

**GLAXO WELLCOME, INC., Plaintiff, -against- EON LABS MANUFACTURING,  
INC., Defendant.**

**FILE UNDER SEAL 00 Civ. 9089 (LMM)**

**UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF  
NEW YORK**

**2003 U.S. Dist. LEXIS 14680**

**August 7, 2003, Decided  
August 22, 2003, Filed**

**PRIOR HISTORY:** Glaxo Wellcome, Inc. v. Eon Labs Mfg., 2003 U.S. Dist. LEXIS 2074 (S.D.N.Y., Feb. 11, 2003)

**DISPOSITION:** [\*1] Defendant's motion for partial summary judgment granted.

**CASE SUMMARY:**

**PROCEDURAL POSTURE:** Plaintiff, the patent holder of two patents which cover sustained release formulations of bupropion hydrochloride (BH), filed suit against defendant, a manufacturer of generic drugs, for patent infringement. The manufacturer filed a motion for partial summary judgment challenging the validity of one patent claim under 35 U.S.C.S. § 112, para. 1 and 2 for lack of definiteness, enablement, and an adequate written description.

**OVERVIEW:** The invention defined in claim 1 of one of the patents was a controlled sustained release tablet containing the active ingredient BH and hydroxypropyl methylcellulose, which caused sustained release of the BH, said tablet having a shelf life of at least one year. However, nowhere in the patent was it explained how the desired shelf life was achieved. Because it was unclear how the shelf life was achieved, the manufacturer argued that claim 1 was invalid for lack of enablement under 35 U.S.C.S. § 112, para. 1 as a matter of law. In response, the patent holder argued that the use of functional language in a claim, without detailing how the claimed result was achieved, did not necessarily render a claim invalid for lack of enablement. The court found that

claim 1 was invalid for lack of enablement. The court reasoned that claim 1 was a broad claim describing a shelf life result but not what produced the result. Cysteine hydrochloride was frequently referred to in the patent, but the patent did not say what it was for. Moreover, the court reasoned that it would require undue experimentation to determine which ingredient was actually responsible for the desired shelf life.

**OUTCOME:** The manufacturer's motion for partial summary judgment was granted on the ground that claim 1 was invalid for lack of enablement.

**LexisNexis (TM) HEADNOTES - Core Concepts:**

*Civil Procedure > Summary Judgment > Summary Judgment Standard Patent Law > Infringement > Summary Judgment*

[HN1] 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.

*Civil Procedure > Summary Judgment > Burdens of Production & Proof Civil Procedure > Summary Judgment > Summary Judgment Standard Patent Law > Infringement > Summary Judgment*

[HN2] 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). 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. If reasonable minds could differ as to the import of the evidence, summary judgment is inappropriate. For a dispute to be genuine requires more than "metaphysical doubt." If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. 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.

***Patent Law > Infringement > Defenses > Invalidity***

[HN3] 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 35 U.S.C.S. § 112. Therefore, the party challenging validity must prove invalidity by clear and convincing evidence.

***Patent Law > Specification & Claims > Description Requirement***

[HN4] See 35 U.S.C.S. § 112, para. 1.

***Patent Law > Specification & Claims > Enablement Requirement***

[HN5] The enablement requirement of 35 U.S.C.S. § 112 demands that the patent specification enable those skilled in the art to make and use the invention as broadly as it is claimed without undue experimentation. The fact that some experimentation is necessary does not preclude enablement, but if unduly extensive experimentation is necessary, the claim will fail.

***Patent Law > Specification & Claims > Enablement Requirement***

[HN6] In the context of 35 U.S.C.S. § 112, it is true that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.

***Patent Law > Specification & Claims > Enablement Requirement***  
***Patent Law > Specification & Claims > Description Requirement***

[HN7] In the context of 35 U.S.C.S. § 112, describing an invention in terms of what it accomplishes does not necessarily render a patent claim improper. However, a claim employing functional language covers any and all

embodiments which perform the recited function. Legitimate concern often properly exists, therefore, as to whether the scope of protection defined thereby is warranted by the scope of enablement indicated and provided by the description contained in the specification.

***Patent Law > Specification & Claims > Enablement Requirement***  
***Patent Law > Specification & Claims > Description Requirement***

[HN8] In the context of 35 U.S.C.S. § 112, broad patent claims with only one enablement described is precluded.

**COUNSEL:** For Glaxo Wellcome Inc, PLAINTIFF: Janet B Linn, Kenneth C Crowell, Morgan, Lewis & Bockius, LLP, Philip L Hirschhorn, Stephen B Judlowe, Morgan, Lewis & Bockus, LLP, New York, NY USA.

For Eon Labs Manufacturing, Inc, DEFENDANT: Thomas C Pontani, Cohen, Pontani, Lieberman & Pavane, New York, NY USA.

For Eon Labs Manufacturing, Inc, COUNTER-CLAIMANT: Thomas C Pontani, Cohen, Pontani, Lieberman & Pavane, New York, NY USA.

**JUDGES:** Lawrence M. McKenna, U.S.D.J.

**OPINIONBY:** Lawrence M. McKenna

**OPINION:**

**MEMORANDUM AND ORDER**

McKENNA, D.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 [\*2] a statutory act of patent infringement. 35 U.S.C. § 271(e)(2)(A). Currently before this Court is Eon's motion for partial summary judgment challenging the validity of claim 1 of the '798 patent under 35 U.S.C. § 112 ("Section 112") PP 1 and 2 for lack of definiteness, enablement, and an adequate written description. n1 For the reasons discussed below, the Court finds claim 1 to be invalid for lack of

enablement, and therefore grants the motion on that ground. n2

n1 Eon's motion for summary judgment challenging the validity of the '798 patent on other grounds than those raised in this motion, and Glaxo's motion for partial summary judgment dismissing Eon's Fifth Affirmative Defense and Fifth Counterclaim are also before the Court and are addressed in separate orders.

n2 In a footnote in its memorandum in opposition to the motion, Glaxo argues that the motion should be dismissed on procedural grounds as being untimely. (Pl. Mem. at 6 n.11.) The Court rejects this argument and proceeds to address the motion on its merits.

[\*3]

#### BACKGROUND

The invention defined in claim 1 of the '798 patent is a controlled sustained release tablet containing the active ingredient BH and hydroxypropyl methylcellulose ("HPMC"), which causes sustained release of the BH, "said tablet having a shelf life of at least one year at 59 [degrees] to 77 [degrees] F. and 35 to 60% relative humidity." ('798 patent, col. 11, lines 40-50.) However, nowhere in the patent is it explained how the desired shelf life is achieved. Eon claims that a stabilizing ingredient, such as cysteine hydrochloride or glycine hydrochloride, is needed to produce the claimed shelf life, and in fact, cysteine hydrochloride is used in the three examples provided by the patent detailing how the tablet is produced. (Def. Mem. at 1; '798 patent, cols. 6-11.) However, neither cysteine hydrochloride nor glycine hydrochloride is included in the actual claim language and nowhere in the patent does it state that cysteine hydrochloride functions as a stabilizing ingredient. ('798 patent, col. 11, lines 40-50; Pl. 56.1 Stmt. at P 45.) Glaxo argues that a stabilizer ingredient is not mentioned in the claim language because it is not necessary to enable the claim. [\*4] (Pl. Mem. at 20.) According to Glaxo, HPMC, which is included in claim 1's language, can produce the desired shelf life on its own. (Id.)

Because it is unclear from the patent how a shelf life of one year is achieved, Eon argues that claim 1 is invalid for lack of enablement under Section 112 P 1 as a matter of law. (Def. Mem. at 8.) In response, Glaxo argues that the use of functional language in a claim, without detailing how the claimed result is achieved, does not necessarily render a claim invalid for lack of enablement. (Pl. Mem. at 19.) In addition, Glaxo argues that in its previous response to certain interrogatories, n3

Eon admitted that "HPMC ... used in sustained release matrix tablets should necessarily be stable (have a shelf life) of 28 months at room temperature." (Hirschhorn Decl., Ex. D. at 6; Pl. Mem. at 20-21.) Furthermore, Glaxo argues that even if a stabilizer is needed to produce the desired shelf life, Eon has previously admitted in these interrogatory responses that "the use of a stabilizer, including the selection of material and amount, is within the purview of one skilled in the art." (Hirschhorn Decl., Ex. D. at 7; Pl. Mem. at 21.)

n3 Specifically, these responses were "Defendant's Supplemental Responses to Plaintiff's First Set of Interrogatories Nos. 1-7." (Hirschhorn Decl. Ex. D.)

[\*5]

#### STANDARD OF REVIEW

[HN1] 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).

[HN2] 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, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (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, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (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. [\*6] " *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (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.

[HN3] Once issued, patent claims are presumed to be valid. 35 U.S.C. § 282. The presumption of validity includes a presumption that the patent complies with § 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

Section 112, paragraph 1, provides in relevant part:

[HN4] The specification shall contain a written description of the invention, [\*7] 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 nearly 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. § 112 P 1.

[HN5] The enablement requirement demands that the patent specification enable "those skilled in the art to make and use the invention as broadly as it is claimed without undue experimentation." In *re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999). The fact that some experimentation is necessary does not preclude enablement, but if unduly extensive experimentation is necessary, the claim will fail. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983). As the Federal Circuit has stated:

[HN6] It is true ... that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does [\*8] not cause a specification to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.

*Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (internal citations omitted).

[HN7] Describing an invention in terms of what it accomplishes does not necessarily render a claim

improper. In *re Swinehart*, 58 C.C.P.A. 1027, 439 F.2d 210, 213 (C.C.P.A. 1971). However, a claim employing functional language "covers any and all embodiments which perform the recited function. Legitimate concern often properly exists, therefore, as to whether the scope of protection defined thereby is warranted by the scope of enablement indicated and provided by the description contained in the specification." *Id.*

In the present case, claim 1 is a broad claim describing a shelf life result but not what produces the result. Cysteine hydrochloride [\*9] is frequently referred to in the patent, but the patent does not say what it is for. (Pl. 56.1 Stmt. P 45.) Maybe a person skilled in the art could put two and two together and determine that cysteine hydrochloride produces the desired shelf life. Nevertheless, in its motion papers, Glaxo itself says that the result could also be achieved by HPMC alone. (Pl. Mem. at 20.) The Court finds that it would require undue experimentation to determine which of these ingredients is actually responsible for the desired shelf life.

In addition, the Court notes that while Glaxo asserts in its motion papers that HPMC can produce a shelf life of one year, it fails to make this statement in the patent, or provide any examples in the patent specification which make use of HPMC alone, without cysteine hydrochloride, to produce tablets with the claimed shelf life. This does not comport with the Court's 2002 decision in this case, [HN8] precluding broad claims with only one enablement described. *Glaxo Wellcome, Inc. v. Eon Labs Mfg., Inc.*, 2002 U.S. Dist. LEXIS 14950, No. 00 Civ. 9089, 2002 WL 1874830, at \*3 (S.D.N.Y. Aug. 13, 2002).

Therefore, the Court finds that claim 1 of the '798 patent is invalid for lack of enablement, [\*10] and grants Eon's motion for partial summary judgment on this ground. Because the Court finds claim 1 invalid for lack of enablement, it need not address Eon's other arguments that the claim is invalid for lack of definiteness or for lack of an adequate written description. n4

n4 The Court also notes that Eon's argument that the claim lacks definiteness and fails to meet the written description requirement is essentially the same: that the patent does not specify how a shelf life of one year will be achieved. The Court believes that this argument more appropriately goes to the issue of enablement rather than definiteness or written description.

#### CONCLUSION

For the reasons discussed above, the Court grants the motion for partial summary judgment. n5

[\*11]

N5 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.

Dated: August 7, 2003

SO ORDERED.

Lawrence M. McKenna

U.S.D.J.