



IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS  
COUNTY DEPARTMENT, CHANCERY DIVISION

WINSTON LABORATORIES, INC.,	)	
	)	
Plaintiff,	)	
	)	No. 02CH 07461
v.	)	
	)	
UNITED STATES ADOPTED NAMES COUNCIL;	)	
DANTEL L. BORING, PhD, in his representative	)	
capacity; EVERETT FLANIGAN, PhD, in his	)	
representative capacity; SOPHIA V. FUERST,	)	
in her representative capacity; WILLIAM M.	)	
HELLER, PhD, in his representative capacity;	)	
JOHN E. KASIK, MC, PhD, in his representative	)	
capacity; and ALICE JEAN MATUSZAK, PhD,	)	
in her representative capacity; AMERICAN	)	
MEDICAL ASSOCIATION, UNITED STATES	)	
PHARMACOPEIA; and AMERICAN	)	
PHARMACEUTICAL ASSOCIATION,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

This matter coming before this court on a motion to dismiss the complaint with prejudice pursuant to 735 ILCS 5/2-615 and 619 filed by defendant, United States Adopted Names Council ("USAN"), and collectively by all defendants, on the grounds that the claims of plaintiff, Winston Laboratories, Inc., ("Winston") have no legal basis; that plaintiff cannot state a claim against defendants and that the relief plaintiff requests is available, if at all, only from the United States Food and Drug Administration ("USFDA"). (See motion at 1). A response has been filed by plaintiff and a reply thereto having also been filed by defendants.

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This court recognizes from the complaint and submissions that each non-USAN defendant has been sued only in the capacity as a member, officer or sponsor of USAN. (See complaint at 3-11,17).

A motion to dismiss filed under 735 ILCS 2-615 challenges the legal insufficiency of the complaint whereas a motion filed under 735 ILCS 2-619 raises legal defects or defenses that negate the plaintiff's cause of action completely, or refute crucial conclusions of law or conclusions of material fact that are unsupported by allegations of specific facts. Lawson v City of Chicago, 278 Ill. App. 3d 628, 634 (1996). Motions filed under either section admit all well-pleaded facts. Lawson, 278 Ill. App. 3d at 634. A conclusion of law or fact which is not supported by specific factual allegations, however, is not admitted. Nuccio v. Chicago Commodities Inc., 257 Ill. App. 3d 437, 443 (1<sup>st</sup> Dist. 1994); Talbert v. Home Savings of America, F.A., 265 Ill. App. 3d 376, 379 (1<sup>st</sup> Dist. 1994). In ruling on either motion, all pleadings and supporting documents are construed in a light most favorable to the nonmoving party. In Re Chicago Flood Litigation, 176 Ill. 2d 179, 184 (1997). Information contained in an exhibit attached to the complaint and incorporated therein controls over a contrary factual allegation in the pleading. (See Smith v. Prime Cable of Chicago, 276 Ill. App. 3d 843, 855 (1<sup>st</sup> Dist. 1995); see also Charles Hester Enterprises, Inc. v. Illinois Founders Insurance Co., 114 Ill. 2d 278, 287 (1980); Dunn v. Baltimore & Ohio R. Co., 114 Ill. 2d 350, 372 (1989)).

Defendants/movants contend that there is no need to reference matters outside the pleadings as plaintiff's complaint, along with the exhibits, fails to state a cause of action under applicable law against the defendants. (See plaintiff's memorandum at 2; see also Storm & Assoc., Ltd. v Cuculich, 298 Ill. App. 3d 1040, 1047 (1<sup>st</sup> Dist. 1998)).

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Plaintiff alleges it is a Delaware corporation engaged in the pharmaceutical business that conducts research and arranges for clinical testing of various pharmaceutical products. (See complaint at 1). USAN is alleged to be a voluntary association that assigns nonproprietary drug names based upon its in house guiding principles. (See complaint at 2,15). It is alleged that in the present case USAN adopted the nonproprietary name "zucapsaicin" in 1993 for cis-8-methyl-N-vanillyl-6-nonenamide in violation of its guiding principles, including that the drug name should be neither confusing nor misleading. (See complaint at 15, 16).

The complaint contains allegations that the USFDA, a federal agency, cooperates with and is represented on USAN's Council that has been engaged in the assignment of nonproprietary drug names since January 1964. (See complaint at 5, 17). One of the five members on USAN is from the USFDA. (See complaint at 5).

The complaint alleges, among other things, that, in 1992, a company called GenDerm submitted an application to ask the defendant USAN for its opinion of what name should be given to a particular drug, which is identified in the complaint as cis-8-methyl-N-vanillyl-6-nonenamide. (See complaint para. 26). GenDerm initially submitted a request for the names of civamide or mecvamide, but that the name "zucapsaicin" was eventually adopted for the drug. (See complaint at 26,27; see also exhibit 4 attached to complaint). According to the complaint, USAN notified GenDerm in November 24, 1993, that the name "zucapsaicin" had been approved for cis-8-methyl-N-vanillyl-6 nonenamide and the name was then officially adopted by federal agencies, including the USFDA. (See complaint at 26-28).

In 1999, after acquiring the rights to the drug called "zucapsaicin", plaintiff, Winston, has decided that it wants the official name for the drug to be changed. (See complaint at 25, 48-46).

Winston now proposes in its complaint a different name because the official name adopted in 1993 is "potentially" confusing and misleading. (See complaint at 21, 26-27, 29).

In July 1999, Winston wrote to USAN and requested that it change its opinion of the name and asked that USAN adopt a new name, "civamide". (See complaint at 38-43, exhibits 3-7 attached to complaint). After considering Winston's demand, USAN reconfirmed its earlier opinion in 1993 that the name of the drug should be remain "zucapsaicin." (See complaint at 38-39, and exhibit 4 attached thereto). In a letter of November 4, 1999, which is attached as exhibit 4 to the complaint, it is stated that the name "civamide" had not been adopted in July of 1993 when GenDerm originally submitted its application for a name of the compound. It is further stated in that letter that GenDerm agreed upon the name zucapsaicin, which is the recommended nonpropriety name for use in all WHO-member countries and is the FDA-recognized nonproprietary name for that drug. (See exhibit 6 and 8 to the complaint). It is also stated in the letters of November 4, 1999, and July 26, 2000, which are attached to the complaint, that zucapsaicin was recommended by representatives of GenDerm who negotiated for the name under USAN's rules and procedures.

Plaintiff alleges that USAN has suggested for plaintiff to pursue a review of the matter with USAN's Review Board and that USAN has furnished plaintiff with a copy of the rules of procedure. (See complaint at 40-45, 46, and exhibits 6 and 8 to the complaint). In the letter of September 10, 2001, which is attached to the pleading, USAN indicated that reconsideration of the adoption of a name change was denied, after USAN claimed it had reviewed the historical background of events and rationale associated with the selection of the name "zucapsaicin". Plaintiff, Winston, has not pursued a review of the matter by USAN's Review Board.

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The complaint asks in its prayer for relief that defendants be enjoined from continuing to use the name zucapsaicin, or any other term containing the word capsaicin, for cis-8-methyl-N-vanillyl-6-nonenamide; that the defendants be required to adopt the name "civamide" or another name acceptable to Winston for cis-8-methyl-N-vanillyl-6-nonenamide. In addition, plaintiff requests this court to order that defendants be required to send an application for the new name to the World Health Organization International Nonproprietary Name Committee.

Defendants argue in their motion and accompanying memorandum that plaintiff's complaint should be dismissed because it fails to state a legal claim for relief against USAN and because the subject matter of its claim is preempted by federal law. (See motion at 1-2). It is also argued by defendants/movants that the doctrine of laches bars any claim because of the eight year period that has elapsed since the name "zucapsaicin" was adopted for the generic drug.

Defendants further contend in their submissions that plaintiff's claim of deceptive practices under the Illinois Deceptive Practices Act is barred because of the applicable three year statute of limitations, specific facts have not been alleged to state a violation of the Act, including any factual allegations that defendants sell, market or distribute the product, and because the naming of the drug is governed by federal regulations of the USFDA and thus exempt. (See 815 ILCS Section 510/4(1)), see also memorandum at 13-15).

Under the Federal Food, Drug and Cosmetic Act ("Federal Drug Act"), the Secretary (of the U.S. Department of Health and Human Services) may designate an official name for any drug or device if it is determined that such action is necessary or desirable in the interest of usefulness and simplicity. (21 U.S.C.A. Section 358(a)). Any official name designated under the Federal Drug Act shall be the only official name of that drug used in any official compendium published

after such name has been prescribed. (See 21 U.S.C.A. Section 358(a)). Under the Federal Drug Act, the Secretary (of the U.S. Department of Health and Human Services) is directed to review and determine that any official name is unduly complex or is not useful for any other reason [emphasis added]. (See 21 U.S.C.A. Section 358(c)). However, if it is determined that the name so recommended is useful, that name shall be the official name of such drug. Id. Moreover, the Secretary is directed when it deems to be necessary or desirable to cause to be published and publically distributed a list of all revised official names of drugs designated under Section 358 of the Federal Drug Act. (See 21 U.S.C.A. 358(c)). At the hearing on the motion, this court was referred to a rule issued by the USFDA on September 25, 1984. In that rule, the USFDA purports to have reviewed the then existing list of official names designated by the agency and indicates that nonproprietary drug names listed in USAN and in USD Dictionary of Drug Names will serve as "established names" under Section 502(e) of the Federal Drug Act (21 U.S.C. 352(e)) so that the USFDA does not need to publish routinely as official names those names listed in the volume. (See the rule 49 FR 37574-01). However, language in the rule further provides that the USFDA will continue to designate any official names for a drug because it finds the names listed in that volume to be unduly complex or not useful. The rule further states that because "a liaison representative of USFDA sits on the USAN Council, the agency plays a more prominent role in the establishment of names listed in the volume than it does in listing products in the compendia". (See 49 FR 37574-01 at 2). By issuing the rule, the USFDA found that the availability to the public of current information on acceptable "established names" of drugs will not be affected.

This court finds that the USFDA, a federal agency, is granted by statute the authority to provide "official name[s]" to drugs. (See 21 U.S.C. Section 358 (a)). The federal agency has responsibility to review both previously assigned "official names" and those drugs without "official names" in order to ensure that no drug bears an inappropriate name. (21 U.S.C.A. Section 358 (c)). If the USFDA has designated an "official name," that name must be used on the drug label. (21 U.S.C. 352 (e)). Also, if the federal agency has designated an "official name" for a drug, then federal law requires that "official name" "shall be the only official name of that drug . . . used in any official compendium published after such name has been prescribed" and "shall be the only official name of that drug . . . for any other purpose of" the Federal, Food, Drug, and Cosmetic Act. (See 21 U.S.C. para 358 (a)).

The USFDA has promulgated regulations pursuant to its statutory authority. (See 21 C.F.R. para 299.4, et seq.). These regulations acknowledge the special expertise of USAN, and that USAN negotiates with manufacturing firms in the selection of nonproprietary names for drugs, which the letters attached to the complaint indicate was done in July of 1993 with representatives of GenDerm in arriving at the name "zucapsaicin". (See exhibits 4,6,8 to the complaint; see also 21 C.F.R. Sec. 299.4(c)). There are insufficient facts alleged to infer a connection between USAN's opinion on the name "zucapascian" and the alleged harm to plaintiff which is referred to in the pleading. (See complaint at 28 and 29). The complaint does not allege that USAN's opinion has a binding legal effect on the USFDA, but alleges generally that "once a name is adopted by USAN, it is also adopted by other agencies". (See complaint at 28, see also 21 C.F.R. Section 299.4(c),299.4(e)). Even if USAN considers changing its opinion of the name for the drug, the parties' submissions indicate that the USFDA can still act if it

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determines that any such name change is unduly complex or not useful for any reason. It is evident from the submissions that the USFDA, as a federal agency, has oversight over drug naming under federal regulations that includes the involvement of USAN, an association, on which USFDA is represented as one of 5 members. The federal regulations also provide a procedure to have the USFDA, a federal agency, review a matter involving drug naming. (See 21 C.F.R. Section 10.30 (2002)). A petition is submitted to request the Commission to take or refrain from taking administrative action and USFDA can determine whether an official or common name is "unduly complex or is not useful for any other reason", or even that two or more drugs are identical in chemical structure, identical in pharmaceutical actions or are substantially identical in strength, quality and purity. (Sec 21 C.F.R. Section 10.30).

A request to name or rename a drug for official adoption by federal agencies is preempted by federal law and USFDA regulations. (See 21 U.S.C.A. Section 358, 21 C.F.R. para. 2999.4(d); see also e.g. Verb v Motorola, Inc., et al., 284 Ill. App. 3d at 460,467 (1<sup>st</sup> Dist. 1996) where the Court indicated the USFDA had exclusive preemption authority to issue health and safety standards in regulating radiation-emitting electronic products even though the agency had not set specific standards because the power to do so resides with the USFDA; see also Schiffner v. Motorola, Inc. 297 Ill. App. 3d 1099,1104-1106 (1<sup>st</sup> Dist. 1998) where the Court noted that Congress can assert exclusive power either by explicit statutory language or by regulating a matter in such detail to leave no room for state involvement and where it is appropriate to approve uniform national standards.

This court finds that the Department of Health and Human Services through the USFDA has legitimate governmental interests as a federal agency with a particular expertise to be

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responsible for determining the official names of drugs that reflect their chemical compositions under federal regulations and national standards.

Plaintiff further alleges in its complaint that USAN should comply with its in house principles, which are contained in its guidelines, for issuing U.S. adopted names for drugs. As stated in the introduction to the guidelines being cited, "these principles take into account practical considerations and logic in the choice of names . . . These guidelines are and must be sufficiently flexible to be revised if this is considered to be described and/or necessary." (See complaint at 15-16; exhibit 2 page 1 to appendix II, to the complaint). In view of the general language used in the guidelines granting USAN its discretion to apply practical considerations, Plaintiff is seeking this court to order USAN to comply with its self-imposed principles, yet sufficient factual allegations have not been alleged to state a claim that a breach of the guidelines occurred and harmed plaintiff. In addition, contrary to the allegations in the complaint, the letters, which are attached to the complaint, contain a purported basis asserted by USAN for the adoption of "zucapsaicin" as the nonproprietary name. (See exhibits 3,6 and 8 to the complaint). The letter of November 4, 1999 appears to explain that there were negotiations with GenDerm's representative in accordance with USCA's procedures prior to adoption of the name "zucapsaicin" on November 24, 1993. According to the letter of November 4, 1999, the proposed name was transmitted to the WHO International Nonproprietary Name Committee for review and approval, which was secured pursuant to USAN's rules of procedure. In the letter of July 26, 2000, USAN refers to "zucapsaicin" as the FDA-recognized nonproprietary name for the compound which was adopted in 1993 after the approval was secured from GenDerm Corporation, the predecessor of plaintiff interested in naming the drug. The complaint does not

contain any allegations that refute any of the aforesaid statements in the letter which are incorporated in the pleading. To the extent that plaintiff continues to challenge USAN's refusal to change the name of the drug, USAN's letter advises that plaintiff can submit the matter to USAN's Review Board which the letter explains was specifically established to resolve nomenclature disputes between the USAN Council and the manufacturer when normal procedures have failed. (See exhibits 6 and 8 to complaint).

Based upon the submissions, USAN's Review Board determines the merits of protests lodged against any adopted name. (See exhibit 9 to complaint, Rules of Procedure, Section 1). The Board consists of six individuals, including a chairperson. (See Rules of Procedure, Section 1). The rules provide for an oral hearing if requested. A decision of the chairman may be appealed to the entire Review Board. There are rules to prevent a member from having a conflict of interest. (See Rules of Procedure, Section 3). The proceedings may be transcribed and statements can be submitted under oath. (See Rules of Procedure Sections 8, 11). A determination will be made by the Board within a designated time frame. (See Rules of Procedure Section 22). Plaintiff would appear to be afforded an opportunity to pursue the matter with USAN even though any determination would be binding between plaintiff and USAN only. (See complaint at 46).

Moreover, this court is not convinced that plaintiff alleges sufficient facts in count 1 for the injunctive relief it seeks, particularly to enjoin the use of the official name by persons that would include federal agencies, that, according to the complaint, have adopted the name since 1993. Sufficient facts are not alleged that plaintiff has a right to have USAN change the official name for the drug. It is not contended that defendant USAN uses the name "zucapsaicin" in its

sale, marketing or distribution of the drug, or that USAN is engaging in conduct that harms plaintiff. Plaintiff has not alleged sufficient facts to complain that the name "zucapsaicin" is misleading and confusing or that the decision not to change the name creates a legal basis for a cause of action against USAN, in view of USAN's review process and the availability of possible federal administrative remedies. (See complaint par. 48, 49). The count also lacks sufficient factual allegations to address the elements required for injunctive relief. Skolnick v. Alzheimer & Gray, 191 Ill. 2d 214 (2000); Hartlein v. Illinois Power Co., 151 Ill. 2d 142 (1992). As pointed out in the movant's submissions, mandatory injunctive relief is issued only with caution. People v. Van Tran Electric Corp., 152 Ill. App. 3d 175, 183 (5<sup>th</sup> Dist 1987); John Deere Co. v. Hinrichs, 36 Ill. App. 3d 255, 269 (1<sup>st</sup> Dist. 1972). The conclusory references in the complaint that the name "zucapsaicin", which was approved in the summer of 1993 by USAN and adopted by federal agencies including the USFDA, is "potentially" confusing and violates USAN's own policies does not state a cause of action for the equitable relief being sought. (See complaint at 21, 29; see also Madison v Melrose, 130 Ill. App. 3d 149; Wilson v Illinois Benedictine College, 112 Ill. App. 3d 938; Skolnick v Alzheimer & Grey, 191 Ill. 2d 214 (2000); Gleicher v University of Health Science, 224 Ill. App. 3d 77 (1996).

Plaintiff has also failed to allege sufficient facts to claim that defendants violated the Illinois Deceptive Trade Practices Act, 815 ILCS 510/2; ("Illinois Deception Act"). It is not alleged with specific facts in paragraph 53 of the complaint the basis for a claim of a violation of the Illinois Deception Act that defendants allegedly committed, the alleged incorrect representation of the compound's composition and the harm that defendants allegedly inflicted

by violating a particular provision of the Act. It is noteworthy that USAN is neither alleged to be a competitor of plaintiff, or a distributor, or supplier of the relevant drug.

Moreover, a three-year statute of limitations applies to claims brought under the Illinois Deception Act. Elrad v United Life and Acc. Ins. Co., 624 F. Supp. 742, 744-745 (N.D. Ill. 1985). The complaint alleges that the name was approved by defendant USAN on or about July 20, 1993, and according to the allegations in the complaint, the name was, subsequently, adopted by federal agencies, including by the USFDA, which is even represented on USAN's Council. Based upon the facts alleged, plaintiff's claim for any alleged improper designation of the name in July of 1993 under the Illinois Deceptive Act would be barred under the three year time limitation under 735 ILCS 5/2-619 (a)(5).

In addition, the Illinois Deception Act also "does not apply to . . . conduct in compliance with the orders or rules of or a statute administered by a Federal, state, or local governmental agency." 815 ILCS 510/4(1). Pursuant to its statutory authority, the USFDA requires that the name "zaccapsaicin" be placed on drug labels in accordance with its regulations. In effect, plaintiff is indirectly seeking relief that directly involves the actions being taken and will be taken by the USFDA under its regulatory authority insofar as the drug's name is concerned.

This court is also not convinced from the allegations in the pleading that USAN has the ultimate authority to designate the "official names" of drugs or to change the names of drugs if the name is no longer useful, after the USFDA has designated a name as an "official name".

IT IS HEREBY ORDERED, based upon the foregoing, defendants' motion and the parties' submissions, that:

Defendants' motion is granted insofar as it seeks to dismiss plaintiff's claim for relief in its complaint that this court declare the official name for cis-8-methyl-N-vanillyl-6-nonemamide to be "civamide" or another name acceptable to plaintiff, Winston, since the USFDA has primary jurisdiction over regulating drug naming and labeling and federal regulation exists for the USFDA to determine if a drug name is not useful because it is confusing, misleading or for any other reason, and any such claim for declaratory relief is dismissed to permit plaintiff to pursue any possible federal administrative remedies under applicable agency rules and/or any possible review of the renaming of the drug with the USAN under its applicable rules of appeal; and

Defendants' motion is granted to dismiss count 2 seeking relief against defendants for deceptive trade practices under the provisions of the Illinois Deceptive Act based upon the allegations in count 2, including that defendants refuse to adopt a new name for cis-8-methyl-N-vanillyl-6-nonemamide since this court has determined that such a matter is subject to federal agency regulation and federal administrative agency review; and

Defendant's motion is granted to dismiss any other equitable claims for relief sought in the complaint without prejudice, based upon the allegations stated in the pleading.

Dated: November 2002

Entered:

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Richard J. Bilik, Jr., Judge