UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUMITOMO DAINIPPON PHARMA CO., LTD. et al., Plaintiffs, v. EMCURE PHARMACEUTICALS LIMITED et al., Defendants.	Civil Action No. 18-2065 (SRC) (Consolidated) **OPINION & ORDER**
SUMITOMO DAINIPPON PHARMA CO., LTD. et al., Plaintiffs, v. AUROBINDO PHARMA LTD. et al., Defendants.	Civil Action No. 18-2620 (SRC)

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Sunovion Pharmaceuticals Inc. and Sumitomo Dainippon Pharma Co., Ltd. and Defendants Emcure Pharmaceuticals Ltd., Aurobindo Pharma Ltd., Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Lupin Ltd., Sun Pharma Global FZE, Accord Healthcare Inc., Amneal Pharmaceuticals, LLC, InvaGen Pharmaceuticals, Inc., Torrent Pharmaceuticals Ltd., Watson Laboratories Inc., and Zydus Pharmaceuticals (USA) Inc. (collectively,

"Defendants"). In these consolidated patent infringement actions, the parties seek construction of claim terms in U.S. Patent No. 9,815,827 ("the '827 patent"), and a subset of the parties seek construction of claim terms in U.S. Patent No. 9,907,794 ("the '794 patent").[1]

These consolidated cases are patent infringement actions under the Hatch-Waxman Act. Plaintiffs are pharmaceutical manufacturers which own the '827 and '794 patents. The '827 patent is directed to methods of using lurasidone, the active ingredient in Plaintiffs' Latuda ® product. The'794 patent is directed to particular lurasidone formulations. Defendants are pharmaceutical manufacturers who seek to manufacture and distribute generic versions of Latuda®.

After opening and responsive briefs were filed, the Court allowed submission of a reply brief. The Court heard oral argument on September 26, 2018, and allowed the parties to submit post-hearing supplemental briefs.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v.

[1] Plaintiffs do not assert the '794 patent against Defendants Torrent, Amneal, or Lupin. Those Defendants, along with Dr. Reddy's and Sun Pharma, take no position on the construction of the '794 patent.

Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

> The focus of claim construction is the claim language itself:
>
> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

The parties dispute a set of related claim terms in the '827 patent and a single term in the '794 patent. At issue in the '827 patent is the meaning of a set of claim terms which, generally, describe the patented method as "without a clinically significant weight gain" or as "without a weight gain."

Plaintiffs, in their opening and responsive briefs, had proposed that the weight gain terms did not limit the claims; in the alternative, Plaintiffs proposed that the weight gain phrases should be understood to have the phrase "on average" inserted into them. Prior to oral argument, Plaintiffs abandoned their primary argument and conceded that the weight gain terms in the '827 patent are claim limitations. Then, in the post-hearing supplemental briefing, Plaintiffs abandoned their proposed alternative construction that sought to interpret the weight gain terms as applying to population averages. Instead, Plaintiffs now ask the Court to construe "a patient" in the '827 patent to mean "a patient population." Plaintiffs argue that, when the Court reaches the infringement analysis, the Court will need to figure out whether to use averages or frequency counts to assess weight gain on a population-wide basis, but that it need not deal with that issue during claim construction.

Although Plaintiffs no longer propose that "on average" be inserted into the claims, their new proposed construction rests on arguments and evidence that were raised in the context of the "on average" construction. Examination of the evidence and arguments concerning weight gain, averages and frequencies in the '827 patent remains relevant. The fact that Plaintiffs now propose a different construction does not erase their previous arguments. Consideration of the

arguments that supported "on average" reveals some conflicts between their prior proposed construction and their latest one.

A. Do the '827 weight gain terms refer to populations and averages?

Plaintiffs had contended that the weight gain terms[2] do not limit the claims, but have conceded that they do so. Plaintiffs had argued, in the alternative, that the weight gain terms, if found limiting, "refer to the average measure of baseline body weight gain." (Pls.' Br. 15.) As of the supplementary briefing, Plaintiffs propose that, instead, the Court should construe "a patient" to mean "a patient population."[3] Defendants contend that the terms have their ordinary meaning, and that "a patient" means "one or more patients."

For example, consider claim 1:

> 1. A method for treating schizophrenia in a patient without a clinically significant weight gain, comprising: administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl met- hyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain.

Plaintiffs had proposed this construction of the body of the claim: "administering orally to the patient [the chemical] or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that, on average, the baseline body weight of patients undergoing treatment does not

---

[2] "Weight gain language," or "weight gain terms," as used herein, refers to phrases like, "such that the patient does not experience a clinically significant weight gain."

[3] In the claims, the weight gain phrases sometimes refer to "a patient" and sometimes to "the patient." Neither the parties nor this Court have treated the difference in article used as meaningful in the context of this analysis.

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.