United States District Court,
D. Utah, Central Division.

SEROCTIN RESEARCH & TECHNOLOGIES,
Plaintiff.
v.
UNIGEN PHARMACEUTICALS, et al,
Defendants.

No. 2:07-CV-00582-TC

Nov. 10, 2008.

Larry R. Laycock, Brett I. Johnson, Charles L. Roberts, David R. Wright, Workman Nydeggerm, Salt Lake City, UT, Richard B. Megley, Jr ., David J. Sheikh, Paul K. Vickrey, Niro Scavone Haller & Niro, Chicago, IL, for Plaintiff.

David O. Seeley, George M. Haley, Cory A. Talbot, Elizabeth B. Harris, William Jacques Athay, Holme Roberts & Owen LLP, Salt Lake City, UT, for Defendants.

ORDER and MEMORANDUM DECISION

TENA CAMPBELL**, Chief Judge.**

Plaintiff, Seroctin Research & Technologies, Inc. ("SRT"), is the owner of United States Patent Number 6,667,308 (the "'308 Patent"). The '308 Patent discloses various uses of several chemical compounds, including 6-methoxy-2, 3-benzoxazolinone ("6-MBOA"). In this action, SRT has alleged that Unigen Pharmaceuticals, Inc. ("Unigen") and a related company, Univera, Inc. ("Univera") (collectively "Defendants"), are infringing claims 16 and 42 of the '308 patent. SRT and Defendants dispute the construction of three terms used in those claims. This Order addresses the construction of the disputed claims.

ANALYSIS FN1

FN1. The court discussed the background and facts of this case in its Preliminary Injunction Order and Memorandum Decision. (Case No. 2:07-CV-582-TC, Dkt. No. 38.)

"The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.' " O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co. Ltd., 521 F.3d 1351, 1360 (Fed.Cir.2008) (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd,* 517 U.S. 370 (1996)). Claim construction is a question of law. Markman, 52 F.3d at 979. "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." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed.Cir.2005). When determining how a person of ordinary skill in the art would understand terms, the terms should be considered "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*. In addition to the claim terms and specification, courts should also refer to the prosecution history where appropriate. *See* Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1367 (Fed.Cir.2004).

With these principles in mind, the court turns to the construction of the disputed terms of the '308 Patent.

Claims 16 and 42

Claims 16 and 42 read (with the disputed terms underlined):

16. A process for treating *depression* in humans by the administration of a *therapeutically effective amount* of one or more chemical compositions defined as: [chemical formula] Wherein "R" represents C_1-C_4 alkoxy, with the provision the R is in the 4 or 5 ring position; Wherein "n" represents one of the integers 0, 1 or 2; Wherein "B" represents H and "A" represents OH, NH_2 or NHCR, where R denotes C_1-C_4 alkyl; and "B A" represents [chemical formula] or pharmaceutically acceptable salts thereof.

U.S. Patent No. 6,667,308 col. 12-13 (filed Apr. 13, 2001).

42. A process for treating *mood disorders* in humans by the administration of a *therapeutically effective amount* of one or more chemical compositions defined as: [chemical formula] Wherein "R" represents C_1-C_4 alkoxy, with stipulation that R is in the 4 or 5 ring position; Wherein "n" represents one of the integers 0, 1 or 2; or pharmaceutically acceptable salts thereof.

Id. at col. 15.

The first disputed term is "depression" found in Claim 16. SRT asserts that "depression" should be construed as "one of several mood disorders, marked by being low in spirits, dejected, or having decreased level of function." (Pl.'s Cl. Construction Br. 1.) Defendants propose that "depression" be construed as "a mental disorder that is a clinically significant behavioral or psychological illness associated with various symptoms that, as a whole, present distress or disability or with a significantly increased risk of suffering death, pain, disability, or an important loss of freedom. 'Being low in spirits, dejected, or having decreased level of function' is not 'depression.' " (Defs.' Cl. Construction Br. 1.) The difference between the parties' proposed constructions is whether the term should be limited to reach only severe types of depression, as Defendants contend, or whether SRT is correct that the Patent is intended for use with varying degrees of depression.

"We begin our claim construction analysis with the words of the claim itself." Mars, Inc. v. H.J. Heinz Co., L.P., 377 F.3d 1369, 1373 (Fed.Cir.2004) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996)). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed.Cir.2005) (citations omitted). Here, nothing in claim 16's language limits the term "depression" to clinical depression. And the specification shows that the inventor chose not to limit claim 16 to "clinical depression." *See* '308 Patent col.1 l.19-22 ("An estimated 35-40 million living American will

suffer major depressive episodes, and many more will experience lesser bouts."); Id. at col.1 l.22-23 ("Of the approximately 17.5 million Americans with ongoing depressions, about 9.2 million are at a clinically debilitating level."); Id. at col.1 l.28-31 ("Clinical depression can be very debilitating both physically and mentally and even lead to death by means of suicide. However, lost productivity and relationship problems are also consequences of lesser depressions.") Id. at col. 1 l.47-49 ("Arousal problems affect over 20 million American males, about two in 10 adult men, with such difficulties often associated with or accompanied by some sort of depression."); Id. at col.8 l.20-23 (The overall average [Hospital Anxiety and Depression Scale (HAD)] score decreased from 21.9 (clinically depressed) at trial onset to 14.4 (not clinically depressed) after six weeks of use,...."); Id. at fig. 4 (table containing 14 active test participants with only 2 having HAD scores exceeding the HAD clinical depression value of 20.0).

Defendants contend that "[d]uring prosecution of the 'depression' claims, SRT never suggested that the claims dealing with the treatment of depression also referred to treatment of stress, anxiety, mood or any other state other than depression." (Defs.' Cl. Construction Br. 3.) Because these terms are not being offered by SRT as part of its proposed construction of depression, the court does not find this argument helpful. Additionally, SRT addresses the examiner's use of the term disease in conjunction with the term "depression" in the prosecution history. SRT contends that the reference to disease was a misquote by the examiner of a proposed claim on depression. (Pl.'s Cl. Construction Br. 5.) In either case, the court is not persuaded that the prosecution history limited the term depression. As the *Phillips* court noted: ("[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes"). 415 F.3d at 1317. Because this was part of the ongoing communication between the PTO and SRT, and because the specification and claims do not limit depression to a disease, the court does not find the file history to be dispositive. For the above reasons, the court construes "depression" as "one of several mood disorders, marked by being low in spirits, dejected, or having decreased level of function."

The next disputed term is "therapeutically effective amount," which is found in both claims 16 and 42. SRT contends that "therapeutically effective amount" does not need to be construed, but if the court disagrees, the term should be construed as "an amount sufficient to produce any effect in the treatment of" either "depression" or "mood disorders." (Pl.'s Cl. Construction Br. 9 .) Defendants' propose that "therapeutically effective amount" be construed to mean "an amount that is proven sufficient to produce a decided, decisive, or desired effect in the treatment of" either "depression" or "mood disorders." (Defs.' Cl. Construction Br. 8 .)

But the court accepts the construction given this term by the Federal Circuit in an analogous case, Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1300 (Fed.Cir.2006) ("A therapeutically effective amount is a quantity that produces a result that in and of itself helps to heal or cure"). Accordingly, for claim 16, the term "therapeutically effective amount" is construed as "a quantity that produces a positive result in the treatment of depression." For claim 42 the term is construed as "a quantity that produces a positive result in the treatment of mood disorders."

The final disputed term is "mood disorders" which is found in Claim 42. SRT takes the position that this term needs no construction but, in the event the court the court disagrees, proposes that "mood disorders" should be construed as "any mental disorder that has a disturbance of mood as the predominant feature." (Pl.'s Cl. Construction Br. 5.) Neither the language of the claim nor the specification provide much guidance to the construction of the term.

Defendants maintain that this term be construed as "the classification of mental disorders having disturbance of mood as the predominant feature and which are debilitating clinical diseases. Mood disorders are clinically significant behavioral or psychological illnesses that are associated with various symptoms that, as a whole, present distress or disability or with a significantly increased risk of suffering death, pain, disability, or an important loss of freedom." (Defs.' Cl. Construction Br. 7.) But the court has already found, as discussed above, that Defendants' attempt to limit the reach of the Patent to clinical disorders is incorrect. Accordingly, the court accepts SRT's proposed construction "Any mental disorder that has a disturbance of mood as the predominant feature." (Pl.'s Cl. Construction Br. 5 .)

SO ORDERED.

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