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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

ABBOTT LABORATORIES and)
CENTRAL GLASS COMPANY LTD.,)
)
Plaintiffs,)
)
v.)
)
BAXTER HEALTHCARE CORP.,)
)
Defendant.)

04 C 836

Judge Ronald A. Guzmán

MEMORANDUM OPINION AND ORDER

Abbott Laboratories and Central Glass Company Ltd. (collectively hereinafter “Abbott”) have sued Baxter Healthcare Corp. (“Baxter”) for alleged infringement of U.S. Patent No. 6,677,492 (“the ‘492 Patent”). In turn, Baxter has moved for summary judgment on non-infringement. For the following reasons, the Court grants Baxter’s motion.

Facts

This action stems from an Abbreviated New Drug Application (“ANDA”) filed by Baxter in 2000 that sought approval to sell the drug sevoflurane in aluminum containers lined with an epoxyphenolic layer. Sevoflurane is a general anesthetic that is administered to patients by inhalation. For many years, Abbott enjoyed a considerable sevoflurane market share. However, after its initial presentation in the market, Abbott discovered that pure sevoflurane has the potential to degrade in the presence of Lewis acids. Among the byproducts of this degradation reaction is hydrofluoric acid – a solution that is extremely hazardous to the human body. After researching possible solutions to this problem, Abbott discovered that the reaction could be prevented by coating the interior of its glass sevoflurane container with a Lewis acid inhibitor

such as water. Abbott applied for a patent for this method and ultimately obtained one on January 13, 2004 in the form of the '492 Patent entitled "Fluoroether Compositions and Methods for Inhibiting Their Degradation in the Presence of a Lewis Acid." (App. Def.'s Mot. Summ. J., Ex. D, '492 Patent at A293.) Claim 1 of the '492 Patent reads:

A method for storing a quantity of sevoflurane, the method comprising the steps of:

 providing a container defining an interior space, said container having an interior wall adjacent said interior space[] defined by said container;
 providing a quantity of sevoflurane;
 coating said interior wall of said container with a Lewis acid inhibitor;
 placing said quantity of sevoflurane in said interior space defined by said container.

(*Id.* at A304 (emphasis added).)

Discussion

"An infringement analysis involves two steps. First, the court determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device." *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (citations omitted). Therefore, the Court must first construe Claim 1 of the '492 Patent at issue, the independent claim upon which each of the remaining '492 Patent claims depends. (*See* App. Def.'s Mot. Summ. J., Ex. D, '492 Patent at A304.)

The parties disagree about the proper construction of the Claim 1 limitation, "coating said interior wall of said container with a Lewis acid inhibitor." (*See* Pls.' Resp. Def.'s Mot. Summ. J. 9; Reply Mem. Supp. Def.'s Mot. Summ. J. 5-7.) Specifically, the parties are at odds over the correct interpretation of one term: the verb "coating." (*See* Pls.' Resp. Def.'s Mot. Summ. J. 9; Def.'s Reply Mem. Supp. Mot. Summ. J. 5-7.)

Claim construction is a question of law to be decided by a judge. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). When interpreting a patent claim term, “[courts] indulge a heavy presumption that a claim term carries its ordinary and customary meaning.” *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (quotation omitted). However, courts must look to the specification, as “[t]he patentee may have acted as his own lexicographer and imbued the claim terms with a particular meaning or ‘disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction.’” *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003) (quoting *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204 (Fed. Cir. 2002)). “[I]n determining whether a statement by a patentee was intended to be lexicographic, it is important to determine whether the statement was designed to define the claim term or to describe a preferred embodiment.” *Id.*

Thus, when construing the term “coating,” the Court must first establish the ordinary and customary meaning of the term and then determine whether Abbott attempted to define “coating” in the specification, or if it simply intended to bring forth a preferred embodiment. When construing a claim, “dictionary definitions may establish a claim term’s ordinary meaning.” *CCS Fitness*, 288 F.3d at 1366. Merriam-Webster’s Dictionary defines the verb “coat” as meaning “to cover or spread with a finishing, protecting, or enclosing layer.” Merriam-Webster’s Collegiate Dictionary 235 (11th ed. 2004). Baxter provides no evidence of an ordinary and customary meaning contrary to the dictionary definition, whereas Abbott contends that the Court should construe “coating” to mean “covering the surface of the object.” (Pl.’s Resp. Def.’s Mot. Summ. J. 12.) The Court construes the term “coating” according to its ordinary and customary meaning: “covering or spreading with a finishing, protecting, or enclosing layer.”

Baxter objects to such a construction and argues that a reading of the '492 Patent's specification requires the Court to construe "coating" to mean "rinsing or washing." (Def.'s Reply Mem. Supp. Mot. Summ. J. 5.) Baxter points to the '492 Patent's "Detailed Description of the Invention," which states, "a container, such as a glass bottle, is first washed or rinsed with the Lewis acid inhibitor and then filled with the fluoroether compound," and "small quantities of the composition containing appropriate amounts of the Lewis acid inhibitor can be used to wash or rinse containers to neutralize any Lewis acids that might be present in the container." (App. Def.'s Mot. Summ. J., Ex. D, '492 Patent, col. 5, lines 34-37, col. 5, line 66-col. 6, line 2; see Def.'s Reply Mem. Supp. Mot. Summ. J. 5.) However, to overcome the presumption that the ordinary meaning of "coating" applies, the '492 Patent's specification must establish that the patentee sought to define "coating" as "washing or rinsing" explicitly and did not merely set out to define a preferred embodiment. See *E-Pass*, 343 F.3d at 1369.

A reading of the specification establishes clearly that the patentee did not intend to act as its own lexicographer by using the "washing or rinsing" language. First, in the sentence directly preceding the first instance of such language in the "Detailed Description," the patentee specifically states that "[t]he composition of the present invention can be prepared in several ways," implying that "washing or rinsing" is only one of several possible embodiments of the patented method. (App. Def.'s Mot. Summ. J., Ex. D, '492 Patent, col. 5, lines 34-35.) Second, three paragraphs later in the "Detailed Description," the patentee teaches that "small quantities of the composition . . . can be used to wash or rinse containers . . ." (*Id.* at col. 5, line 66-col. 6, line 1) (emphasis added). Given this language, the Court finds that the patentee did not give a lexicographic effect to the "washing and rinsing" language but, rather, sought to describe several preferred embodiments of the patented method.

Baxter contends that this plain-meaning interpretation would render the '492 Patent invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, paragraph 1, which states:

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 nearly connected, to make and use the same.

35 U.S.C. § 112, ¶ 1 (2009).

Baxter merely argues that because nothing in the original 1997 parent application or the issued '492 Patent indicates that the inventors had possession of any kind of solid, non-soluble Lewis acid inhibitor, a plain-meaning construction of Claim 1 would render the '492 Patent invalid for failure to satisfy the written description requirement. (Def.'s Reply Mem. Supp. Mot. Summ. J. 13.)

The Court disagrees. It is undisputed that the patentee intended a lexicographic effect when it stated in the '492 Patent's specification, "[a]s used herein, 'Lewis acid inhibitor' refers to any compound that interacts with the empty orbital of a Lewis acid thereby blocking the potential reaction sites of the acid." (*Id.* at col. 4, lines 51-54) Therefore, the Court construes Claim 1's "coating said interior wall of said container with a Lewis acid inhibitor" limitation to mean "to cover or spread the interior of the container with a finishing, protecting, or enclosing layer composed of any compound that interacts with the empty orbital of a Lewis acid."

Accordingly, a plain-meaning construction of coating does not necessarily require Claim 1 to encompass solid Lewis acid inhibitors. Rather, Claim 1's breadth, after this Court's construction, encompasses those Lewis acid inhibitors that interact with the empty electron orbital of a Lewis acid, regardless of the inhibitor's state of matter. Because Baxter has failed to establish by clear and convincing evidence that the '492 Patent does not satisfy the written

description of section 112, the Court rejects Baxter's arguments that the '492 Patent is invalid.

Next, the Court must compare the allegedly infringing container in Baxter's ANDA to Claim 1 of the '492 Patent as construed above to determine whether summary judgment on the issue of noninfringement is warranted. *See Cybor Corp.*, 138 F.3d at 1454; *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990) (stating that the presumption of validity of issued patents pursuant to 35 U.S.C. §282 stands unless the movant presents clear and convincing evidence to the contrary). Summary judgment is appropriate if "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "[A] party seeking summary judgment always bears the initial responsibility 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 Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party carries this burden, "[Rule 56] requires the nonmoving party to go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Id.* at 324 (quotations omitted). The nonmovant "must do more than simply show that there is some metaphysical doubt as to the material facts."

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986).

Baxter has moved for summary judgment on the issue of noninfringement under both literal infringement and doctrine of equivalents theories. (*See* Def.'s Reply Mem. Supp. Mot. Summ. J. 9-10.) Unlike claim construction, "[a] determination of non-infringement, either literal or under the doctrine of equivalents, is a question of fact." *Miken Composites, L.L.C. v. Wilson Sporting Goods Co.*, 515 F.3d 1331, 1336 (Fed. Cir. 2008). "Those determinations are questions

of fact, and on summary judgment, the issue is whether there is no genuine issue of material fact regarding infringement.” *In re Gabapentin Patent Litig.*, 503 F.3d 1254, 1259 (Fed. Cir. 2007).

“Literal infringement requires that each and every claim limitation be present in the accused product.” *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1378 (Fed. Cir. 2006). For the following reasons, having compared Baxter’s allegedly infringing method of coating its container to that claimed in the '492 Patent, the Court finds that no genuine issue of material fact exists regarding literal infringement.

Baxter’s aluminum container contains an internal epoxyphenolic liner. (See Pls.’ LR 56.1(b)(3)(A) Stmt. ¶ 17.) As established in previous litigation between the parties, this internal liner is “dispensed through a spray nozzle” depositing the “internal lacquer on the base and the side walls of the open [container].” (Def.’s Resp. Pl.’s Mot. Summ. J., Ex. G, Chupak Dep., SA46, lines 5-14.) The entire cylindrical container is covered with the lacquer, as “the guns spray the bottoms and the side walls.” (*Id.* at SA51.) After the liquid liner is applied in this fashion, the liner is “cured in a curing oven,” transforming the applied lacquer into a permanent solid form. (*Id.* at SA50.) Therefore, because it constitutes an application of a solid liner that encloses the inside of Baxter’s aluminum container, there exists no genuine issue of material fact concerning whether Baxter’s method covers or spreads the interior of Baxter’s container with a finishing, protecting, or enclosing layer as construed in Claim 1 of the '492 Patent.

However, to prevail in the present action, Abbott must also establish that Baxter’s epoxyphenolic liner is a Lewis acid inhibitor, *i.e.*, a compound that interacts with the empty orbital of a Lewis acid via covalent bonding or complexing, wherein electrons are shared between atoms or molecules to render the resulting bonded molecule inert and unavailable for subsequent Lewis acid interaction. *See In re Gabapentin*, 503 F.3d at 1262. Claim 1 of the '492

Patent mandates that the coating step of an infringing method must apply a Lewis acid inhibitor, *i.e.*, any compound that interacts with the empty electron orbital of a Lewis acid. (*See* App. Def.'s Mot. Summ. J., Ex. D, '492 Patent at A293.)

Abbott argues that the deposition of Dr. Ralph A. Lessor from a 2001 action between the parties raises a genuine issue of material fact as to whether the epoxyphenolic liner acts as a Lewis acid inhibitor. (Pls.' Resp. Def.'s Mot. Summ. J. 3). In the deposition, Lessor stated that, because the molecular structure of the epoxyphenolic liner utilized in Baxter's container contains a phenol group, the liner has the ability to complex with a Lewis acid. (*See* Pls.' Resp. Def.'s Mot. Summ. J., Ex. I, Lessor Dep. at SA 67:9-16.) However, after establishing the theoretical possibility that such complexing could occur, Lessor also downplayed the likelihood of such phenol/Lewis acid interaction in Baxter's container:

Q: Is it your understanding that phenols have the ability to complex with a Lewis acid?
[Lessor.] They do have that ability.
Q. Is there any reason why the epoxyphenolic resin of the Baxter aluminum container cannot complex with a Lewis acid?
[Lessor.] Well, it's not soluble in the sevoflurane.

(*Id.* at SA67:14-21). Further, Lessor's testimony fails to state that any testing was conducted to reinforce the soundness of his theory that Baxter's liner could complex with Lewis acids. Therefore, Lessor's assertion that Baxter's liner could act as a Lewis acid inhibitor is based solely on scientific theory.

Similarly, Abbott points to the 2001 trial testimony of Dr. Charles Rogers, Abbott's polymer science expert, in an attempt to establish a genuine issue of material fact concerning the Lewis acid-inhibiting nature of Baxter's liner. (*See* Pls.' Resp. Def.'s Mot. Summ. J. 4.) Rogers testified that, because the liner contained hydroxy groups and it was, in his opinion, well-

established that hydroxy groups have the ability to complex with Lewis acids, the purported fact that the epoxyphenolic liner would act as a Lewis acid inhibitor should be given more weight than mere scientific theory typically affords. (See App. Def.'s Mot. Summ. J., Ex. A, Am. Bench Op. at A34.) However, Rogers, like Lessor, failed to offer any empirical data from testing to establish the validity of this theory. (See *id.*)

“[I]n determining whether a claim in a patent has been infringed, the scientific theories utilized must establish the presence of the limitations recited in the claim.” *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994). For example, in the infringement action *In re Gabapentin*, the plaintiff, Warner Lambert, had discovered that under certain conditions the active ingredient in one of its drugs tended to form a lactum, which rendered the drug unstable. 503 F.3d at 1257. In an effort to cure this deficiency, Warner Lambert developed and patented a method of ensuring that the drug remained stable. *Id.* Claim 7 of the *In re Gabapentin* patent-at-issue included a limitation that the active ingredient in the drug contain “less than 20 ppm of an *anion of a mineral acid.*” *Id.* at 1258 (emphasis in original). Therefore, in order to prove infringement, Warner Lambert was required to show that the samples of the allegedly infringing drug contained less than 20 parts per million of an anion of a mineral acid. *See id.* at 1262. Warner Lambert offered results from pH tests conducted on the samples, which established that the samples could contain between 7 and 17 parts per million anions. *Id.* at 1261. Because “pH testing can indicate whether a sample contains less than 20 ppm of acidic chloride by measuring the pH, or acidity, of the solution and comparing it against a sample with a known amount of acid,” the *In re Gabapentin* court held that Warner Lambert had raised a genuine issue of material fact for trial, and denied the defendant’s summary judgment motion on the issue of noninfringement. *Id.* at 1262.

However, unlike Warner Lambert, by failing to offer any test results that establish whether Baxter's epoxyphenolic liner acts as a Lewis acid inhibitor, Abbott has not raised a genuine issue of material fact for trial on the issue of literal infringement. Buttressing this determination is Rogers' testimony from the 2001 action, wherein he stated that he tried three times to back his opinion with test data, but two of the tests were inconclusive and the third was stopped prematurely at the request of Abbott's attorneys. (*See* App. Def.'s Mot. Summ. J., Ex. A, Am. Bench Op. at A34-A35.) Additionally, no evidence on the present record indicates that Abbott has conducted any further tests to date. Clearly, this is insufficient to create a triable issue.

Therefore, Abbott has failed to present evidence to establish that Baxter's liner is in fact a Lewis acid inhibitor as defined by the '492 Patent's specification. Consequently, by failing to present any test results to legitimize its experts' scientific theories, Abbott has not raised a genuine issue of material fact for trial regarding the Lewis acid inhibitor claim limitation, or literal infringement of the '492 Patent.

The infringement inquiry, however, does not stop at literal infringement, because "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 732 (2002). The doctrine of equivalents holds that:

'[T]he substantial equivalent of a thing, in the sense of the patent law, is the same as the thing itself; so that if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape.'

Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 35 (1997) (quoting *Union Paper-Bag Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1878)).

Baxter argues, however, that Abbott is barred from relying on a doctrine of equivalents

theory because prosecution history estoppel applies. The doctrine of prosecution history estoppel holds that when a “patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent.” *Festo*, 535 U.S. at 733-34. “Prosecution history estoppel . . . is a question of law.” *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1251 (Fed. Cir. 2000).

The Court finds that prosecution history estoppel does not bar Abbott from asserting that Baxter’s epoxyphenolic liner is an equivalent to the Lewis acid inhibitor limitation of Claim 1. Originally, the claims of patent application 10/190,271 (which eventually issued as the '492 Patent) were drawn to, for example, “[a]n anesthetic composition comprising a fluoroether compound having an alpha fluoroether moiety . . . ,” and “[a] method of stabilizing a fluoroether compound having an alpha fluoroether moiety” (See App. Def.’s Mot. Summ. J., Ex. E, '492 Patent File Wrapper at A337, A358.) The examiner rejected all of the original claims for indefiniteness, finding that the terms “alpha fluoroether moiety” and “fluoroether compound” did not “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention” as required by 35 U.S.C. § 112. (*Id.* at A351.) Further, the examiner rejected all of the original claims due to obvious-type double patenting. (*Id.* at A352.) Abbott then canceled all of the original application’s claims and replaced them with the claims that eventually issued in the '492 Patent, which are drawn to completely different subject matter, namely, “[a] method of storing a quantity of sevoflurane.” (*Id.* at A358.)

Because the '492 Patent’s amended claims are drawn to completely different subject matter than the claims as originally filed, the Court finds that the amendment was not a “narrowing amendment,” and that prosecution history estoppel does not apply to the “coating”

step at issue. *See Festo*, 535 U.S. at 737 (“Though prosecution history estoppel can bar a patentee from challenging a wide range of alleged equivalents made or distributed by competitors, its reach requires an examination of the subject matter surrendered by the narrowing amendment.”). Comparing the relative scopes of the “anesthetic composition” claims of the original application to the “method of storing a quantity of sevoflurane” claims of the '492 Patent would be an impossible inquiry, akin to comparing apples and oranges. Therefore, although Abbott did indeed amend its application, Abbott did not surrender patent coverage drawn to equivalents of “coating said interior wall of said container with a Lewis acid inhibitor.”

Because prosecution history does not apply, the Court must conduct a doctrine of equivalents inquiry to determine if there exists a genuine issue of material fact as to whether Baxter’s container with the epoxyphenolic liner “[(1)] do[es] the same work [(2)] in substantially the same way, and [(3)] accomplish[es] substantially the same result” as the method claimed in the '492 Patent. *See Warner-Jenkinson*, 520 U.S. at 35. As discussed above, no genuine issue of material fact exists as to whether Baxter’s container accomplishes substantially the same result as the '492 Patent, *i.e.*, prevents sevoflurane degradation by coating the container with a compound that interacts with the empty electron orbital of a Lewis acid. Thus, the Court’s inquiry will focus on whether Baxter’s container does substantially the same work in substantially the same way as claimed in the '492 Patent. *See id.*

Again, because Abbott has not brought forth evidence that the epoxyphenolic liner chemically reacts in any way with available Lewis acids, no genuine issue of material fact exists concerning whether Baxter’s container does substantially the same work in substantially the same way as claimed in the '492 Patent. Although Abbott contends that the testimony and depositions of Lessor and Rogers raise a genuine issue of material fact as to this issue, as the

Court has explained above, this argument falls short due to the lack of test data on record. (*See* Pls.' Resp. Def.'s Mot. Summ. J. 3-4.) Though the Baxter liner does in fact inhibit Lewis acid degradation, it does so by forming a physical barrier between the aluminum surface and the sevoflurane, not by interacting chemically with the empty electron orbital of present Lewis acids as claimed in the '492 Patent. (*See* App. Def.'s Mot. Summ. J., Ex. A, Am. Bench Op. at A37.) Therefore, by simply serving as a buffer layer for mechanical separation, Baxter's liner does not do the same work in substantially the same way as claimed in the '492 Patent. Abbott, by relying simply on untested scientific theory, has done no more than establish a metaphysical doubt as to the simple mechanical blocking function of Baxter's liner. Therefore, there exists no genuine issue of material fact for trial concerning infringement by the doctrine of equivalents.

Conclusion

The Court grants defendants' motion for summary judgment [doc. no. 52]. This case is hereby terminated and all other motions are stricken as moot.

SO ORDERED.

ENTERED:

9/17/09

Ronald A. Guzman

HON. RONALD A. GUZMAN
United States District Judge