United States District Court,
S.D. Indiana, Indianapolis Division.

Christian J. JANSEN, Jr,
Plaintiff.
v.
REXALL SUNDOWN, INC,
Defendant.

No. IP00-1495-C-T/G

Sept. 25, 2002.

John C McNett, Woodard Emhardt Naughton Moriarty & McNett, Indianapolis, IN, for plaintiff.

Lynn Bavaro Morreale, Woodcock Washburn Kurtz Mackiewicz, Philadelphia, PA, John F Prescott Jr., Ice Miller, Indianapolis, IN, for defendant.

ENTRY ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DEFENDANT'S REQUEST FOR ORAL ARGUMENT FN1

FN1. This Entry is a matter of public record and is being made available to the public on the court's web site, but it is not intended for commercial publication either electronically or in paper form. Although the ruling or rulings in this Entry will govern the case presently before this court, this court does not consider the discussion in this Entry to be sufficiently novel or instructive to justify commercial publication or the subsequent citation of it in other proceedings.

JOHN DANIEL TINDER**, Judge.**

This is a case of claimed patent infringement. Plaintiff, Christian J. Jansen, Jr. (Jansen), alleges that Defendant, Rexall Sundown, Inc. (Rexall), is inducing infringement of his patent and contributing to infringement of his patent in violation of 35 U.S.C. s. 271. Rexall contends that it is entitled to summary judgment because the use of its accused vitamin preparation does not directly infringe Dr. Jansen's patent and Rexall does not induce or contribute to any infringement of his patent. Rexall also requests oral argument on its summary judgment motion. The court rules as follows.

I. Background

The following facts are not in dispute, or if in dispute, are taken as documented by the Plaintiff. Of course, all facts are viewed in the light most favorable to the Plaintiff. Dr. Christian J. Jansen, Jr. is the named inventor of U.S. Patent No. 4,945,083 (the "'083 patent"), which was issued on July 31, 1990. The '083 patent claims priority, through a string of six intermediate applications to Jansen's original application,

Serial No. 05/057,302, which was filed almost twenty years earlier, on July 22, 1970. FN2 The ' 083 patent has two independent claims, claims 1 and 4. Claim 1 recites:

FN2. The original and intermediate applications were rejected on the basis of obviousness.

A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B_{12} deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof comprising at least about 0.5 mg. of vitamin B_{12} and at least about 0.5 mg. of folic acid.
(Def.'s Ex. A, the '083 patent 6/20-6/27) (emphasis added).FN3 Claim 4 recites:
FN3. References in the x/y format are to the column (x) and line(s)(y) of the patent.

A method for treating or preventing macrocytic-magaloblastic [sic] anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B_{12} deficiency which comprises orally administering combined vitamin B_{12} nd folic acid to a human in need thereof in sufficient amounts to achieve an oral administration of at least about 0.5 mg. of vitamin B_{12} and at least about 0.5 mg. of folic acid within one day.
(*Id*. 6/37-6/44) (emphasis added). Each of the dependent claims inherently carries these limitations as well. On February 1, 1989, Dr. Jansen filed U.S. Patent Application Serial No. 07/305,422 (the '422 application), which led to the '083 patent at issue in this case. The '422 application contained an original claim 8 which recited:

A method of treating or preventing anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B_{12} deficiency which comprises administering a daily oral dosage of a vitamin preparation containing at least about 0.5 mg. of vitamin B_{12} and at least about 0.5 mg. of folic acid.

(Def.'s Ex. I(1)). Original claim 11 recited:

A method for treating or preventing anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B_{12} deficiency which comprises orally administering combined vitamin B_{12} and folic acid in sufficient amounts to achieve an oral administration of at least about 0.5 mg. of vitamin B_{12} and at least about 0.5 mg. of folic acid within one day.

(Id.) On October 6, 1989, the examiner rejected the claims of the ' 422 application as unpatentable based on obviousness. (Def.'s Ex. I(2)). In response, Dr. Jansen through counsel participated in an interview with the examiner. (Def.'s Ex. I(3)). Thereafter, Dr. Jansen agreed to limit the claims to the type of anemia being treated or prevented. (Id.).

Dr. Jansen therefore amended claims 8 and 11. In claim 8 after the word "preventing" Dr. Jansen inserted "macrocytic-megaloblastic"; after the word "preparation" he inserted the phrase "to a human in need thereof"; and he changed the word "containing" to "comprising." (Def.'s Ex. I(3)). In claim 11 after the word "preventing" he inserted the phrase "macrocytic-megaloblastic" and in line 4 after the word "acid" inserted the phrase "to a human in need thereof". (Id.) With these amendments, claims 8 and 11 were allowed, (Def.'s Ex. I(4)), and became claims 1 and 4 of the '083 patent.

Rexall markets a dietary supplement known as Folic Acid XTRA ™ (the "Product") previously marketed under other trade names which contains, *inter alia,* 0.5 mg. of vitamin B_{12} and 0.8 mg of folic acid. The Product is marketed, at least in part, as an aid to help maintain low blood levels of homocysteine, which low levels have been associated with healthy heart and circulatory function. A deficiency of vitamin B_{12} and folic acid can lead to increased levels of homocysteine in the blood which can cause damage to artery walls and buildup of plaque in the blood vessels, leading to coronary heart disease, stroke, peripheral vascular disease and atherosclerosis. Combinations of vitamin B_{12} and folic acid have been used to treat other conditions including depression, dementia, psychosis and placental abruption. Rexall's Product is marketed and sold to the general public.

II. Discussion

Rexall contends that it is entitled to summary judgment because there are no genuine issues of material fact relating to the composition of its Product, its activities in advertising, marketing, labeling and selling the Product, or the nature of the purchaser-users of the Product. Thus, Rexall argues that resolution of its motion hinges on claim construction. Rexall maintains that under the proper claim construction, to establish direct infringement Jansen must show that the users of Rexall's Product come under the definition of "human[s] in need" of treatment for, or prevention of, macrocytic megaloblastic anemia, and that the users ingest the Product for the specific purpose of treating or preventing that disease. Dr. Jansen responds that Rexall's motion is premised upon an unsupportable interpretation of his patent claims. He also argues that there is a genuine issue of material fact regarding the marketing of Rexall's allegedly infringing product, Folic Acid XTRA ™.

A. Summary Judgment Standard

Summary judgment may be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The purpose of summary judgment "is to isolate and dispose of factually unsupported claims or defenses[.]" Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986).

The moving party bears the burden "of informing the district court of the basis for its motion, and identifying those portions of ... [the record] which it believes demonstrate the absence of a genuine issue of material fact." Celotex, 477 U.S. at 323. If the moving party meets this burden, then the non-moving party must "designate 'specific facts showing that there is a genuine issue for trial.' " Id. at 324 (quoting Fed.R.Civ.P. 56(e)). Thus, the non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio, 475 U.S. 574, 588 (1986).

"The mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). The disputes must be over "facts that might affect the outcome of the suit under the governing law." Id. at 248. The court views the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. Id. at 255. "[I]f the evidence is such that a reasonable jury could return a verdict for the nonmoving party" then summary judgment may not be granted. Id. at 248.

B. Applicable Patent Law

Analysis of a patent infringement claim involves two steps: construction of the patent claim and determination whether the claim as construed was infringed. Markman v. Westview Instrs., Inc., 517 U.S. 370, 384 (1996); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed.Cir.1996). Claim construction is a question of law. Markman, 517 U.S. at 384; *Vitronics,* 90 F.3d 1582. The determination whether a claim was infringed is generally a question of fact. Markman, 517 U.S. at 384. However, this determination may be made as a matter of law when no reasonable jury could find infringement. *See* Bai v. L & L Wings, Inc., 160 F.3d 1350, 1358 (Fed.Cir.1998).

In construing a claim, the court may consider intrinsic and extrinsic evidence. Vitronics, 90 F.3d at 1582. The court first should consider the intrinsic evidence, *i.e.,* the patent claims, the patent specification and, if in evidence, the prosecution history. Kopykake Enterp., Inc. v. Lucks Co., 264 F .3d 1377, 1381 (Fed.Cir.2001); Vitronics, 90 F.3d at 1582. The intrinsic evidence is "the most significant source of the legally operative meaning of disputed claim language." Vitronics, 90 F.3d at 1582. In most cases, analysis of the intrinsic evidence will resolve any ambiguity as to a claim term. When this occurs, the court may not rely on extrinsic evidence. Id. at 1583.

The court should start with the "words of the claims themselves," giving the words their ordinary and customary meanings, unless the patentee clearly stated a different meaning in the patent specification or prosecution history. Vitronics, 90 F .3d at 1582. The court then should consider the patent specification, which contains a written description of the invention, to determine whether the patentee used any terms in a manner inconsistent with their ordinary meanings. *Id*. Third, the court may consider the prosecution history, which contains "the complete record of all proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." *Id*. The prosecution history often is of "critical significance" in claim construction. *Id*. Amendments made during the prosecution of a patent application give meaning to terms in the claims. Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation ... disclaimed during prosecution."); E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1438 (Fed.Cir.1988), *cert. denied,* 488 U.S. 986 (1988).

Infringement of a patent can be direct or indirect. 35 U.S.C. s. 271. Dr. Jansen does not claim direct infringement against Rexall; rather, he claims indirect infringement. Indirect infringement is necessarily predicated on direct infringement. *See* Kendall Co. v. Progressive Med. Tech., Inc., 85 F.3d 1570, 1573 (Fed.Cir.1996); C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 673 (Fed.Cir.1990). Thus, to prove his claim of indirect infringement against Rexall, Dr. Jensen must first show direct infringement of the '083 patent by the users of the Rexall's Product. *See* id.

C. Application of Law to Facts

The parties' dispute over claim construction is based on the significance and meaning of the phrases "a method of treating or preventing macrocytic megaloblastic anemia in humans" and "human in need thereof". Rexall contends that the claims should be construed to mean that the vitamin preparation of folic acid and B_{12} is taken or used with the purpose of treating or preventing macrocytic megaloblastic anemia in a human who either has the disease or has a recognized risk of developing the disease. Without this construction, Rexall urges, the patent claims would have the same scope as those which were rejected. Dr. Jansen submits

that his claims should be interpreted to include the use of vitamin supplement products, like Rexall's, which may be administered as a treatment or preventative.

In construing the claims of the '083 patent, the court must give meaning to the words and phrases in the claims. Claim 1 recites a "method of treating or preventing macrocytic-megaloblastic anemia in humans ... which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof...." Claim 4 recites a "method for treating or preventing macrocytic-magaloblastic [sic] anemia in humans ... which comprises orally administering combined vitamin B_{12} and folic acid to a human in need thereof...." Thus, the court must give meaning to the phrases "method of treating or preventing," "macrocytic-megaloblastic anemia" and "human in need thereof". The meaning of "macrocytic-megaloblastic anemia" may be the easiest to construe as the phrase refers to a specific anemia which results from deficiencies of either vitamin B_{12} or folic acid. (Jansen Decl. para. 8.)

As for "human in need thereof," Dr. Jansen submits that all humans need vitamins for their health and substantially all humans are at risk of developing macrocytic-megaloblastic anemia. (Jansen Decl. para. 8; *see also* id. para. 20 (referring to "the human need to treat or prevent macrocytic-megaloblastic anemia")). Thus, he implies that "a human in need thereof" should be construed as meaning "substantially all humans," which seemingly would include the users of Rexall's Product.

The prosecution history of the '422 application shows that Dr. Jansen's construction cannot be correct. The original claims in the application did not contain the language "a human in need thereof", and the examiner rejected those claims. In response, Dr. Jansen added this language to the claims. Only after this (and other) language was added were the claims were allowed. In Smith v. Magic City Kennel Club, Inc., 282 U.S. 784 (1931), the Court said:

limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, must be strictly construed against the inventor and looked upon as disclaimers. The patentee is thereafter estopped to claim the benefit of his rejected claim or such a construction of his amended claim as would be equivalent thereto.

Id. at 293 (quotations and citations omitted); *see also* Lewis v. Avco Mfg. Corp., 228 F.2d 919, 924 (7th Cir.1956). And, as stated, amendments made during the prosecution of a patent application give meaning to the terms in the claims. *See, e.g.,* Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995). Thus, the language "human in need thereof" must be construed against Dr. Jansen and understood as giving meaning to the claims.

Moreover, because the original claims in the '422 application already provided that the method was for treating or preventing anemia in "humans," the language "human in need thereof" must mean something more than simply "human." In addition, the words "in need thereof" which follow and modify "human," cannot be equated with the term they modify. To do so would leave "in need thereof" mere surplusage. *Cf*. Elekta Instr. S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1307 (Fed.Cir.2000) (avoiding claim construction which would render a term superfluous); Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1444 (Fed.Cir.1997) (same). The court, however, need not resolve more precisely the meaning of the phrase "human in need thereof".

This is because of the language "[a] method of treating or preventing macrocytic-megaloblastic anemia in humans" in each of the claims at issue. This languages states the intended purpose of the claims: treating or

preventing macrocytic-megaloblastic anemia in humans. The stated purpose of a claim limits the claim. *See* Manning v. Paradis, 296 F.3d 1098, 1102-03 (Fed.Cir.2002) (concluding that the stated purpose in the preamble of count limited and gave meaning to the claim); Rapoport v. Dement, 254 F.3d 1053, 1059 (Fed.Cir.2001) (noting that the phrase "treatment of sleep apnea" in preamble of count should be treated as a claim limitation).

Rapoport, though not directly on point, offers this court guidance. The claim at issue there stated in relevant part "[a] method for treatment of sleep apneas comprising of a therapeutically effective regimen ... [of buspirone] to a patient in need of such treatment...." 254 F.3d at 1056. Rapoport argued that prior art anticipated the claim. The Board of Patent Appeals and Interferences found that although the prior art addressed treatment of a symptom of sleep apnea, the prior art did not address treatment of sleep apnea. Id. at 1060. The court affirmed, reasoning in part that "[t]here is no disclosure in [the prior art] of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition." Id. at 1061. The court noted that the prior art mentioned the possibility of administering buspirone to patients with sleep apnea, but explained that it was "for the purpose of treating anxiety in such patients, not *for the purpose of* treating the sleep apnea disorder itself[.]" *Id*. (emphasis added). Thus, the court rejected Rapoport's argument that the reason for administering buspirone to the patient was irrelevant. *Id*.

The court concludes that inclusion of the language "[a] method of treating or preventing macrocytic-megaloblastic anemia in humans" limits the claims and gives them meaning. Thus, the court finds that the claims as properly construed require, *inter alia,* that the vitamin preparation (claim 1) or combination of vitamin B_{12} and folic acid (claim 4) be taken or used for the purpose of treating or preventing macrocytic-megaloblastic anemia in a human.

Rexall submits that Dr. Jansen cannot produce any evidence to create a triable issue as to whether the users of its Product are "humans in need" of treatment or prevention of macrocytic megaloblastic anemia or that they use the Product specifically to treat or prevent macrocytic megaloblastic anemia. Rexall therefore contends that Dr. Jansen cannot prove direct infringement.

It is undisputed that Rexall sells its Product to the general public. It is quite possible, that some users of Rexall's Product would be considered "human [s] in need thereof" *and* use the Product to treat or prevent macrocytic megaloblastic anemia, and, thus, directly infringe the '083 patent. However, at best, Dr. Jansen has presented evidence that users of Rexall's Product could be considered "human[s] in need thereof" (see Jansen Aff. para. (stating that substantially all humans are at risk of developing macrocytic megaloblastic anemia)). He has offered absolutely no evidence that any user of Rexall's Product takes the Product for the purpose of treating or preventing macrocytic megaloblastic anemia. That the Product if used as directed would necessarily treat or prevent macrocytic megaloblastic anemia is beside the point. There is no direct infringement of the '083 patent unless the users take the Product for the purpose of treating or preventing macrocytic megaloblastic anemia. *See* Rapoport, 254 F.3d at 1061.

The court finds that Dr. Jansen has not come forward with sufficient evidence to create a triable issue of fact regarding direct infringement of the '083 patent. Without sufficient evidence of direct infringement, no reasonable jury could find that Rexall's Product indirectly infringes the '083 patent. Accordingly, Rexall is entitled to summary judgment in its favor on all claims asserted in Dr. Jansen's Complaint.

III. Request for Oral Argument

Oral argument is unnecessary as the court is able to decide Rexall's motion for summary judgment without it. Therefore, Rexall's request for oral argument is DENIED.

IV. Conclusion

The court finds that Dr. Jensen has presented insufficient evidence to raise a reasonable inference of direct infringement of the '083 patent by any user of Rexall's Product and, consequently, has produced insufficient evidence to raise a reasonable inference of indirect infringement of the '083 patent by Rexall. As a result, Rexall's motion for summary judgment will be GRANTED. Oral argument is unnecessary; therefore, Rexall's request for oral argument is DENIED. Judgment shall be entered accordingly.

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