NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, Defendants.	**Civil Action No. 15-3324 (SRC)** **OPINION** (consolidated for discovery purposes with Civil Action Nos. 16-4918, 16-9035, 15-3327, 16-4921, 15-3326, and 16-4920)
HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC., Defendants.	
HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC., Defendants.	

CHESLER, U.S.D.J.

This matter comes before this Court on the motion for summary judgment of invalidity by Defendants Dr. Reddy's Laboratories Inc., Dr. Reddy's Laboratories Ltd., Mylan Inc., Mylan Laboratories Limited, and Mylan Pharmaceuticals Inc. (collectively, "Defendants.") Defendants move for summary judgment of invalidity of U.S. Patent Nos. 9,220,698 (the "'698 patent") and 9,393,208 (the "'208 patent") on the ground of indefiniteness. Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc. (collectively, "Plaintiffs") have opposed the motion. For the reasons that follow, the motion will be granted.

These cases arise from Hatch-Waxman litigation regarding patents related to the drug Vimovo®. Plaintiffs hold the patents and the various Defendants are pharmaceutical companies which have filed ANDA applications to produce generic versions. Both patents at issue disclose methods of treatment using pharmaceuticals containing naproxen and esomeprazole. Both patents have only one independent claim, which is claim 1 in each patent.

Defendants move for summary judgment of invalidity on the ground of indefiniteness. Claim 1 of the '698 patent is representative:[1]

> A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need thereof an AM unit dose form and, 10 hours (.+-.20%) later, a PM unit dose form, wherein:
>
> the AM and PM unit dose forms each comprises: naproxen, or a pharmaceutically

[1] Claim 1 of the '208 patent is quite similar. During the Markman briefing, at the Markman hearing, and in the present briefing, the parties have uniformly treated claim 1 of the '698 patent as representative of the independent claims in both patents. No one has contended that claim 1 of the '698 patent differs materially from claim 1 of the '208 patent with regard to the "target" claim language at issue on this motion. This Court will therefore focus in this opinion, as it did in the Markman opinion, on claim 1 of the '698 patent, but will draw conclusions about the first claims of both patents.

> acceptable salt thereof, in an amount to provide 500 mg of naproxen, and esomeprazole, or a pharmaceutically acceptable salt thereof, in an amount to provide 20 mg of esomeprazole; said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater,
>
> the AM and PM unit dose forms target:
>
> i) a pharmacokinetic (pk) profile for naproxen where: a) for the AM dose of naproxen, the mean C.sub.max is 86.2 .mu.g/mL (.+-.20%) and the median T.sub.max is 3.0 hours (.+-.20%); and b) for the PM dose of naproxen, the mean C.sub.max is 76.8 .mu.g/mL (.+-.20%) and the median T.sub.max is 10 hours (.+-.20%); and ii) a pharmacokinetic (pk) profile for esomeprazole where: a) for the AM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the AM dose is administered to 10 hours (.+-.20%) after the AM dose is administered (AUC.sub.0-10,am) is 1216 hr*.mu.g/mL (.+-.20%), b) for the PM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the PM dose is administered to 14 hours (.+-.20%) after the PM dose is administered (AUC.sub.0-14,pm) is 919 hr*.mu.g/mL (.+-.20%), and c) the total mean area under the plasma concentration-time curve for esomeprazole from when the AM dose is administered to 24 hours (.+-.20%) after the AM dose is administered (AUC.sub.0-24) is 2000 hr*.mu.g/mL (.+-.20%);
>
> and the AM and PM unit dose forms further target a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

Defendants contend that the claim language involving "target" is indefinite. Claim 1 contains two "target" clauses, the first of which begins with, "the AM and PM unit dose forms target," and the second of which begins with, "and the AM and PM unit dose forms further target." These shall both be referred to as "the target clauses."

In the Markman Opinion, this Court construed "target" to mean "set as a goal," but reserved decision on the issue of whether the target clauses operate as claim limitations. Defendants had contended that the target clauses do not limit the claims, while Plaintiffs posited the contrary. Although Defendants still contend that the target clauses are not limiting, they make this motion based on the contingency that this Court might rule in Plaintiffs' favor in

finding that the target clauses limit the claims. The parties agree that this issue is the threshold issue for the present motion: if this Court decides that the target clauses are not claim limitations, the motion is moot. Thus, this Court begins with the question of whether the target clauses are claim limitations. The parties did not rebrief this issue, and so the Court considers the arguments presented during the Markman proceeding.

During the Markman proceeding, Defendants argued that the target clauses do not limit the claims because they merely recite intended results of the claimed method, citing the Federal Circuit's decision in Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001). In BMS, the Federal Circuit held that the preamble of a method claim did not operate as a claim limitation on these grounds: "[W]e agree with the defendants that this language is only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claim." Id. Defendants also cite Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed. Cir. 2005), in which the Federal Circuit affirmed the district court's decision that a term within the body of the claim, "in a stabilizing amount," was not limiting because it only described the intended result of a method step.

Plaintiffs argue that the target clauses limit the claims for several reasons, one of which is quite strong: the applicants clearly treated them as such during prosecution. Plaintiffs point to the response to final office action, dated September 25, 2015, filed by the applicants. (Krumplitsch Dec. Ex. K.) Here, the applicants responded to the examiner's rejection of various claims, including claim 19, which matured into claim 1 of the '698 patent, for obviousness over Hassan-Alin in view of Plachetka. (Id. at PZC_00031651.) The applicants argued:

> To establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art. . . Once again, the examiner has not

addressed at least the following highlighted claim features:

(Id.) The applicants then quoted claim 19 in its entirety, highlighting all the claim text that followed the first instance of "target." (Id. at PZC_00031651-52.) The applicants then wrote: "There simply is no question, on the record, that the cited art lacks any teaching or suggestion of these features." (Id. at PZC_00031652.)

The Federal Circuit has held: "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). Although the target clauses are not preambles, this principle applies. The prosecution history shows that the applicants relied on the target clauses to distinguish the claimed invention from the prior art. To overcome an obviousness rejection, the applicants argued that the prior art did not teach or suggest the "features"[2] contained in the target clauses. This demonstrates that the applicants used the target phrases to define, in part, the claimed invention. The target phrases limit the claims.

The specification supports this conclusion. It states, in relevant part:

> Over 15 million Americans take nonsteroidal anti-inflammatory drugs (NSAIDs) each day as a treatment for pain or inflammation. Unfortunately, many of these NSAIDs are associated with a high incidence of gastrointestinal complications . . . A major factor contributing to the development of gastrointestinal lesions appears to be the presence of acid in the stomach and upper small intestines.
>
> During recent years, attempts have been made to reduce the gastrointestinal risk associated with taking NSAIDs by administering agents that inhibit stomach acid

[2] The use of the word "features," itself, indicates that the applicants understood the stated characteristics to be distinctive and important.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.