

UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO: 75/781056

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MARK: ORPHAN MEDICAL

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Please provide in all correspondence:

1. Filing date, serial number, mark and applicant's name.
2. Date of this Office Action.
3. Examining Attorney's name and Law Office number.
4. Your telephone number and e-mail address.

RE: Serial Number 75/781056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	ORPHAN MEDICAL INC.	:	BEFORE THE
Trademark:	ORPHAN MEDICAL	:	TRADEMARK TRIAL
Serial No:	75781056	:	AND
Attorney:	Stephen R. Baird	:	APPEAL BOARD
Address:	Winthrop & Weinstein, P.A. Suite 3500 225 South Sixth Street Minneapolis, MN 55402-4629	:	ON APPEAL

EXAMINING ATTORNEY'S APPEAL BRIEF

Applicant has appealed the Trademark Examining Attorney's final refusal to register the term "ORPHAN MEDICAL" for a "housemark for pharmaceutical preparations for the prevention, treatment and aiding in the treatment of human and animal conditions, illnesses and

diseases" on the grounds that the mark is merely descriptive within the meaning Section 2(e)(1) of the Trademark Act, 15 U.S.C. §1052(e)(1) and had not acquired distinctiveness under Section 2(f) of the Trademark Act, 15 U.S.C. §1052(f).

I. FACTS

On August 20, 1999, the applicant originally applied for registration on the Principal Register for the mark "**ORPHAN MEDICAL**" for "pharmaceutical preparations for the prevention, treatment and aiding in the treatment of human and animal conditions, illnesses and diseases." In an initial review of the application, the trademark examining attorney believed that the identification of goods required clarification and that "**medical**" should be disclaimed. Upon further review of the application however, the Trademark Examining Attorney withdrew the disclaimer requirement and determined that the applicant's composite mark was merely descriptive of the goods.

While considering the applicant's subsequent 2(f) claim, the Trademark Examining Attorney found that given the nature of the mark, the attached evidence was insufficient to allow registration under Section 2(f) as well. Registration was finally refused on July 16, 2002 because the description of goods was still indefinite and because the mark was merely descriptive and had not acquired distinctiveness as an indicator of source. While the identification of goods requirement was withdrawn on April 18, 2003, the remainder of the applicant's Motion for Reconsideration was denied. This appeal, timely filed, follows the Trademark Examining Attorney's final refusal to register and the partial denial of the applicant's Motion for Reconsideration.

II. OBJECTION TO NEW EVIDENCE

Initially, the applicant seeks to enter new evidence into the record to show that the mark "**ORPHAN MEDICAL**" is not merely descriptive. Labeled in the applicant's appeal brief as

"Exhibit A," the new evidence appears to be a dictionary page from The American Heritage Dictionary of The English Language (3rd Edition). However, the Trademark Examining Attorney objects to the applicant's inclusion of any additional evidence with its appeal brief for the following reasons.

In pertinent part, 37 C.F.R. Section 2.142(d) clearly states:

The record in the application should be complete prior to the filing of an appeal. The Trademark Trial and Appeal Board will ordinarily not consider additional evidence filed by the appellant or by the examiner after the appeal is filed. After an appeal is filed, if the appellant or the examiner desires to introduce additional evidence, the appellant or the examiner may request the Board to suspend the appeal and to remand the application for further examination.

The applicant has not complied with these requirements; thus, the applicant's new evidence should not be considered a part of the record.

III. ARGUMENT

A. THE APPLICANT'S MARK, "ORPHAN MEDICAL" FOR A "HOUSEMARK FOR PHARMACEUTICAL PREPARATIONS FOR THE PREVENTION, TREATMENT, AND AIDING IN THE TREATMENT OF HUMAN AND ANIMAL CONDITIONS, ILLNESSES, AND DISEASES" IS MERELY DESCRIPTIVE WITHIN THE MEANING OF SECTION 2(e)(1) OF THE TRADEMARK ACT, 15 U.S.C. §1052 (e)(1).

A mark is merely descriptive under Trademark Act Section 2(e)(1), 15 U.S.C. §1052(e)(1), if it describes an ingredient, quality, characteristic, function, feature, purpose or use of the relevant goods or services. *In re Gyulay*, 820 F.2d 1216, 3 USPQ2d 1009 (Fed. Cir. 1987). Also, it is not necessary that a term describe all of the purposes, functions, characteristics or features of the goods or services to be merely descriptive. It is enough if the term describes one attribute of the goods or services. *In re H.U.D.D.L.E.*, 216 USPQ 358 (TTAB 1982); TMEP §1209.01(b).

In addition, a mark that combines descriptive terms may be registrable if the composite creates a unitary mark with a separate, nondescriptive meaning. However, if each component

retains its descriptive significance in relation to the goods or services, the combination results in a composite that is itself descriptive. *In re Tower Tech, Inc.*, 64 USPQ2d 1314 (TTAB 2002).

Here, **ORPHAN MEDICAL** is merely descriptive of a “housemark for pharmaceutical preparations for the prevention, treatment and aiding in the treatment of human and animal conditions, illnesses and diseases” and is so descriptive that the mark has not acquired distinctiveness or secondary meaning.

First, it must be noted that the Trademark Examining Attorney *never* refused the entire mark as a generic name or reference for the goods described in the application. Whether **ORPHAN MEDICAL** is a generic designation has *never* been at issue, and therefore it is not mandatory for the Trademark Examining Attorney to show that the relevant public or third party users refer to the applicant’s genus of goods as **ORPHAN MEDICAL** to deny registration under Section 2(e)(1) or Section 2(f). Ultimately however, the fact that a term or phrase is not found in the dictionary is not controlling on the question of registrability. *In re Gould Paper Corp.*, 834 F.2d 1017, 5 USPQ2d 1110 (Fed. Cir. 1987).

With that in mind, “**orphan**” refers to drugs or pharmaceuticals that combat certain rare diseases or conditions. While there may not be an actual dictionary definition for **ORPHAN MEDICAL** as a whole, according to one online dictionary, “**orphan drugs**” are defined as “drugs that treat rare diseases and conditions for which the manufacturer receives special tax credits and marketing rights as an incentive to develop the drug.” In addition, an entry from the On-line Medical Dictionary stated in pertinent part, that an “**orphan drug**” is a “pharmaceutical that has been abandoned or neglected during its development because it is seen as having only limited potential for profit.”

Understanding the benefit of producing “**orphan drugs**,” Congress enacted an “*Orphan Drug*” law and since 1983, at least two hundred thirty eight (“238”) “**orphan drugs**” have been

approved for treatment.¹ In further support, the examining attorney attached articles evidencing the use of “*orphan*” in the pharmaceutical industry. For example, note the following excerpts from three different articles:

- As a designated **Orphan Drug**, orBEC^(TM) is eligible for tax benefits based upon clinical development costs, as well as assistance from the FDA in guiding the drug through the regulatory approval process.
- Although **orphan drugs** need to be studied in the same way as regular products, one problem...is that even fairly common adverse events will not be detected....
- "Our approval reflects FDA's goal of making safe and effective treatments to improve lives available as rapidly as possible, in this case through our critically important **orphan drugs** program."

Moreover, in an attempt to assist with the approval process, the Food and Drug Administration (“FDA”) established the Office of **Orphan** Products Development. The FDA web page, found at <http://www.fda.gov/orphan/designat/faq/htm>, even provides relevant information regarding “**orphan** products” and states that “[w]hen submitting a request for **orphan** designation, the sponsor must submit the original and one copy.” Therefore, “**orphan**” clearly denotes a specific type or category of drug.

In addition, the determination of whether a mark is merely descriptive is considered in relation to the identified goods, not in the abstract. *In re Polo International Inc.*, 51 USPQ2d 1061 (TTAB 1999). As such, the applicant’s promotional materials also state that its preparations are used to combat rare conditions and diseases. The applicant even promotes its product line and services as being “**DEDICATED TO PATIENTS WITH UNCOMMON DISEASES.**” As such, the applicant’s goods also fit within the meaning of an “**orphan drug.**”

Since “**orphan**” refers to a class of pharmaceuticals or drugs and the relevant public would understand this term to refer to the class or genus of goods at issue, “**orphan**” is incapable of

¹ Pharma Marketletter, April 11, 2003, “The Future of Orphan Drugs: FDLI Meeting.”

indicating a particular source for the applicant's goods. *In re Merrill Lynch*, 828 F.2d at 1569, 4 USPQ2d at 1142.

Like "orphan," "medical" is widely used in the pharmaceutical and prescription drug industry as well. By definition, "medical" means "of or relating to the practice of medicine" or "requiring treatment by medicine." As the applicant's goods are used to treat various illnesses and diseases, they are clearly related to the practice of medicine. In addition, as the attached registrations revealed, the Office disclaims "*medical*" from registered marks that identify pharmaceutical preparations and related services. Indeed, "medical" is even disclaimed from the *applicant's two registrations* containing **ORPHAN MEDICAL** for services related to prescription drugs. *See also U.S. Registrations Nos. 2427341 and 2012249 with "medical" disclaimed.*

Furthermore, other third party manufacturers of prescription drugs routinely describe their pharmaceuticals as "medical preparations." For example, the following third party registrations incorporate "medical" in the common commercial name for the goods:

PHARMAGENESIS (U.S. Reg. No. 1871803):	pharmaceutical and medical preparations...
LIVOGARD (U.S. Reg. No. 2375678):	pharmaceutical and medical preparations...
MARS (U.S. Reg. No. 2379078):	pharmaceutical and medical preparations...
SITE RELEASE (U.S. Reg. No. 1192702):	pharmaceutical and medical preparations
THE MEASURE OF ... (U.S. Reg. No. 1322918):	full line of medical preparations
NOVAG (U.S. Reg. No. 2351389):	medical preparations for controlling blood pressure; medical preparations for the treatment of gastric dyspepsia

In addition, other previously attached articles from the Lexis/Nexis® database provided the following usage of "medical" as well:

- This is because she has been specifically engineered to manufacture proteins for use in **medical** drugs like clot busters, another source of income for Nexia.
- Also, Israel has developed **medical** drugs in cancer treatments.
- The institute's researchers also work to develop new **medical** drugs.

It is therefore apparent that others commonly use "**medical**" in referencing preparations that treat diseases or conditions. As such, protection of "**medical**" would deprive competitors and other third party users of an apt description of their goods. Plus, "**medical**" is so frequently used that consumers are unlikely to perceive the term when used in the manner of a trademark as indicating source or origin. *No Nonsense Fashion, Inc. v. Consolidated Foods Corp.*, 226 USPQ 502 (TTAB 1985). And keep in mind that a term need not be a noun to be generic. *Miller Brewing Co. v G. Heileman Brewing Co.*, 561 F.2d 75, 80, 195 USPQ 281, 285 (7th Cir. 1977), *cert. denied*, 434 U.S. 1025, 196 USPQ 592 (1978); TMEP §1209.01(c)(ii).

As each component in the applicant's mark retains its highly descriptive significance in relation to the applicant's pharmaceutical preparations, the resulting composite is also descriptive and the Section 2(e)(1) refusal is warranted.

Turning to the applicant's arguments, the examining attorney must consider descriptiveness in relation to the relevant goods. The fact that "*orphan*" may have different meanings in another context is not controlling on the question of descriptiveness. *In re Bright-Crest, Ltd.*, 204 USPQ 591 (TTAB 1979). TMEP §1209.03(e). Also, the fact that an applicant may be the first and only user of a merely descriptive or generic designation does not justify registration if the term is merely descriptive. *In re National Shooting Sports Foundation, Inc.*, 219 USPQ 1018 (TTAB 1983). TMEP §1209.03(c).

More fundamentally, trademark rights are not static, and eligibility for registration must be determined on the basis of the facts and evidence in the record at the time registration is sought. A term that was once arbitrary or suggestive may lose its distinguishing and origin denoting

characteristics through use in a descriptive sense over a period of time, and come to be regarded by the purchasing public as nothing more than a descriptive designation. *In re Digital Research, Inc.*, 4 USPQ2d 1242, 1243 (TTAB 1987). Thus, the fact that the applicant owns two registrations for similar marks that were registered in July of 1994 and July of 1995 does not guarantee registration of **ORPHAN MEDICAL** for pharmaceutical preparations.

Next, the applicant asserts that since U.S. Registration Nos. 1,906,107 (**ORPHAN MEDICAL** and design with a disclaimer of **MEDICAL**) and 1,843,925 **ORPHAN MEDICAL** in typed form with a disclaimer of **MEDICAL**) have achieved "incontestable status," that the mark contained in the current application for related goods should not be refused as merely descriptive under Section 2(e)(1) of the Trademark Act.

However, both the Court of Appeals ("CAFC") for the Federal Circuit and the TTAB have consistently held that in *ex parte* examination, each application stands on its own merits and must be evaluated on those merits even if the application involves a term that has been previously registered and given incontestable status under Section 15.

Continuing, the relevant statute states that the incontestability provided by law applies specifically to *use* but excludes the registration procedures at the United States Patent and Trademark Office. 15 U. S.C. §1056. Hence, the only thing that becomes incontestable is the right of the registrant to *use* the mark for the good or services for which the mark is registered. *In re Merrill Lynch, Pierce, Fenner, & Smith Inc.*, 4 USPQ2d 1141 (Fed. Cir. 1987).

Moreover, the TTAB has also held that the incontestable status of a registration in an *ex parte examination* does not alter the analysis of a later application for a similar mark. *In re BankAmerica Corporation*, 231 USPQ 873 (TTAB 1986). In this decision, the TTAB further reiterated its stance that "each application for registration of a mark for particular goods or services must be separately evaluated." *Id* at 875-876. Viewing the opinion *In Strang Corp. v. The Stouffer*

Corp., 16 USPQ2d 1309 (TTAB 1309, 1311), it is evident at this point that incontestability has no application to the *ex parte* examination process.

Given the merits of this case and the fact that each component retains its descriptive significance in relation to pharmaceutical preparations, the Trademark Examining Attorney finds that "ORPHAN MEDICAL" is merely descriptive and registration must be refused under Section 2(e)(1) of the Trademark Act.

B. THE APPLICANT'S MARK, "ORPHAN MEDICAL" IS SO HIGHLY DESCRIPTIVE THAT THE MARK HAS NOT ACQUIRED DISTINCTIVENESS UNDER SECTION 2(f).

In the alternative, the applicant argues that the mark has acquired distinctiveness under Section 2(f). However, given the facts of the case and a review of the applicant's supporting evidence, the mark has not acquired distinctiveness under Section 2(f).

First, the burden of proving that a mark has acquired distinctiveness is on the applicant. *In re Meyer & Wenthe, Inc.*, 267 F.2d 945, 122 USPQ 372 (C.C.P.A. 1959). The applicant therefore must establish that the purchasing public has come to view the typed wording or phrase **ORPHAN MEDICAL** as an indicator of origin.

While the applicant has stated that between 1996 and 2001 it has generated over \$28 million in revenue based upon the sale of its products with the **ORPHAN MEDICAL** mark, allegations of sales and advertising expenditures cannot per se establish that a term has acquired significance as a mark. It is still necessary to examine the advertising material to determine how the term is used, the commercial impression created by such use, and the significance the term would have to prospective purchasers. The ultimate test in determining acquisition of distinctiveness under Trademark Act Section 2(f) is not applicant's efforts, but applicant's success in educating the public to associate the claimed mark with a single source. *In re Packaging Specialists, Inc.*, 221 USPQ 917 (TTAB 1984).

Moreover, the kind and amount of evidence necessary to establish that a mark has acquired distinctiveness in relation to goods or services depends on the *nature* of the mark and the circumstances surrounding the use of the mark in each case. *Yamaha Int'l Corp. v. Hoshino Gakki Co. Ltd.*, 840 F.2d 1572, 6 USPQ2d 1001 (Fed. Cir. 1988).

As such, the specimens and promotional materials showing the **ORPHAN MEDICAL** house mark generally contain the wording as well as a stylized design element. In fact, on the **ANTIZOL®** and the **BUSULFEX®** boxes as well as the printed matter for ordering the applicant's products, the phrase **ORPHAN MEDICAL** is accompanied by the design element. Prominent in relation to the overall commercial impression of the mark that appears on the packaging, the public arguably associates not just the words, but the words *and* the design as the single source indicator for the goods.

Also, while the attached affidavits or declarations that assert recognition of the mark as a source indicator are relevant in establishing acquired distinctiveness, proof of distinctiveness requires more than proof of the existence of a relatively small number of people who associate a mark with the applicant. *In re The Paint Products Co.*, 8 USPQ2d 1863, 1866 (TTAB 1988). These types of statements are also subject to bias and are generally collected from those who have dealt with or have a relationship with the applicant and not from the average, ordinary consumer.

The major bar to Section 2(f) registration of the applicant's mark however is the nature of the mark itself. Again, "*orphan*" is highly descriptive if not generic as applied to the goods and virtually incapable of distinguishing them from others. Indeed, "**orphan**" is repeatedly used to designate a particular class of drug ("**orphan drugs**"). In addition, "**medical**" is widely used and has a clear, recognizable meaning. And as the attached articles provided, pharmaceutical preparations are often referred to as "*medical drugs*."

Reliance upon the applicant's prior registrations as proof of distinctiveness is inadequate as well since "*medical*" is disclaimed in both registrations. Moreover, U.S. Registration No. 1906107 contains a design element which evokes a different commercial impression from the mark at hand and both of the applicant's registrations identify services for prescription and over the counter drugs and not the actual goods or preparations.

Therefore, given the nature of the applicant's mark and the evidence regarding the mere descriptiveness of "**ORPHAN MEDICAL**," the applicant's evidence fails to establish that its mark has acquired distinctiveness under Section 2(f).

IV. CONCLUSION

The applicant's mark is merely descriptive of the identified goods under Section 2(e)(1), 15 U.S.C. §1052(e)(1). Furthermore, given the nature and usage of the terms "**orphan**" and "**medical**," the applicant's supporting evidence is insufficient to support a claim of acquired distinctiveness. For the foregoing reasons, the Section 2(e)(1) refusal to register should be affirmed.

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