United States District Court,
S.D. New York.

GLAXO WELLCOME, INC,
Plaintiff.
v.
EON LABS MANUFACTURING,
INC. Defendant.

No. 00 Civ. 9089(LMM)

Aug. 22, 2003.

Patentee sued generic drug manufacturer for alleged infringement of patents covering sustained release formulations of active ingredient in anti-depression medication. Manufacturer moved for summary judgment challenging validity of one patent. The District Court, McKenna, J., held that factual issue precluded summary judgment for manufacturer on grounds of invalidity.

Motion denied.

33,994. Cited.

MEMORANDUM AND ORDER

MCKENNA**, J.**

Plaintiff Glaxo Wellcome ("Glaxo") holds United States Patent Reissue No. 33,994 (" '994 patent") and United States Patent No. 5,427,798 (" '798 patent"), which cover sustained release formulations of bupropion hydrochloride ("BH"), the active ingredient in the anti-depression drug Wellbutrin. Defendant Eon Labs Manufacturing ("Eon") makes generic drugs, and filed an Abbreviated New Drug Application ("ANDA") in July 2000, seeking FDA approval to market a generic version of Wellbutrin. Glaxo brought an action for patent infringement against Eon based on the ANDA filing, which itself is a statutory act of patent infringement. 35 U.S.C. s. 271(e)(2)(A). Currently before this Court is Eon's motion for summary judgment challenging the validity of the '798 patent under 35 U.S.C. s. 112 ("Section 112") para. 1. FN1 For the reasons discussed below, the Court denies the motion.

FN1. Eon's motions for partial summary judgment on the validity of claim 1 of the '798 patent and Glaxo's motion for partial summary judgment regarding the delisting of the '994 patent from the FDA's Orange Book are also before the Court, and are addressed in separate orders.

BACKGROUND

The invention claimed in the '798 patent is a "sustained release tablet" containing the active ingredient BH together with hydroxypropyl methylcellulose ("HPMC"). (Def. Mem. at 1.) HPMC is the ingredient which causes the tablet to release the active ingredient into the patient's bloodstream in a sustained release, and exists in a variety of grades. (Id.)

The '798 patent contains three examples, which describe how to make 150 mg., 100 mg. and 50 mg. sustained release tablets embodying the claimed invention. ('798 patent, col. 6, line 55-col. 11, line 38.) In each example, the list of the tablet's ingredients includes BH and, as the sustained release ingredient, "Hydroxypropyl Methylcellulose 2910, USP." (Id.) There is no description in the patent of a tablet which uses any other grade of HPMC to achieve sustained release of BH. However, the '798 patent concludes with 19 claims, each of which defines a sustained release tablet comprising or containing both BH and HPMC generally. ('798 patent, col. 11, line 40-col.12, line 67.) None of the claims are limited to tablets containing HPMC 2910.

It is for this reason that Eon currently moves for summary judgment, arguing that the claims of the '798 patent are invalid under Section 112 para. 1 because the written description of the invention in the patent's specification is not as broad as the language of the claims. (Def. Mem. at 1.)

STANDARD OF REVIEW

In ruling on a motion for summary judgment, the court views the evidence in the light most favorable to the nonmoving party and resolves all evidentiary doubts in the nonmovant's favor. C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 672 (Fed.Cir.1990).

Summary judgment should be granted only "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); Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). A dispute regarding a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). "If reasonable minds could differ as to the import of the evidence," summary judgment is inappropriate. Id. at 250. For a dispute to be genuine requires more than "metaphysical doubt." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (citations omitted). The burden on the moving party may be discharged by "showing that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once issued, patent claims are presumed to be valid. 35 U.S.C. s. 282. The presumption of validity includes a presumption that the patent complies with s. 112. *N*. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed.Cir.1990). Therefore, the party challenging validity must prove invalidity by clear and convincing evidence. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1359 (Fed.Cir.1998); Atlas Powder Co. v. E.I. Du Pont de Nemours, 750 F.2d 1569, 1573 (Fed.Cir.1984).

DISCUSSION

A. *Written Description Requirement of* Section 112

Section 112 provides:

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, or with which it is most clearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention

35 U.S.C. s. 112 para. 1.

"[A]n applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." ' Regents of the Univ. of California v. Eli Lilly, 119 F.3d 1559, 1566 (Fed.Cir.1997) (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed.Cir.1997)). "The adequate written description requirement, which is distinct from the enablement and best mode requirements, serves 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." ' In re Alton, 76 F.3d 1168, 1172 (Fed.Cir.1996).

Each case involving the written description requirement of Section 112 must be decided on its own facts. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed.Cir.1991). "Thus, the precedential value of cases in this area is extremely limited." *Id*.

B. ***Analysis***

In the present case, the Court finds that there is an issue of genuine fact as to whether the '798 patent's specification adequately describes the claims for HPMC. It is true that the examples provided in the '798 patent specification only implement HPMC 2910, and do not make mention of the three other grades of HPMC, even though the patent claims HPMC in general. However, "[e]very species in a genus need not be described in order that a genus meet the written description requirement." Eli Lilly, 119 F.3d at 1568. "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass." *Id*. (noting that in chemical cases, the written description of a patent need not be as specific as in cases involving genetic materials). "Mention of representative compounds encompassed by generic claim language clearly is not required by s. 112 or any other provision of the statute." In re Robins, 57 C.C.P.A. 1321, 429 F.2d 452, 456 (Fed.Cir.1970). In fact, the Federal Circuit has held that claimed subject matter need not be described *in haec verba* in the specification for that specification to satisfy the description requirement. In re Smith, 481 F.2d 910, 914 (Fed.Cir.1973).

In opposition to the instant motion, Glaxo has submitted an affidavit from Dr. Uhrich, in which she states that "All grades and USP types of HPMC are capable of forming a hydrogel and retarding the release of active ingredients from a matrix tablet ... One of skill in the art would understand from the specification and original claims of the '798 patent that ... the invention included HPMC as a class of polymeric materials and was not limited to any specific grade or type of HPMC." (Hirschhorn Aff. Ex. 6, para. 13.) Therefore, a finder of fact could conclude that the specification clearly conveyed to those skilled in the art that the applicant invented the specific subject matter claimed. Smith, 481 F.2d at 914.

CONCLUSION

For the reasons discussed above, the Court denies the motion for summary judgment. FN2

FN2. This Memorandum and Order is filed under seal because several of the parties' submissions are filed under seal. The parties are directed to notify the Court within two weeks of the date of this Memorandum and Order whether it is necessary for it to remain sealed.

S.D.N.Y.,2003.
Glaxo Wellcome, Inc. v. Eon Labs Mfg., Inc.