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UNITED STATES PATENT AND TRADEMARK OFFICE

Trademark Trial and Appeal Board

In re Sanofi-Aventis

Serial No. 78278816

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for Sanofi-Aventis.

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116 (M.L. Hershkowitz, Managing Attorney).

Before Drost, Zervas, and Cataldo, Administrative Trademark
Judges.

Opinion by Drost, Administrative Trademark Judge:

On July 25, 2003, applicant Sanofi-Aventis, a
corporation of France, applied to register the mark
INCLUSIVE, in typed or standard character form, on the
Principal Register for services ultimately identified as
"clinical research in the field of hypertension and anti-
hypertensive pharmaceuticals; medical and scientific

research, namely, conducting clinical trials for anti-hypertensive pharmaceuticals" in Class 42.¹

The examining attorney refused to register applicant's mark on the ground that the mark, when used in association with the identified services, is merely descriptive under Section 2(e)(1) of the Trademark Act, 15 U.S.C.

§ 1052(e)(1). The examining attorney argues (Brief at unnumbered p. 4, footnote omitted):

The term INCLUSIVE, meaning "comprehensive," is merely descriptive in this instance because it *immediately* describes a feature of the Applicant's inclusive clinical research services that *include* a diverse patient group. That is, the Applicant's clinical research services are inclusive or comprehensive in nature because as the Applicant's specimen and evidence of record specifically indicates, the Applicant's INCLUSIVE trial "was the first to include a broad range of patient groups, including the elderly, African-American, and Hispanic/Latino patients, as well as patients with type 2 diabetes or the metabolic syndrome."

The examining attorney maintains that the "evidence of record showing multiple references to 'inclusive research' in a wide variety of fields shows the consumers' exposure to and understanding of the term INCLUSIVE in the research context." Brief at unnumbered p. 5. The examining attorney specifically points to applicant's specimen that

¹ Serial No. 78278816 was based on an allegation of a bona fide intention to use the mark in commerce. Subsequently, the examining attorney accepted applicant's second amendment to allege use. The date of first use and first use in commerce in that amendment was identified as November 8, 2003.

"indicates that its INCLUSIVE trial 'was the first to include a **broad** range of patient groups.'" Brief at unnumbered pp. 6-7. Therefore, the examining attorney determined that the mark was merely descriptive.

In response, applicant disputes the examining attorney's conclusion that its mark is merely descriptive for its services. It argues (Brief at 5) that the examining attorney "wrongly equates the meaning of 'inclusive' with the meaning of 'diverse.'" Finally, applicant maintains (Brief at 7-8) that:

Applicant coined the mark INCLUSIVE as an acronym based on the full name of a study, **I**rbesarta**N**/HCTZ **b**lood press**U**re reductions in **d**IVERse patient populations... It is common practice in the pharmaceutical industry for companies to choose marks for clinical trials that are based on acronyms derived from words describing the subject matter of the study. For example, applicant has another study named REACH, which is an acronym for **R**eduction of **A**therothrombosis for **C**ontinued **H**ealth... Consumers for pharmaceutical clinical trials, including doctors and patients who participate in the studies are aware of this practice. Thus, when these consumers see the mark in connection with the services, they will perceive the name of the study as a trademark identifying the source of the study and not as a descriptor of the study.

After the examining attorney made the refusal final, applicant appealed to this board.

A mark is merely descriptive if it immediately describes the ingredients, qualities, or characteristics

of the goods or services or if it conveys information regarding a function, purpose, or use of the goods or services. In re Abcor Development Corp., 588 F.2d 811, 200 USPQ 215, 217 (CCPA 1978). See also In re MBNA America Bank N.A., 340 F.3d 1328, 67 USPQ2d 1778, 1780 (Fed. Cir. 2003) (A "mark is merely descriptive if the ultimate consumers immediately associate it with a quality or characteristic of the product or service"); In re Nett Designs, 236 F.3d 1339, 57 USPQ2d 1564, 1566 (Fed. Cir. 2001).

To be merely descriptive, a term need only describe a single significant quality or property of the goods or services. In re Gyulay, 820 F.2d 1216, 3 USPQ2d 1009, 1009 (Fed. Cir. 1987); Meehanite Metal Corp. v. International Nickel Co., 262 F.2d 806, 120 USPQ 293, 294 (CCPA 1959). See also In re Oppedahl & Larson LLP, 373 F.3d 1171, 71 USPQ2d 1370, 1371 (Fed. Cir. 2004) ("A mark may be merely descriptive even if it does not describe the full scope and extent of the applicant's goods or services") (internal quotation marks omitted). We view the mark in relation to the goods or services, and not in the abstract, when we consider whether the mark is descriptive. Abcor, 200 USPQ at 218.

We now look at the evidence to determine whether the term INCLUSIVE would be merely descriptive of applicant's clinical research services. We start with a definition of the term that the examining attorney included with her final Office action:² "Inclusive" - "taking a great deal or everything within its scope, comprehensive: an *inclusive survey of world economic affairs.*" Next, we look at applicant's specimen of use (entitled INCLUSIVE: Irbesartan/HCTZ Blood Pressure Reductions in Diverse Patient Populations) (footnotes omitted):

A fixed-dose combination pill containing 2 antihypertensive drugs, an angiotensin receptor blocker (ARB), and a thiazide-type diuretic (HCTZ) has been shown to produce significant benefit in patients whose blood pressure is usually regarded as more difficult to control. The Irbesartan/HCTZ blood pressure reductions in diverse patient populations (INCLUSIVE) trial was the first to include a broad range of patient groups, including elderly, African-American, and Hispanic/Latino patients, as well as patients with type 2 diabetes or the metabolic syndrome. The patients in all of these subgroups all had a higher rate of blood pressure control than obtained on monotherapy, and since no effort was made to intervene in diet or exercise in this study, this was almost all attributable to the drug therapy, the INCLUSIVE investigators believe.

INCLUSIVE

The aim of INCLUSIVE, a prospective open-label, single-arm study, was to determine the efficacy and

² We have not considered any online dictionaries entries that were submitted during the appeal stage of this case. In re Total Quality Group, Inc., 51 USPQ2d 1474, 1476 (TTAB 1999) (We "do not normally take judicial notice of on-line dictionaries that are submitted for the first time on appeal").

safety of irbesartan/HCTZ 150/12.5 mg and 300/25 mg fixed combinations in a diverse population of adults with systolic blood pressure (SBP) uncontrolled on antihypertensive monotherapy. In addition to the study's overall enrollment, investigators also actively sought to recruit at least 100 patients in several predefined subgroups who have blood pressure that is traditionally deemed difficult to control.

Patients

The study started with 1005 patients (mean age 57.2 +/- 11.2 years, 52% women) recruited at 119 sites throughout the United States. In line with the aim of the study to recruit patients from subgroups with hard-to-control blood pressure, they included:

- 46% with the metabolic syndrome (3 or more criteria according to the National Cholesterol Education Program [NCEP] definition);
- 30% with type 2 diabetes (defined as fasting plasma glucose \geq 126 mg/dL and/or on antidiabetic medication);
- 25% elderly (aged \geq 65 years);
- 23% African American; and
- 14% Hispanic/Latino.

We also look at the evidence (emphasis added in examples) that the examining attorney has included in order to establish the descriptiveness of the term "Inclusive." Applicant does point out that several of these articles involve research in the social sciences. One (www.ccsd.ca) is "*Inclusive* Social Policy Development:

Ideas for Practitioners.”³ A website from the Open University (www.open.ac.uk) has an entry: “Self Advocacy and Research: an analysis of the talk in *inclusive* research with members of a People First group.” An Australian article (www.vcross.org.au) is entitled “*Inclusive* research: The opportunities and challenges of engaging and empowering diverse communities.” The Center for the Study of Experimental Psychotherapy (www.utoledo.edu) in its research protocol for a study concerning “emotion-based treatment of depression” under the category Clients/Patients” refers to “realistic clinical populations (*inclusive* sample)” and “very limited exclusion criteria: exclude psychotic, actively suicidal, antisocial pd, current severe substance abuse/dependence or other current severe crises.”

³ While applicant argues that the references to foreign publications are irrelevant, the board has determined that these articles can have some relevance. “[I]t is reasonable to assume that professionals in medicine, engineering, computers, telecommunications and many other fields are likely to utilize all available resources, regardless of country of origin or medium. Further, the Internet is a resource that is widely available to these same professionals and to the general public in the United States. Particularly in the case before us, involving sophisticated medical technology, it is reasonable to consider a relevant article from an Internet web site, in English, about medical research in another country, Great Britain in this case, because that research is likely to be of interest worldwide regardless of its country of origin.” In re Remacle, 66 USPQ2d 1222, 1224 n.5 (TTAB 2002). These foreign articles have some limited relevance in this case involving clinical research services, although they are not critical to the result here.

Applicant argues (Brief at 5) that the examining attorney's evidence only serves "to show that INCLUSIVE can be descriptive of certain research methodology in the social sciences, they have no bearing on the issue of whether INCLUSIVE is descriptive of applicant's research." However, the evidence is not limited to the social sciences. For example, a webpage for BioMechanics Lab⁴ describes it as a "source for basic and applied research. Its mission is to design, test and evaluate new treatment modalities that will advance the quality of patient care and outcomes." Among the lab features is "*Inclusive* research and testing capabilities, combining design, prototyping, macro and sub-micro scale material testing, motion analysis, and finite element modeling."

Another website from the Breast Cancer Forum⁵ contains an article that is entitled "The Clinical Trial Dilemma: How to Choose and Prioritize." In discussing clinical trials, it reports that the "FDA also imposes some eligibility criteria and is very strict about who can take new drugs and treatments." The article proposes that a "solution would be having a trial that is as *inclusive* as possible. By testing a drug or treatment on a large

⁴ www.edtech.connect.msu.edu.

⁵ www.breastcancercenter.his.ucsf.edu.

population, it would be determined how it affects a cancer population as a whole."

An article concerning the National Rural Health Association (www.nhraural.org) contains the following information: "Federal agencies that seek to promote more 'population *inclusive*' research should be instructed to formally establish funding relationships with grant programs." Another website⁶ reports that: "There's growing attention being paid to gay and lesbian health care issues, said Smith, with new group's advocating improved services and more *inclusive* research." An Ontario Public Health Association resolution (www.opha.on.ca) explains that "the lack of comprehensive and *inclusive* research and its dissemination results in inequitable distribution of health care resources and inaccessible, inappropriate and ineffective health services for lesbians and gay men."

A bulletin from the U.S. Department of State (<http://lists.state.gov>) with the subject "HIV Vaccine Trials Must Include Women, Teens, Experts Say" reports that the World Health Organization "brought together this panel of specialists to focus on the need to make the

⁶ www.valleyadvocate.com.

composition of trial populations more *inclusive* and broaden participation by gender, age and race... Clinical trial enrollment needs to be more *inclusive*, so the benefits of research are more fairly distributed." The American Heart Association website (www.ahajournals.com) includes an article entitled "Heterogeneity of Stroke Pathophysiology and Neuroprotective Clinical Trial Design." It indicates that: "Strategies to enhance the proportion with tissue substrate for neuroprotection could reduce sample size to 500 per group and simultaneously reduce total number of patients screened compared with *inclusive* trials." Finally, the World Summit against Cancer for the New Millenium (www.cancersafe.com) reports that "the parties seek to enable rapid, powerful and *inclusive* trials that ethically engage and also empower people with cancer."

This evidence lead us to conclude that the term "inclusive" describes a characteristic, feature, or attribute of applicant's services of clinical research in the filed of hypertension and anti-hypertensive pharmaceuticals; medical and scientific research, namely, conducting clinical trials for anti-hypertensive pharmaceuticals. The term "inclusive" means "taking a great deal or everything within its scope, comprehensive."

Applicant's specimen describes a study that takes a great deal within its scope.

The aim of INCLUSIVE, a prospective open-label, single-arm study, was to determine the efficacy and safety of irbesartan/HCTZ 150/12.5 mg and 300/25 mg fixed combinations *in a diverse population of adults* with systolic blood pressure (SBP) uncontrolled on antihypertensive monotherapy. In addition to the study's overall enrollment, *investigators also actively sought to recruit at least 100 patients in several predefined subgroups* who have blood pressure that is traditionally deemed difficult to control.

In addition, the "study started with 1005 patients (mean age 57.2 +/- 11.2 years, 52% women) recruited at 119 sites throughout the United States in line *with the aim of the study to recruit patients from subgroups* with hard-to-control blood pressure." The groups that applicant's research was designed to include were those with metabolic syndrome, type 2 diabetes, the elderly, African Americans, and Hispanics/Latinos. Applicant's research concerning patients whose blood pressure is usually regarded as more difficult to control falls within the dictionary definition of "Inclusive."

Applicant argues that its research "was not comprehensive because it necessarily excluded the general population who might otherwise have qualified to participate in the study." Brief at 6. However, applicant's study was inclusive because by its own

definition, it was not a study of the general population or even the general population with high blood pressure but rather it was limited to patients whose blood pressure is usually regarded as more difficult to control.

Applicant's study certainly takes in a great deal within its scope and, therefore, it is accurately described by the term "inclusive."

In addition, applicant argues (Brief at 5) that the "examiner wrongly equates the meaning of "inclusive" with meaning of "diverse." Applicant's argument rests heavily on the point that its "clinical trial was not 'inclusive,' because it is a study of a drug on a limited population of patients in certain sub-groups, not in a large population of patients with high blood pressure as a whole." Reply Brief at 2. As discussed above, we have found this general argument unpersuasive. Applicant also argues that "diverse" is defined as "made up of distinct characteristics, qualities, or elements." Applicant's research, as its title demonstrates, is admittedly a study involving a diverse patient universe (INCLUSIVE: Irbesartan/HCTZ Blood Pressure Reductions in Diverse Patient Populations). The issue of descriptiveness in this case does not require that we find that "inclusive" and "diverse" are synonyms. While the terms "inclusive"

and "diverse" are not necessarily interchangeable, they are certainly not unrelated. For instance, evidence that a diverse population was included as part of the study supports an argument that the research was inclusive. In this case, if patients with metabolic syndrome or type 2 diabetes or those who were elderly, African American, or Hispanic/Latino were excluded, the study would not have included a diverse population and it would be unlikely to be considered an inclusive study. The fact that applicant's study included a diverse population supports the examining attorney's position that the study is described by the term "inclusive."

Finally, applicant argues (Brief at 8) that its "mark is an acronym for the subject matter of the clinical study on hypertensive pharmaceuticals, and is not descriptive." There are several problems with applicant's argument. First, it is not clear that applicant's term is an acronym. An acronym is defined as "a word formed from the initial letters or groups of letters of words in a set phrase or series of words as *Wac* from *Women's Army Corps* or *OPEC* from *Organization of Petroleum Exporting Countries*." *The Random House Dictionary of the English*

Language (unabridged) (2d ed. 1987).⁷ Applicant maintains (Brief at 7) that the term INCLUSIVE is an acronym composed of the highlighted letters from the following phrase: "Irbesarta**N**/HCTZ b**L**ood press**U**re reduction**S** in d**I**verse patient populations." Thus, it is composed of the first and last letter of the first word, the second letter of the next term (HCTZ), the second letter of the third word, the sixth letter of the fourth term, the last letter of the fifth term, and the third, fourth, and fifth letters of the third to the last term. Applicant's phrase with the letters highlighted looks more like a ransom note or a secret message rather than a traditional acronym.

This observation aside, we will assume for the purposes of this decision, that prospective purchasers will recognize applicant's term, after studying applicant's literature, as an acronym. However, even acronyms may be merely descriptive of an applicant's goods or services. See In re North American Free Trade Association, 43 USPQ2d 1282, 1288 (TTAB 1997) (The "evidence shows that NAFTA is an acronym for the North American Free Trade Agreement, and applicant's identified

⁷ We take judicial notice of this definition. University of Notre Dame du Lac v. J.C. Gourmet Food Imports Co., 213 USPQ 594, 596 (TTAB 1982), aff'd, 703 F.2d 1372, 217 USPQ 505 (Fed. Cir. 1983).

services are the promotion of trade and investment in the countries which are signatory to that trade agreement, and the providing of advice regarding investments with respect to the free trade area. Therefore, NAFTA is merely descriptive of applicant's services, and must be disclaimed"). The fact that applicant can make an acronym of a descriptive or generic term does not eliminate the term's descriptive or generic significance. For example, the term TIRE would remain generic for vehicle tires even if an applicant argued that it used the term as an acronym for **Traction Improvement - Response Enhancer**.

The term INCLUSIVE has a meaning that would be immediately understood by prospective purchasers or users of applicant's identified clinical services, i.e., that its services are comprehensive in nature. "The fact that applicant may be the first and possibly the only one to utilize this notation in connection with its services cannot alone alter the basic descriptive significance of the term." In re Gould, 173 USPQ 243, 245 (TTAB 1972).

Decision: The examining attorney's refusal to register under Section 2(e)(1) of the Trademark Act is affirmed.