

**EXHIBIT**

TTAB

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

In Re Application of Orphan Medical, Inc.

Serial No.: 75/781,056

Filed: August 20, 1999

Mark: ORPHAN MEDICAL

Examining Attorney:  
Brain Brown  
Law Office 105



01-21-2003

U.S. Patent & TMOs/TM Mail Rcpt. Dt. #40

**BOX TTAB FEE**  
Commissioner for Trademarks  
2900 Crystal Drive  
Arlington, Virginia 22202-3513

To the Trademark Trial and Appeal Board:

Applicant hereby appeals to the Trademark Trial and Appeal Board from the July 16, 2002 final refusal of the Examining Attorney to allow registration of the subject mark in the above-identified application.

A check in the amount of \$100 is enclosed herewith to cover the required fee. If this amount is for any reason insufficient, the Commissioner is authorized to draw on the Deposit Account of Fish & Richardson, Account No. 01-1050 with reference to 11318-045001.

02/12/2003 KGIBBONS 00000075 75781056

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**CERTIFICATE OF MAILING BY FIRST CLASS MAIL**

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Trademarks, 2900 Crystal Drive, Arlington, VA 22202-3513.

January 16, 2003

Date of Deposit

*Julie Lindner*

Signature

*Julie Lindner*

Typed or Printed Name of Person Signing Certificate

Respectfully submitted,

Date: January 16, 2003

Marsha Stolt  
Marsha Stolt, Esq.  
Fish & Richardson P.C., P.A.  
3300 Dain Rauscher Plaza  
60 South Sixth Street  
Minneapolis, Minnesota 55402  
(612) 337-2579



01-21-2003

U.S. Patent & TMOs/TM Mail Rcpt. Dt. #40

Attorney Docket No. 11318-045001

CERTIFICATE OF MAILING  
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Trademarks, BOX RESPONSES – NO FEE, 2900 Crystal Drive, Arlington, VA 22202-3513, on the date below:

1-16-03  
Date

Julie Gindner  
Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Orphan Medical, Inc.

Serial No.: 75/781,056

Examiner: Brian Brown  
Trademark Attorney  
Law Office 105

Mark: **ORPHAN MEDICAL**

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BOX RESPONSES – NO FEE  
Commissioner for Trademarks  
2900 Crystal Drive  
Arlington, Virginia 22202-3513

**REQUEST FOR RECONSIDERATION**

This responds to the Office Action dated July 16, 2002, in which the Examining Attorney continues to object to the identification of goods as being “vague” and “lack[ing] clarity.” Applicant respectfully requests that the Examining Attorney accept Applicant’s present identification of goods because, as shown below, the identification is in conformance with Trademark Office policy.

In addition, the Examining Attorney finally refused registration of Applicant’s mark under Section 2(e)(1) of the Trademark Act, 15 U.S.C. 1052(e)(1), because the Examining Attorney continues to believe that the Applicant’s mark, ORPHAN MEDICAL, is merely descriptive of the goods identified in the Application, namely, a “house mark for pharmaceutical preparations for the prevention, treatment, and aiding in the treatment of human and animal conditions, illnesses, and diseases.” Applicant

respectfully requests that the Examining Attorney reconsider and withdraw his refusal because, as the newly offered evidence and arguments further support, Applicant's mark is not merely descriptive of Applicant's goods.

The Examining Attorney is advised that Applicant has filed concurrently with this Request for Reconsideration a Notice of Appeal with the Trademark Trial and Appeal Board.

**I. Applicant's Identification of Goods is Proper and Consistent with Trademark Office Practice**

The Examining Attorney maintains that the Applicant must "specify the condition or disease to be treated and the type of animal for whom treatment is proposed." When a trademark is used as a house mark in connection with pharmaceutical preparations, the Trademark Office accepts identifications of goods that do not specify the conditions to be treated or the particular type of animal for whom treatment is proposed. Attached hereto as Exhibit 1 are true and correct printouts from the Patent and Trademark Office's Trademark Electronic Search System database of a number of registrations for house marks used in connection with pharmaceutical preparations. As Exhibit 1 shows, it is customary that registrations for house marks used in connection with pharmaceutical preparations do not specify the condition to be treated. In addition, Exhibit 1 shows that when house marks are at issue, the type of animal for whom treatment is proposed is generally not identified, and when it is, the animal is simply listed as "human" and/or "animal," just like in the present application. Exhibit 1 includes the following registrations, among others:

- Registration No. 2,648,565 issued November 12, 2002 and covering "pharmaceutical preparations, namely, a house mark for a full line of pharmaceutical preparations."

- Registration No. 2,638,080 issued October 22, 2002 and covering “house mark for a full line of pharmaceutical preparations.”
- Registration No. 2,605,657 issued August 6, 2002 and covering “house mark for a full line of pharmaceutical preparations.”
- Registration No. 2,534,124 issued January 29, 2002 and covering “house mark for a full line of pharmaceuticals pharmaceutical preparations.”
- Registration No. 2,588,792 issued July 2, 2002 and covering “a house mark for a full line of medicinal and pharmaceutical preparations for the treatment of human beings and animals.”
- Registration No. 2,583,190 issued June 18, 2002 and covering “house mark for a full line of pharmaceutical products for human consumptions.”
- Registration No. 2,528,777 issued January 15, 2002 and covering “house mark used in association with a full line of prescription and non-prescription pharmaceutical and medical goods.”
- Registration No. 2,499,673 issued October 23, 2001 and covering “house mark for a full line of pharmaceutical preparations.”
- Registration No. 2,387,161 issued September 19, 2000 and covering “pharmaceutical preparations, namely, a house mark for a full line of pharmaceutical preparations.”
- Registration No. 2,353,386 issued May 30, 2000 and covering “house mark for a full line of pharmaceutical and chemical preparations for medical purposes.”
- Registration No. 2,507,459 issued November 13, 2001 and covering “house mark for a full line of medicinal and pharmaceutical preparations for the treatment of human beings and animals.”
- Registration No. 2,189,503 issued September 15, 1998 and covering “house mark for a full line of pharmaceutical preparations.”
- Registration No. 2,293,963 issued November 23, 1999 and covering “house mark for pharmaceutical preparations.”
- Registration No. 2,317,044 issued February 8, 2000 and covering “house mark for a full line of pharmaceutical preparations.”
- Registration No. 2,213,879 issued December 29, 1998 and covering “house mark for a line of prescription and non-prescriptions pharmaceutical preparations.”

- Registration No. 2,128,170 issued January 13, 1998 and covering “house mark for a line of prescription and non-prescription pharmaceutical preparations.”
- Registration No. 2,120,388 issued December 9, 1997 and covering “house mark for a line of pharmaceuticals.”
- Registration No. 1,683,426 issued April 14, 1992 and covering “house mark for line of pharmaceutical preparations.”
- Registration No. 1,988,757 issued July 23, 1996 and covering “house mark for a full line of pharmaceutical preparations.”
- Registration No. 1,851,282 issued August 30, 1994 and covering “house mark for a full line of pharmaceutical preparations.”

The Trademark Office recognizes that it would be inefficient to require an applicant to specify all the conditions the applicant’s pharmaceuticals are used to treat when the mark at issue is a house mark. To be sure, if that were not the case, the identification of goods contained in house mark registrations owned by large pharmaceutical companies would be pages long. In addition, each time a pharmaceutical company offered a new product that treated a condition previously untreated by the company’s products, the company would be forced to file a trademark application for the product mark and one for the house mark, if it wanted the benefits of a federal registration for both marks. By allowing applicants to describe their goods as “a full line of pharmaceutical products” and other similarly broad descriptions, the Trademark Office validates what is already the common practice in this and other industries of applying a house mark to each and every product that it sells, in addition to the individual mark of the single product. This practice eliminates the inefficiency and expense of forcing a Registrant to file a new application every time a single product is added to its line.

In light of the numerous registrations containing identification of goods such as “a full line of pharmaceutical preparations” and the like, and the obvious policy reasons behind allowing such broad identifications, the identification of goods contained in the instant application – namely, “house mark for pharmaceutical preparations for the prevention, treatment, and aiding in the treatment of human and animal conditions, illnesses, and diseases” – is proper. Accordingly, Applicant respectfully requests that the Examining Attorney accept the present identification of goods.

## **II. The ORPHAN MEDICAL Composite Mark Is Not Merely Descriptive of Pharmaceutical Preparations**

ORPHAN MEDICAL is a composite mark that is not merely descriptive of pharmaceutical preparations. While the term “orphan” may be used by a limited segment of the scientific community to refer to characteristics of certain drug products, the term itself is unique, clever, and witty. The term “orphan,” as generally used, refers to a parentless child who is often overlooked and deprived of advantage. The term “orphan,” when used in connection with drugs, plays on the generally understood meaning of “orphan” and refers to drugs used to treat rare, uncommon, or overlooked diseases. These diseases, like the orphan child, are underserved and needing attention. Although the term “orphan” has been adopted by a segment of the scientific community to refer to characteristics of drugs, the word does not possess the inherent descriptive qualities that merely descriptive words do because the word itself when used in connection with drugs is witty and clever. It takes thought and imagination, or at least an insider’s knowledge of the pharmaceutical industry, to understand what “orphan” refers to in connection with drugs. As such, even though the term may be used to refer to characteristics of certain drug products, the word is not an inherently merely descriptive word.

When coupled with the term “MEDICAL,” the term ORPHAN takes on a suggestive connotation. This is not only due to the clever meaning behind the word “orphan,” but also due to the vague nature of the term “medical” and the fact that “medical” is not generally connected with pharmaceutical preparations. “Medical” is not a term frequently used by pharmaceutical companies or on pharmaceutical products. Rather, “medical” refers to, as noted by the Examining Attorney, “the practice of medicine.” The practice of medicine is conducted by physicians and other healthcare providers, not pharmaceutical companies. Notably, Applicant is not seeking a registration for the mark ORPHAN DRUGS used in connection with pharmaceutical preparations. The Applicant’s mark is ORPHAN MEDICAL, which is not merely descriptive of pharmaceutical preparations, but is rather suggestive and, as such, entitled to registration on the Principle Register.

### **III. Applicant’s Submits Further Evidence of Distinctiveness**

The Examining Attorney has not attached a single piece of evidence showing the words “orphan medical” being used to describe pharmaceutical preparations. This omission is telling. Applicant conducted a search of the Nexis database for recent news articles containing the term “orphan” appearing within three words of the term “medical.” Attached hereto as Exhibit 2 are printouts of the 27 news articles containing “orphan” within three of “medical” that were published between December 14, 2002 and January 14, 2003. Of these 27 news articles, 25 refer to the Applicant. In the remaining two news articles, the word “orphan” is referring to an orphan child and “medical” is used in connection with the words “worker” or “aid.” Not one article uses the words “orphan medical” to describe pharmaceutical products. These news articles are further support



that the designation ORPHAN MEDICAL is not merely descriptive and is in fact distinctive of Applicant and the pharmaceutical products sold by Applicant.

Likewise, a search of the Internet for the term “ORPHAN MEDICAL” reinforces the fact that ORPHAN MEDICAL mark is not merely descriptive and is distinctive. Attached hereto as Exhibit 3 are the first 50 responses to an Internet search for the words “orphan medical” using the Google search engine. As Exhibit 3 shows, every one of the first 50 articles retrieved in response to the search shows the words “Orphan Medical” referring to Applicant. The term ORPHAN MEDICAL, as further demonstrated by Exhibits 2 and 3, primarily refers to Applicant and the products offered by Applicant.

Over the recent past, Orphan Medical has received vast coverage in the media. Applicant is the manufacturer of the brand name drug XYREM, which is used to treat complications caused by narcolepsy. One of the ingredients in the XYREM pharmaceutical is gamma hydroxybutyrate, or GHB, which is a controlled substance that is also known as the “date rape” drug. Because XYREM is very effective in treating narcolepsy and the disease’s related symptoms, the Food and Drug Administration approved XYREM for use in July 2002. The FDA’s approval of the drug was widely publicized given that the drug contains GHB. Attached hereto as Exhibit 4 are several of the many news articles available on Internet discussing Orphan Medical and its XYREM product. The FDA’s approval of XYREM catapulted Orphan Medical into the national spotlight. The articles attached as Exhibit 4 show the commercial strength the Orphan Medical name has achieved and further demonstrate that ORPHAN MEDICAL is distinctive of Applicant and its pharmaceutical products.

To further support this convincing circumstantial evidence of distinctiveness, Applicant attaches hereto as Exhibit 5 declarations from two doctors and a pharmacist attesting to the fact that ORPHAN MEDICAL, as used on pharmaceutical preparations, serves as a distinctive source identifier for Applicant. As the Examining Attorney will read, these professionals view ORPHAN MEDICAL as a source indicator, associate the mark with the Applicant, and are not aware of any other company using the words “Orphan Medical” to promote, identify, or describe its pharmaceutical preparations. These declarations are direct evidence that Applicant’s mark is distinctive.

**IV. Applicant Has Submitted Overwhelming Evidence of Acquired Distinctiveness**

Applicant has already made several compelling showings that its ORPHAN MEDICAL mark has acquired distinctiveness. Applicant submitted a claim of acquired distinctiveness based on Applicant’s substantially exclusive and continuous use of the ORPHAN MEDICAL mark in commerce for at least five years, and has claimed acquired distinctiveness based on the prior incontestable registration of the mark ORPHAN MEDICAL used in connection with the distribution of drugs, among other services (Registration No. 1,843,925). Applicant advised the Examining Attorney that the marks depicted in this prior registration and the instant application are the “same” because the marks are identical and they are both used in connection with products and services that are substantially related. As noted in Applicant’s January 14, 2002 response, the instant application covers products and Registration No. 1,843,925 covers the distribution of those products. Despite this remarkably close connection between the products and services at issue, the Examining Attorney refused to accept ownership of incontestable Registration No. 1,843,925 as evidence of acquired distinctiveness.

Applicant also claimed acquired distinctiveness based on its ownership of prior incontestable Registration No. 1,906,107 for the mark ORPHAN MEDICAL and Design, registered and used in connection with “research and development of prescription and over the counter drugs for others.” Although the research and development services relate to pharmaceutical preparations and pharmaceutical preparations are identified in the present application, the Examining Attorney again refused to accept ownership of incontestable Registration No. 1,906,107 as evidence of acquired distinctiveness.

As further evidence that ORPHAN MEDICAL has become distinctive of Applicant pharmaceutical preparations, Applicant submitted the declaration of Applicant’s Chairman and Chief Executive Officer, John H. Bullion. In the declaration, Mr. Bullion advised the Examining Attorney that (i) Applicant is a publicly traded corporation, (ii) between 1996 and June 30, 2001, Applicant generated over \$28 million from sales of pharmaceutical products sold under the ORPHAN MEDICAL house mark, and (iii) between 1996 and June 30, 2001 Applicant spent over \$16 million on advertising and marketing the pharmaceutical products sold under the ORPHAN MEDICAL house mark. In addition, Applicant attached to Mr. Bullion’s declaration specimens showing the prominent manner in which the ORPHAN MEDICAL house mark appears on Applicant’s packaging, product labels, and informational inserts that accompany Applicant’s pharmaceutical products. With Mr. Bullion’s declaration, Applicant also submitted specimens showing the prominent manner in which the ORPHAN MEDICAL house mark appears on Applicant’s promotional and educational materials. Despite this persuasive evidence of acquired distinctiveness, the Examining Attorney still refused to accept Applicant’s Section 2(f) claim.

Now Applicant submits news articles taken from the Nexis database, search results of an Internet search for "Orphan Medical," and articles found in the press discussing the Applicant and its well-known XYREM drug. The newly submitted evidence taken from the Internet and the Nexis database further confirms that the words "Orphan Medical" are not merely descriptive and in fact are not used to describe any type of pharmaceutical product.

Finally, Applicant has now also submitted direct evidence that ORPHAN MEDICAL is a distinctive trademark of Applicant in the form of declarations from two doctors and a pharmacist confirming that when they encounter the words "ORPHAN MEDICAL" on or in connection with pharmaceutical preparations, they view the words as an indication of source and associate the words solely with Orphan Medical. The Declarations also confirm that these parties are not aware of any other pharmaceutical company using the "ORPHAN MEDICAL" mark and that they are not aware of any other pharmaceutical preparation offered under the "ORPHAN MEDICAL" mark. The combined weight of this evidence is more than sufficient to establish that Applicant's mark has acquired distinctiveness through its extensive and exclusive use in connection with pharmaceutical products.

### **CONCLUSION**

ORPHAN MEDICAL is a composite mark that is not inherently descriptive of pharmaceutical preparations. To the extent that the word "ORPHAN" has become descriptive of pharmaceutical preparations, only a small segment of the population is aware of the descriptive meaning of the word, while the market for Applicant's products includes the entire population of the United States and the rest of the world. Further, to

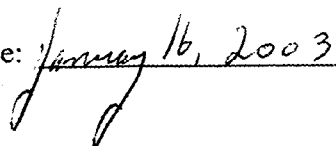
the extent the mark may be considered descriptive of Applicant's goods, the extensive evidence of Applicant's use of the words ORPHAN MEDICAL to solely refer to Applicant's products constitutes compelling evidence that the ORPHAN MEDICAL mark has acquired distinctiveness in connection with the pharmaceutical products offered by Applicant.


Applicant respectfully submits that the Examining Attorney's continued refusal of registration in light of this extensive evidence of acquired distinctiveness, as well as his continued refusal to accept Applicant's description of goods despite the numerous registrations issued for marks covering identical or substantially similar goods, are both unwarranted and contrary to the established practice of the Trademark Office.

Accordingly, Applicant respectfully requests that the Examining Attorney withdraw his objection to the identification of goods and withdraw his refusal of registration under Section 2(e)(1) of the Act and issue a Notice of Publication for the mark.

Respectfully submitted,

Date: January 16, 2003



  
Marsha Stolt, Esq.  
Joel D. Leviton, Esq.  
Attorneys for Applicant  
FISH & RICHARDSON P.C., P.A.  
3300 Dain Rauscher Plaza  
60 South Sixth Street  
Minneapolis, Minnesota 55402  
(612) 337-2579

# FISH & RICHARDSON P.C., P.A.



01-21-2003

U.S. Patent & TMO/TM Mail Rept. Dt. #40

3300 Dain Rauscher Plaza  
60 South Sixth Street  
Minneapolis, Minnesota  
55402

Telephone  
612 335-5070

Facsimile  
612 288-9696

Web Site  
www.fr.com

Frederick P. Fish  
1855-1930

W.K. Richardson  
1859-1951

January 16, 2003

## BOX TTAB FEE

Commissioner for Trademarks  
2900 Crystal Drive  
Arlington, Virginia 22202-3513

Re: ORPHAN MEDICAL

Applicant: Orphan Medical, Inc.

Serial No.: 75/781,056; Filing Date: August 20, 1999

Our Ref.: 11318/045001

Madam:

Enclosed for filing in connection with the above-referenced application please find the following:

1. Notice of Appeal;
2. Copy of Request for Reconsideration filed concurrently with the Patent and Trademark Office; and
3. Return postcard.

A check in the amount of \$100.00 is enclosed to cover the required fee. Should any additional fees be required the Assistant Commissioner for Trademarks is authorized to deduct said fees from Fish & Richardson Deposit Account No. 06-1050 with reference to 11318/045001.

Please date stamp and return the enclosed postcard to acknowledge receipt of these materials.

Very truly yours,

Marsha Stolt

## CERTIFICATE OF MAILING

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Trademarks, 2900 Crystal Drive, Arlington, Virginia 22202-3513.

1-16-03 Julie Pindner  
Date of Deposit Signature

BOSTON  
DELAWARE  
NEW YORK  
SILICON VALLEY  
SOUTHERN CALIFORNIA  
TWIN CITIES  
WASHINGTON, DC