UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC. and BARR LABORATORIES, INC., Defendants.	)	Case No. 1:10-cv-1376-TWP-DKL

ENTRY ON CLAIM CONSTRUCTION

This patent infringement case is before the Court for construction of patent terms relevant to methods of administering the compound pemetrexed disodium ("pemetrexed"), the active pharmaceutical ingredient in the drug ALIMTA®. The Plaintiff in this matter is Eli Lilly and Company ("Lilly") and the Defendants are Teva Parenteral Medicines, Inc., App Pharmaceuticals, LLC, Pliva Hrvatska, D.O.O., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (collectively, "Defendants"). On April 24, 2012, the Court conducted a *Markman* hearing at which time the parties presented oral arguments as to the proper construction of two disputed terms of the patent at issue, U.S. Patent No. 7,772,209 (the "'209 patent"). The parties submitted thorough and well-crafted briefs and helpful presentations at the *Markman* hearing. Jurisdiction is proper under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

I. FACTUAL BACKGROUND

Lilly and Defendants are companies involved in the formulation and manufacture of pharmaceuticals. The patent at issue in this infringement suit, the '209 patent, relates to Lilly's

anti-cancer agent ALIMTA®, which is used to treat mesothelioma – the cancer caused by asbestos exposure – and other forms of lung cancer. Lilly contends that the Abbreviated New Drug Applications ("ANDAs") filed by the Defendants with the Food and Drug Administration ("FDA") for the manufacture and sale of generic versions of ALIMTA® before the '209 patent expires, infringes upon the '209 patent. As a result, Lilly filed this action against Defendants on October 29, 2010.

ALIMTA's® active ingredient, pemetrexed, is an antifolate that is known to disrupt the folic acid pathway which can contribute to the reduction of cancer cells. The '209 patent relates to a method of administering pemetrexed, along with folic acid and vitamin B12, a methylmalonic acid lowering agent, in order to reduce the toxicities associated with the administration of pemetrexed. This discovery made by Lilly results in a significant reduction of certain toxic effects caused by the administration of antifolates, such as pemetrexed, through the presence of a methylmalonic acid lowering agent without adversely affecting therapeutic efficacy. Dkt. 1-1, col. 2, ll. 32-37. As a result of ALIMTA® therapy, mesothelioma patients often live longer and the severity of the disease has been lessened so that patients are able to have a more normal life.

Originally, Defendants had five claims that they proposed were in dispute, however, the parties now agree upon the construction of three of those terms. Only two terms remain in dispute as they relate to the '209 patent: 1) the first concerns the proper construction of the term "patient" and 2) the second concerns the proper construction of the term "vitamin B12." Additional facts are added below as needed.

II. LEGAL STANDARD

Prevailing in a patent infringement suit requires "a finding that the patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim mean.'" *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) (citation omitted); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581-82 (Fed. Cir. 1996) ("A literal patent infringement analysis involves two steps: the proper construction of the asserted claim, and a determination as to whether the accused method or product infringes the asserted claim as properly construed."). The construction of patent claims, which requires determining the meaning and scope of the claims, is a matter of law for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995), *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed. 2d 577 (1996). The Federal Circuit has emphasized that "[i]t 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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citations and quotations omitted); *see also Vitronics*, 90 F.3d at 1582 ("we look to the words of the claims themselves…to define the scope of the patented invention").

The words in patent claims are "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." *Phillips*, 415 F.3d at 1313; *see Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) ("customary meaning" refers to the "customary meaning in [the] art field"). "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," in which case claim construction "involves little more than the application of the widely accepted meaning of the commonly understood words." *Phillips*, 415 F.3d at 1314; *see also Renishaw PLC v. Marposs*

Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (articulating that when there are several common meanings for a certain term, "the patent disclosure serves to point away from the improper meanings and toward the proper meaning"). However, there are two exceptions to the general rule of applying the ordinary meaning to claim terms: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

To become one's own lexicographer, a patentee must set forth a definition of the disputed claim term other than the term's ordinary and plain meaning. *Id.* Moreover, "it is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *See id.*; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) ("[T]he inventor's written description of the invention, for example is relevant and controlling insofar as it provides *clear lexicography*...") (emphasis added). Additionally, "[t]he patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expression of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002).

In the absence of an express intent to impart a new meaning to a claim term, the court, when interpreting claim terms, first reviews the intrinsic evidence, which includes the claims themselves, the specification, and the prosecution history. *See Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("The words used in the claims are interpreted in light of the intrinsic evidence of record, including the written description, the drawings, and the prosecution history, if in evidence."). With respect to the specification, it

serves an important purpose by providing for a written description of the invention that would allow a person of ordinary skill in the art to make and use the patented invention.[1] *See Phillips*, 415 F.3d at 1317. Moreover, in reviewing the specification or prosecution history, if these intrinsic sources define a claim term, that definition shall apply even if it differs from the term's ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed. Cir. 2002). However, although claims must be read in light of the specification, the court should not limit a claim by restricting its scope based on a preferred embodiment within the specification. *Phillips*, 415 F.3d at 1323.

Along with the specification, the Court may also review the prosecution history, as part of the intrinsic record, in determining whether a patentee intended to define a particular term differently from its ordinary and customary meaning. *Teleflex*, 299 F.3d at 1326. Further, the prosecution history can act to "limit[] the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." *Id.* (citing *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)).

In addition to relying on intrinsic evidence in ascertaining the scope of an invention's claim, the Court also can rely upon extrinsic evidence, which includes evidence outside of the patent and prosecution history, such as expert testimony, dictionaries, and learned treatises. *Phillips*, 415 F.3d at 1317. However, "[C]ourts may rely on dictionary definitions when construing claim terms, 'so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." (internal citation omitted); *see also Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999).

[1] Pursuant to 35 U.S.C. § 112, "the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains…to make and use the same…." 35 U.S.C. § 112 ¶ 1.

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.