THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

APOPHARMA, INC. ET AL.	§	
	§	
Plaintiffs,	§	
	§	
v.	§	CASE NO. 2:16-CV-528
	§	
TARO PHARMACEUTICAL INDUSTRIES, LTD., ET AL.,	§	
	§	
	§	
Defendants.	§	
	§	

CLAIM CONSTRUCTION OPINION AND ORDER

Before the Court is the opening claim construction brief of Plaintiffs ApoPharma Inc., ApoPharma USA, Inc. and Apotex Technologies Inc. (collectively, "ApoPharma" and/or "Plaintiffs") (Dkt. No. 55, filed on March 22, 2017), the response of Defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, "Taro" and/or "Defendants") (Dkt. No. 59, filed on April 5, 2017), and the reply of Plaintiffs (Dkt. No. 60, filed on April 12, 2017). The Court held a claim construction hearing on May 5, 2017. Having considered the arguments and evidence presented by the parties at the hearing and in their claim construction briefing, the Court issues this Claim Construction Order.

Table of Contents

I. BACKGROUND

Plaintiffs brings suit alleging infringement of United States Patent No. 7,049,328 ("the '328 patent" or "patent-in-suit") by the Defendants. Defendants have filed an Abbreviated New Drug Application ("ANDA") seeking approval from the United States Food and Drug Administration to market a generic version of Plaintiffs' FERRIPROX® product prior to the expiration of the '328 patent.

The U.S. application leading to the '328 patent was filed on April 4, 2003, and is based on a PCT application filed on June 28, 2001, which claims priority to Canadian provisional patent application 2313270, filed on June 30, 2000. The '328 patent issued on May 23, 2006 and is entitled "Use for Deferiprone." In general, the '328 patent is directed to a method of treating iron induced cardiac disease by administering deferiprone to the patient (such as a patient with thalassemia). The Abstract of the '328 patent states:

> A method of treating iron induced cardiac disease in a patient with iron overload, such as in thalassemia or the like comprising administering to the patient a therapeutically effective amount of deferiprone or a physiologically acceptable salt thereof sufficient to treat iron induced cardiac disease normally associated with iron overload.

Claims 2, 4, 5, 7, 8, 11, and 19 are asserted and contain the terms to be construed. Claim 2 of the '328 patent recites:

> 2. A method of treating iron loading in the heart of a blood transfusion dependent patient experiencing an iron overload condition of the heart, said method comprising administering to the transfusion dependent patient a therapeutically effective amount of deferiprone or a physiologically acceptable salt thereof *sufficient to reduce further iron overload in the heart normally associated with iron induced cardiac disease*.

The parties' dispute centers on the meaning of the italicized terms, namely whether the italicized phrase is limiting. A similar dispute exists as to the similar claim terms in the other asserted claims.

II. LEGAL PRINCIPLES

Claim construction is guided by the Federal Circuit's decision in *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *Phillips* explained that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

Patent claims are generally given their ordinary and customary meaning, which "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." *Id.* at 1312-13. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention and that patents are addressed to, and intended to be read by, others skilled in the particular art. *Id.*

Despite the importance of claim terms, *Phillips* made clear that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* The written description set forth in the specification, for example, "may act as a sort of dictionary, which explains the invention and may define terms used in the claims."

Markman, 52 F.3d at 979. Thus, as the *Phillips* court emphasized, the specification is "the primary basis for construing the claims." *Phillips*, 415 F.3d at 1314–17. However, it is the claims, not the specification, which set forth the limits of the patentee's invention. Otherwise, "there would be no need for claims." *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc).

The prosecution history plays an important role in claim interpretation as intrinsic evidence that is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims. *Phillips*, 415 F.3d at 1314–17; *see also Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) (noting that "a patentee's statements during prosecution, whether relied on by the examiner or not, are relevant to claim interpretation"). The prosecution history helps to demonstrate how the inventor and the United States Patent and Trademark Office ("PTO") understood the patent. *Id.* at 1317. Because the prosecution history, however, "represents an ongoing negotiation between the PTO and the applicant," it may sometimes lack the clarity of the specification and thus be less useful in claim construction. *Id.*

Courts are also permitted to rely on extrinsic evidence, such as "expert and inventor testimony, dictionaries, and learned treatises," *id.* (quoting *Markman*, 52 F.3d at 980), but *Phillips* cautioned that claim construction should be consistent with the intrinsic record. *Id.* at 1319. "In cases where . . . subsidiary facts are in dispute, courts will need to make subsidiary factual findings about [the] extrinsic evidence. These are the 'evidentiary underpinnings' of claim construction [discussed] in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

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.