a multilayer tablet comprising a single core and one or more layers outside of said single core, wherein:

i) said NSAID is present in said core;

ii) said coating that does not release said NSAID unless the pH of the surrounding medium is 3.5 or higher surrounds said core; and

iii) said acid inhibitor is in said one [or] more layers outside said core.

('907 patent at col. 20, line 9 to col. 24, line 6.)

Product does not infringe the '907 patent. (Dkt. 380). Accordingly, the only infringement dispute at trial was whether DRL's ANDA II Product infringes the '285 patent. Most of the trial was focused on Defendants' contentions that claims in the Asserted Patents are invalid under 35 U.S.C. § 103 and/or § 112.

We held a six day bench trial on those issues from January 12–20, 2017 and heard closing arguments on May 17, 2017.[5] We heard live testimony from seven witnesses. Dr. John Plachetka, called by Horizon, was the named inventor on the Asserted Patents. (Tr. 15–192.) Dr. David Metz, called by Defendants, was qualified as an expert in gastroenterology, including the treatment of acid peptic disorder. (Tr. 260–396.) Dr. Arthur Kibbe, called by Defendants, was qualified as an expert in pharmaceutical formulation and development. (Tr.

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[4] The asserted claims of the '285 patent are as follows:

1. A pharmaceutical composition in unit dosage form comprising therapeutically effective amounts of:

(a) esomeprazole, wherein at least a portion of said esomeprazole is not surrounded by an enteric coating; and

(b) naproxen surrounded by a coating that inhibits its release from said unit dosage form unless said dosage form is in a medium with a pH of 3.5 or higher;

wherein said unit dosage form provides for release of said esomeprazole such that upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium.

2. The pharmaceutical composition of claim 1, wherein naproxen is present in said unit dosage form in an amount of 200-600 mg.

3. The pharmaceutical composition of claim 1, wherein esomeprazole is present in said unit dosage form in an amount of from 5 to 100 mg.

4. The pharmaceutical composition of claim 1, wherein naproxen is present in said unit dosage form in an amount of between 200-600 mg and esomeprazole in an amount of from 5 to 100 mg per unit dosage form.

('285 patent at col. 22, lines 8–28.)

[5] The trial transcript is separated into seven volumes, but the pages are numbered consecutively. (See dkt. 458 (Vol. 1), dkt. 461 (Vol. 2), dkt. 463 (Vol. 3), dkt. 466 (Vol. 4), dkt. 468 (Vol. 5), dkt. 471 (Vol. 6), and dkt. 491 (Vol. 7).) We will cite to the trial transcript using the designation "Tr." without indicating the specific volume.

408–565.) Dr. Michael Mayersohn, called by Defendants, was qualified as an expert on pharmacokinetics and pharmacodynamics. (Tr. 569–603; Tr. 610–707.) Dr. Robert Williams, III, called by Horizon, was qualified as an expert in pharmaceutical formulation. (Tr. 716–842; Tr. 849–1017.) Dr. David Taft, called by Horizon, was qualified as an expert in pharmacokinetics. (Tr. 1018–1102.) Dr. David Johnson, called by Horizon, was qualified as an expert in gastroenterology. (Tr. 1108–1266.) The parties also submitted designated deposition testimony from Brian Ault (DTX-1393); Mark Sostek (DTX-1396); Jeff Sherman (DTX-1397); Dennis McNamara (DTX-1398); Abhijit Desmukh (PTX-581); John Horn (PTX-582); T. Sudhakar Koudinya (PTX-583); Snehalatha Movva (PTX-584); and Badri Viswanathan (PTX-585).[6]

This opinion follows the parties' division of the relevant legal issues raised at trial and addresses the interrelated infringement and § 112 issues in Section III, infra, and the interrelated obviousness and § 112 issues in Section IV, infra. In support of their arguments, Horizon and Defendants submitted separate post-trial briefs on the issues addressed in Section III (dkt. 489-2; dkt. 489-3) and Section IV (dkt. 489; dkt. 489-1).

For the reasons below, we conclude that DRL's ANDA II Product infringes the '285 patent and that the asserted claims are not invalid under 35 U.S.C. § 103 and/or § 112. Accordingly, we will grant judgment in Horizon's favor and issue an appropriate order.

[6] Defendants object to Dr. Horn's deposition testimony as inadmissible hearsay. (Dkt. 472.) We conclude that Dr. Horn's testimony is admissible because it satisfies the requirements of the hearsay exception in Federal Rule of Civil Procedure 32(a) for deposition testimony of an unavailable witness. See Novozymes A/S v. Genencor Int'l, Inc., No. 05-160, 2006 WL 318936, at *1 (D. Del. Feb. 10, 2006). We note, however, that the exclusion of Dr. Horn's testimony would not have changed any of our conclusions in this opinion.

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