BULKY DOCUMENTS

(Exceeds 300 pages)

Proceeding/Serial No: 91162,204

Filed: 9/8/05

Title: Ophan Medical, Inc.,

v.

ISTA PHARMACEUTICALS, INC.

Part 1 **of** 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Orphan Medical, Inc.,

Opposer,

v.

ISTA Pharmaceuticals, Inc.,

Applicant.

Opposition No.: 91,162,204

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313-1451, on

August 25, 2005
(Date)

Stacey R. Halpern

ISTA'S PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT

Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451

08-29-2005
U.S. Patent & TMOfc/TM Mail Rcpt Dt. #01

Dear Sir:

ISTA Pharmaceuticals, Inc. ("Applicant") respectfully moves the Trademark Trial and Appeal Board (the "Board") pursuant to Rule 56 of the Federal Rules of Civil Procedure for summary judgment in the above-referenced Opposition proceeding. A Memorandum in Support Applicant's Motion for Summary Judgment and the Declarations of Tom Mitro and Stacey R. Halpern are being filed concurrently herewith.[1]

Orphan Medical, Inc. ("Opposer") asserts in its Notice of Opposition that Applicant's mark XIBROM so resembles Opposer's XYREM mark that, when used on or in connection with the goods identified in Applicant's U.S. Trademark Application Serial No. 78/298,369, it is likely to cause confusion. Opposer also asserts that its mark is famous and that Applicant's application dilutes Opposer's mark.

However, there are no genuine issues of material fact in dispute which would preclude the Board from granting summary judgment in this proceeding. The only dispute in this proceeding is to the legal conclusion to

[1] Opposer's responses to Applicant's discovery requests are attached as Exhibit 2 to the Halpern Decl. As portions of Opposer's responses are designated "Confidential" and/or "Attorney's Eyes Only," such portions were redacted from the attached copies.

be drawn from the facts. Applicant will establish that the legal conclusion must be that there is **no** likelihood of confusion between the marks in issue. Applicant will also establish that the legal conclusion must be that Applicant's mark does not dilute Opposer's mark.

Specifically, when viewed in their entireties, the marks XIBROM and XYREM fundamentally differ in overall appearance and commercial impression. Moreover, the goods offered in connection with each mark are distinguishable and unrelated. In fact, the goods are not competitive with each other in any manner. Additionally, both parties' goods can only be obtained after they are selected and ordered by a physician and dispensed only by a pharmacist. These types of well-educated and highly-trained individuals are likely to be careful and discriminating in their selection of prescription pharmaceutical products. Moreover, both parties' goods are regulated by the Food and Drug Administration and cannot be sold to the average consumer without a prescription from a healthcare/medical professional. More importantly, unlike some pharmaceutical preparations, which can be filled at a consumer's local pharmacy or through mail order, Opposer has admitted that its XYREM products can **only be** distributed by means of one third-party pharmacy

As the function and purpose of the goods are dissimilar, a healthcare/medical professional would not prescribe a prescription pharmaceutical preparation if it was not appropriate for treating the patient's condition. As the conditions treated by Applicant's XIBROM product (ocular disorders) are unrelated to the conditions treated by Opposer's XYREM product (narcolepsy, fibromyalgia, insomnia and myositis), there is no likelihood of confusion.

Considering the differences in the marks, the differences in the functions and purposes of the goods, the highly specialized nature of both parties' goods, the sophistication and knowledge of the purchasers, and the fact that prescription pharmaceutical products are not purchased on impulse but only after careful consideration of the functions, purposes, and side effects of the drugs, there is no likelihood that consumers and potential consumers would think that the parties' products emanate from or are otherwise associated with or sponsored by the same source.

Additionally, given the differences in the marks, the channels of trade, the weakness of Opposer's mark, the undisputed facts demonstrate that Applicant's mark does not dilute Opposer's mark.

Therefore, Applicant respectfully submits that a grant of summary judgment based on no likelihood of confusion and no dilution in this proceeding is appropriate and requests that the Board enter such judgment in favor of Applicant and thereby dismiss Opposer's opposition against U.S. Trademark Application Serial No. 78/298,369.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 25, 2005

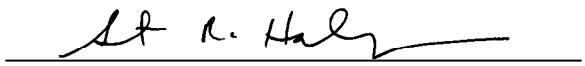
By: _____

Steven J. Nataupsky
Michael K. Friedland
Stacey R. Halpern
Tirzah Abé Lowe
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404
Attorneys for Applicant,
ISTA Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing **ISTA PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT** upon Opposer's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on August 25, 2005, addressed as follows:

Stephen R. Baird
Troy E. Arnlund
WINTHROP & WEINSTINE, P.A.
225 South 6th Street, Suite #3500
Minneapolis, MN 55402



Stacey R. Halpern

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

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August 25, 2005
(Date)

Stacey R. Halpern

MEMORANDUM IN SUPPORT OF ISTA PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT

Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451

I. INTRODUCTION

This is a trademark opposition brought by Orphan Medical, Inc. ("Opposer"), against ISTA Pharmaceuticals, Inc.'s ("Applicant") U.S. Application Serial No. 78/298,369 ("Applicant's Application") for the mark XIBROM ("Applicant's Mark") for "pharmaceutical preparations, namely, a topical preparation for the treatment of ocular disorders," ("Applicant's Goods").

In Opposer's Notice of Opposition, Opposer alleges that Applicant's Mark when used on or in connection with Applicant's Goods is likely to cause confusion or mistake as to source with Opposer's XYREM mark ("Opposer's Mark") in connection with "pharmaceutical preparations for the treatment of diseases of the central nervous system and a variety of conditions, symptoms, and diseases, namely, narcolepsy, fibromyalgia, insomnia and myositis and providing telephone support services to patients regarding the safe and appropriate use and distribution of medications used to treat sleep disorders; providing medical information via telephone and in the form of written educational materials to patients in connection with the safe and appropriate use and distribution of medication for the treatment of sleep disorders" (all of the foregoing goods and services collectively referred to hereinafter as "Opposer's Goods"). Opposer also alleges that Applicant's Mark dilutes the distinctive quality of Opposer's Mark.

The dispositive issues in this case are: (1) whether a likelihood of confusion exists between Applicant's Mark in connection with Applicant's Goods and Opposer's Mark in connection with Opposer's Goods; and (2) whether Applicant's Application dilutes Opposer's Mark.

Opposer's assertion of likelihood of confusion is unfounded. It is clear that the parties' respective marks are so significantly different in overall appearance and commercial impression as to completely avoid a likelihood of confusion. Furthermore, it is clear that Opposer's Goods and Applicant's Goods are non-competitive and unrelated. Additionally, Opposer's Goods are not sold through the same channels of distribution as Applicant's Goods. Moreover, the purchasers of both parties' goods are discerning and careful consumers. Finally, Opposer's mark is a weak mark and is only entitled to a narrow scope of trademark protection. Accordingly, there is no genuine issue of material fact as to a likelihood of confusion, and a grant of summary judgment for Applicant is appropriate in this instance.

Similarly, Opposer's assertion of dilution is also unfounded. The parties' respective marks are too different for any concern over dilution to properly arise. Moreover, Opposer has not and cannot demonstrate its mark is famous. Furthermore, the undisputed facts demonstrate that there has not been any blurring, tarnishment or any sort of lessening of the distinctiveness of Opposer's Mark. Nor, is there a likelihood that Applicant's mark will cause blurring, tarnishment or any sort of lessening of the distinctiveness of Opposer's Mark.

II. FACTUAL BACKGROUND

Applicant filed Applicant's Application with the U.S. Patent and Trademark office ("PTO") on September 10, 2003 seeking registration of Applicant's Mark for "pharmaceutical preparations, including, a topical preparation for the treatment of ocular disorders" based upon Applicant's bona-fide intention to use the mark in the United States. The only Office Action issued against Applicant's Application was a priority Office Action requesting amendments to the identification of goods (which amended the goods to "pharmaceutical preparations, namely, a topical preparation for the treatment of ocular disorders"). Accordingly, no prior pending applications or registrations, including any of the

registrations Opposer asserts in its Notice of Opposition, were cited as a bar to registration by the PTO Examining Attorney. Applicant's Application was published for opposition on August 11, 2004.

On September 16, 2004, Opposer filed a Notice of Opposition with the Trademark Trial and Appeal Board (the "Board") claiming that Applicant's use of the mark XIBROM on or in connection with Applicant's Goods was likely to cause confusion or mistake with Opposer's XYREM Mark. Furthermore, Opposer argues that purchasers and prospective purchasers are likely to mistakenly believe that Applicant's Goods are sponsored by, endorsed or approved by Opposer or are in some way affiliated, connected or associated with Opposer. Finally, Opposer alleges that Applicant's Mark dilutes the distinctive qualities of Opposer's Mark.

III. SUMMARY JUDGMENT STANDARD AND BURDEN OF PROOF

Summary judgment should be granted where, as here, it is shown that there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Federal Rule of Civil Procedure ("FRCP"), Rule 56(c). FRCP 56(c), in pertinent part, states that a summary judgment should be granted where, as here, "the pleadings, . . . answers to interrogatories, and admissions on file, together with the affidavits . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." These general principles of summary judgment apply under FRCP 56 to inter-parties proceedings before the Board. See, e.g., Sweats Fashions, Inc. v. Pannill Knitting Co., 833 F.2d 1560, 4 U.S.P.Q.2d 1793, 1797 (Fed. Cir. 1987).

Summary judgment is an appropriate method of disposing of an opposition in which there is no genuine issue of material fact on the question of likelihood of confusion or dilution. Kellogg Co. v. Pack'Em Enterprises, Inc., 14 U.S.P.Q. 2d 1545 (T.T.A.B. 1990) (add dilution cite). As the Federal Circuit stated in Pure Gold, Inc. v. Syntex (U.S.A.), Inc., 222 U.S.P.Q. 741, 743 (Fed. Cir. 1984):

> The basic purpose of summary judgment procedure is one of judicial economy -- to save the time and expense of a full trial when it is unnecessary because the essential facts necessary to decision of the issue can be adequately developed by less costly procedures, as contemplated the **FRCP** rules here involved, with a net benefit to society.

Likewise, summary judgment in an opposition proceeding is designed to save the time and expense of a

full opposition proceeding where there is no genuine issue as to any material fact. Bet Lock Corp. v. Schlage Lock Co., 413 F.2d 1195 (C.C.P.Q. 1969).

Applicant, as the moving party, has the burden of demonstrating that it is entitled to summary judgment. Celotex Corp. v. Catrett, 477 U.S. 317, 324-25 (1986). By meeting its burden of identifying undisputed facts, Applicant is entitled to relief. Opposer cannot respond merely by pointing to allegations or denials in the pleadings. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Instead, Opposer must submit specific facts showing that there is a genuine issue for trial. Id. at 587. In doing so, Opposer must present evidence from which a reasonable trier of fact might return a verdict in its favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249-250 (1986).

IV. THERE IS NO GENUINE ISSUE OF MATERIAL FACT ON THE QUESTION OF LIKELIHOOD OF CONFUSION

Likelihood of Confusion Test

15 U.S.C. § 1052(d), Section 2(d) of the Trademark Act, allows for registration of a mark unless the mark "so resembles a mark previously used in the United States by another and not abandoned, as to be likely, when used on or in connection with the goods of the applicant, to cause confusion, or cause mistake, or to deceive."

There is no rigid test for analyzing likelihood of confusion. However, T.M.E.P. § 1207.01 lists thirteen factors as relevant in determining the registrability of a mark over an allegedly confusingly similar mark. Of those thirteen factors, the most important factors in this matter are: (1) the differences in the marks when viewed in their entireties as to overall appearance and commercial impression; (2) the dissimilarity and nature of the goods as described in the application and registration or in connection with which a prior mark is used; (3) the conditions under which, and the buyers to whom sales are made, i.e., impulse vs. careful, sophisticated purchasing; and (4) the weakness of the mark. See Application of E.I. DuPont DeNemours & Co., 476 F.2d 1357, 177 U.S.P.Q. 563, 567 (C.C.P.A. 1973).

In this matter, Opposer cannot carry its burden to prove the elements of "likelihood of confusion." Instead, overwhelming evidence shows just the opposite to be true. In applying the factors

summarized above in this matter, it must be concluded that Applicant is entitled to summary judgment in this matter.

Opposer's allegation in its Notice of Opposition as to how the marks could be considered confusingly similar is that "Applicant's proposed mark XIBROM so resembles Opposer's XYREM mark as to be likely, when used on or in connection with the pharmaceutical preparations described in the Application, to cause confusion, mistake or to deceive." Notice of Opposition ¶¶ 17-20. However, as is detailed below, it is clear from simply looking at the two marks, that the marks differ in overall appearance and commercial impression.

Moreover, due to the differences in function and purpose of the parties' respective goods, Applicant's Goods are not likely to be confused with Opposer's Goods. Likewise, the trade and purchasing public are not likely to believe that Applicant's Goods originate with or are otherwise authorized, licensed or sponsored by Opposer. Furthermore, due to the nature of the parties' goods (specialized pharmaceutical products), they can and will only be purchased by sophisticated purchasers after very careful consideration and investigation.

The lack of any likelihood of confusion between the marks can be determined just from looking at Applicant's Mark and Opposer's Mark in relation to the significant differences between Applicant's Goods and Opposer's Goods. There is no genuine issue of material fact involved in this determination.

There is also no genuine issue of material fact regarding the sophistication of the purchasers of the goods and the channels of trade. Accordingly, the likelihood of confusion claim is appropriate for a summary judgment decision.

Furthermore, Opposer alleges in its Notice of Opposition that purchasers and prospective purchasers are likely to mistakenly believe that Applicant's Goods are sponsored by, endorsed or approved by Opposer or are in some way affiliated, connected or associated with Opposer. Notice of Opposition ¶ 22. However, as is discussed in detailed below, given the nature of Opposer's Goods and Opposer's admission that no instances of actual confusion have occurred, there is also no genuine issue of material fact regarding this determination.

Opposer also alleges in its Notice of Opposition that because a theoretical patient could mistakenly ingest Applicant's Goods instead of Opposer's Goods, Applicant's Application should be denied. Notice of Opposition ¶¶ 21, 23-24.

However, the identification of goods in Applicant's Application limits Applicant's Goods to topical application. Moreover, due to the differences in the packaging, format and channels of distribution for each party's product, a consumer could not mistakenly ingest Applicant's Goods instead of Opposer's Goods or mistakenly apply Opposer's Goods instead of Applicant's Goods.

Furthermore, both parties' names and products were examined and have been approved by the Food and Drug Administration ("FDA"). Applicant notes that in addition to requiring a prescription, Opposer's product can only be offered for sale and sold under extremely strict guidelines. As all of Opposer's arguments regarding a likelihood of confusion fail as a matter of law, Applicant is entitled to summary judgment.

1. The Marks XYREM and XIBROM Are Dissimilar in Overall Appearance and Commercial Impression

Applicant seeks registration for the mark XIBROM. Conversely, Opposer's Mark is the term XYREM either alone or followed by other terms and/or designs. A comparison of Applicant's Mark and Opposer's Mark shows that the parties' marks are quite dissimilar in overall appearance and commercial impression, as set forth in more detail herein.

a. The Marks Must be Compared in Their Entireties

It is well founded that in making a determination of likelihood of confusion, marks must be compared in their entireties and should not be dissected and their parts compared separately. See Estate of P. D. Beckwith, Inc. v. Comm. of Patents, 252 U.S. 538 (1920) (the commercial impression of a composite mark is derived from the mark as a whole, not its separate elements). In fact, it has been held that it is a violation of the anti-dissection rule to ignore elements of a mark in deciding whether confusion is likely. Franklin Mint Corp. v. Master Mfg. Co., 667 F.2d 1005, 1007 (C.C.P.A. 1981). In other words, splitting a mark into its various components and comparing only certain portions of one mark with

another mark is not proper. Massey Junior College, Inc. v. Fashion Institute of Technology, 492 F.2d 1399, 181 U.S.P.Q. 272 (C.C.P.A. 1974). Thus, as described below, a proper comparison of Applicant's XIBROM mark to Opposer's XYREM mark shows that the marks are quite dissimilar in overall appearance and commercial impression.

b. The Marks Are Different in Overall Appearance, Meaning and Commercial Impression

Opposer alleges that there is a likelihood of confusion because Applicant's XIBROM mark and Opposer's XYREM mark both start with an X and end with a M. Notice of Opposition ¶ 19. However, when the marks are compared in their entities, the marks are not visually similar. Opposer also alleges that both marks contain an identical "r" sound and then a similar short vowel sound. Notice of Opposition ¶ 19. However, Applicant's mark does not contain an "r" sound. Instead, Applicant's mark contains the blended sound "br."

More importantly, the second syllable of Applicant's mark is BROM, which is suggestive of the generic name of the product, bromfenac ophthalmic solution 0.09%. Declaration of Tim Mitro in Support of Ista Pharmaceuticals, Inc.'s Motion for Summary Judgment ("Mitro Decl.") at ¶ 5. Conversely, the second syllable of Opposer's mark is REM, which Opposer undoubtedly selected to connote the fact that its XYREM product helps patients who are having difficultly in obtaining proper rapid eye movement or REM sleep. See Opposer's documents produced in its Responses to Applicant's Document Requests ("Opposer's Documents"), attached as Exhibit 3 to the Declaration of Stacey R. Halpern in Support of Ista Pharmaceuticals, Inc.'s Motion for Summary Judgment ("Halpern Decl.") at ¶ 3; Halpern Decl. at ¶ 4.[1]

Generally, sleep disorders affect the quality, duration, and onset of sleep. Rapid eye movement latency (the time it takes to achieve REM sleep) may be affected by a sleep disorder like narcolepsy. Halpern Decl. at ¶ 4. Medications, such as the XYREM product, act on some neurotransmitter systems to produce suppression of REM sleep and consequently improve the symptoms of sleep disorders. Id.

[1] As portions of Opposer's responses are designated "Confidential" and/or "Attorney's Eyes Only," such portions were redacted.

Thus, while Applicant's Mark and Opposer's Mark each begin with the letter X and end with the letter M, the undisputed facts demonstrate that the marks are not phonetically similar and do not proffer the same meaning or connotation. This factor alone is sufficient to grant Applicant's Motion for Summary Judgment.

Moreover, as is discussed in detail below, the differences in the parties' goods, the differences in the channels of trade, the sophistication of the purchasers of the goods, and the differences in the ultimate consumers of the goods, require a finding that confusion is unlikely.

2. Applicant's Goods Are Dissimilar to Opposer's Goods

Applicant submits that there is no genuine issue of a material fact regarding the differences in Applicant's Goods and Opposer's Goods. In Opposer's Notice of Opposition, Opposer states that it has used its XYREM mark in connection with pharmaceutical preparations for the treatment of diseases of the central nervous system and a variety of conditions, symptoms, and diseases, namely, narcolepsy, fibromyalgia, insomnia and myositis and providing telephone support services to patients regarding the safe and appropriate use and distribution of medications used to treat sleep disorders; providing medical information via telephone and in the form of written educational materials to patients in connection with the safe and appropriate use and distribution of medication for the treatment of sleep disorders. Notice of Opposition ¶¶ 6, 8-15.

All these goods and services are clearly related to treatment of diseases of the central nervous system and sleep disorders. None of these goods or services has anything to do with treating postoperative inflammation in patients who have undergone cataract extraction. Mitro Decl. at ¶ 10. In fact, Opposer admits that the only conditions treated by its XYREM product are cataplexy, narcolepsy, hypersomnia, insomnia, fibromyaliga pain and sleep disorders/disturbances. Opposer's Responses to Applicant's Interrogatories Nos. 3, 4 and 8, attached as Exhibit 2 to Halpern Decl. at ¶ 3.

Moreover, in Opposer's Response to Applicant's Interrogatory No. 42, Opposer lists its competitors and its competitors' products. Notably absent from this list is Applicant and Applicant's XIBROM product. Furthermore, in Opposer's response to Applicant's Interrogatory No. 30, Opposer

stated that it "is not aware of any medical link between narcolepsy and ocular disorders." Exhibit 2 to Halpern Decl. at ¶ 3. Furthermore, Opposer's product is not topically applied but ingested orally. Opposer's Response to Interrogatory No. 8, attached as Exhibit 2 to Halpern Decl. at ¶ 3.

In contrast to Opposer's orally ingested drug used to treat central nervous system and sleep disorders, Applicant seeks registration for a topical preparation used for the treatment of ocular disorders. Unlike Opposer's product, Applicant's product is not orally ingested. Instead, Applicant's XIBROM product is dispensed (by prescription only) in a plastic squeeze bottle with a dropper tip and is topically applied by placing one drops on to the outer surface of a patient's eyes. Mitro Decl. at ¶ 8.

Thus, it would be impossible for a patient to mistakenly ingest Applicant's product under the mistaken belief it was Opposer's drug. Similarly, it would be impossible for a patient to mistakenly apply Opposer's drug to his or her eye under the mistaken belief it was Applicant's product. In fact, the only arguable similarity between Opposer's Goods and Applicant's Goods is their classification in the same International Class of Goods.

Despite Opposer's allegations to the contrary, the issue of whether or not two products are related does not revolve around the question of whether a term can be used that describes them both, or whether both can be classified under the same general category. Electronic Data Systems Corp. v. EDSA Micro Corp., 23 U.S.P.Q.2d 1460, 1463 (T.T.A.B. 1992). Past decisions of the Board and the Federal courts have concluded that a "per se" rule that goods and services in the same general field and bearing the same mark are so similar or related that confusion as to origin is likely are contrary to the basic tenets of trademark law. See In re The Shoe Works, Inc., 6 U.S.P.Q.2d 1890, 1891 (T.T.A.B. 1990) (no "per se" rule for wearing apparel); Interstate Brands v. Celestial Seasonings, 576 F.2d 926, 928, 198 U.S.P.Q. 151, 152 (C.C.P.A. 1978) (no "per se" rule that the use of the same mark on different food items is likely to cause confusion).

Thus, the fact that Applicant's Goods and Opposer's Goods are both "pharmaceutical products" does not make the goods related. Instead, the Board has consistently held that in order to support a likelihood of confusion, there must be some similarity between the goods beyond the fact that each can

be classified into the same broad category.

In fact, the Board and the courts have concluded that it is even possible for identical marks to be used on closely related goods without a likelihood of confusion. See e.g., Phoenix Closures Inc. v. Yen Shaing Corp., 9 U.S.P.Q.2d 1891, 1894 (T.T.A.B. 1988) (no likelihood of confusion between the marks "PHOENIX and BIRD DESIGN" for bottle closures, liners and the like and the mark "PHOENIX and BIRD DESIGN" for vacuum bottles, thermal food jars, and similar goods); Hi-Country Foods v. Hi Country Beef Jerky, 4 U.S.P.Q.2d 1169, 1172 (T.T.A.B. 1987) (no likelihood of confusion between the marks "HI-COUNTRY and DESIGN" and "HI-COUNTRY" both for "impulse" food); In re British Bulldog, Ltd., 224 U.S.P.Q. 854 (T.T.A.B. 1984) (no likelihood of confusion between the mark "PLAYERS" for shoes and the mark "PLAYERS" for men's underwear); In re Sydel Lingerie Co., 197 U.S.P.Q. 629 (T.T.A.B. 1977) (no likelihood of confusion between the mark "BOTTOMS UP" for ladies' and children's underwear and the mark "BOTTOMS UP" for men's suits, coats and trousers); J.C. Penney Co. v. Arctic Enterprises, Inc., 375 F. Supp. 913, 183 U.S.P.Q. 342 (Minn. 1974) (no likelihood of confusion between the mark "EL TIGRE" for snowmobiles and the mark "EL TIGRE" for automobile tires and minibikes); and Federal Telephone & Radio Corp. v. Federal Television Corp., 84 U.S.P.Q. 394 (2nd Cir. 1950) (no likelihood of confusion between the mark "FEDERAL" for television receivers and the mark "FEDERAL" for radio receivers).

3. The Conditions Under Which and the Buyers to Whom Sales are Made

A finding of no likelihood of confusion is mandated by the highly specialized nature of the goods, the different channels of trade associated with the parties' goods, and the sophistication and care of the consumers and potential consumers of the goods. In fact, as is discussed above, Opposer has admitted the parties' goods are not competitive and that the conditions treated by the parties' goods are not related. Thus, the case at hand presents itself as one in which there will be no competitive proximity between the parties' respective goods and services.

Furthermore, unlike other products, the ultimate consumer of a prescription pharmaceutical product (i.e., the patient) does not make the purchasing decision. Rather, such prescription products are

selected and ordered by a physician and dispensed by a pharmacist after a prescription has been received. Mitro Decl. at ¶ 11. As both parties' goods are selected by well-educated and highly-trained medical and healthcare personnel, these individuals are likely to be careful and discriminating in their selection of pharmaceutical products.

Moreover, highly specialized prescription drugs are not purchased on impulse but only after careful consideration of the functions, purposes, and side effects of the drugs. The more sophisticated and knowledgeable the purchasers, the less likely it is that those purchasers will be confused by similar marks. See In re Endress + Hauer, Inc., 191 U.S.P.Q. 238, 239 (T.T.A.B. 1976) ("Endress"). In fact, in Applicant's case, its XIRBOM product would be selected and order by an ophthalmologist, a medical practitioner specializing in conditions, treatments and surgery of the eye. Mitro Decl. at ¶ 11.

As the "purchasers" of Applicant's XIBROM product and Orphan's XYREM product are healthcare/medical professionals with an intimate knowledge of competing products, their purchasing decision is not primarily based on a comparison of the marks, per se, but is based on a deep understanding of the products and their manufacturers.

Additionally, the realities of the marketplace mandate consumer orientation to primarily focus on the specific utility or function of a product necessary to fulfill the consumer's specific needs. A perusal of the Applicant's Goods and Opposer's Goods indicates that the goods are not interchangeable. In other words, a topical ocular product could not be used to fulfill the utility or function of an orally ingested drug used to treat sleep disorders, and vice-versa. Mitro Decl. at ¶ 10.

In Endress, supra., the Board held identical marks used on sophisticated pieces of equipment which were specialized in their application were not likely to be confused. The Board reached this conclusion, even though the identical marks involved the phenomenon of vibration. The Board reasoned that there was no likelihood of confusion given the different roles played by the two goods, both as to purpose and function.

Similarly, in Reynolds & Reynolds Company v. I.E. Systems, Inc. ("Reynolds"), 5 U.S.P.Q.2d 1749 (T.T.A.B. 1987), the opposer marketed accounting programs, whereas the applicant marketed a

sophisticated highly specialized computer software program. The Board concluded that there was no likelihood of confusion because the applicant marketed its products to an entirely different set of consumers than the opposer. Id. at 1752.

Likewise, in the case at hand, both parties' goods are highly specialized. Thus, the source of Applicant's Goods are not likely to be confused with the source of Opposer's Goods, just as the Board found that the applicant's specialized products in Endress were not likely to be confused with the goods in the cited registration and just as the Board found that the applicant's specialized computer software program in Reynolds was not likely to be confused with the opposer's program.

Moreover, unlike most goods in the marketplace, both Opposer and Applicant were required to obtain FDA approval for their marks. Opposer Documents, Exhibit 3 to Halpern Decl. at ¶ 2; Mitro Decl. at ¶¶ 5 and 9. Similar to the PTO, to minimize confusion between pharmaceutical product names, the FDA reviews brand names and rejects names that look or sound alike. Mitro Decl. at ¶ 7. Furthermore, the FDA's involvement does not end with approval of the parties' names. Instead, both parties' products are regulated by the FDA and cannot be sold without a prescription. Opposer Documents, Exhibit 3 to Halpern Decl. at ¶ 2; Mitro Decl. at ¶ 8. The FDA also requires that the established or official name, or in the absence of an official name, the common or usual name, appears on labels and labeling of pharmaceutical products. Mitro Decl. at ¶ 9.

More importantly, unlike some pharmaceutical preparations, which can be filled at a consumer's local pharmacy or through mail order, Opposer has admitted that its XYREM products can **only be** distributed by means of one third-party pharmacy. See Opposer's Response to Applicant's Interrogatory No. 15, Exhibit 2 to Halpern Decl. at ¶ 2 and Opposer Documents, Exhibit 3 to Halpern Decl. at ¶ 2.

In fact, a condition of the FDA approving Opposer's XYREM drug was the requirement that Opposer's XYREM product not be sold at retail pharmacies, that a single third-party pharmacy be the **exclusive** distributor of the XYREM product, and that the pharmacy only sell the product under extremely strict guidelines. Opposer Documents, Exhibit 3 to Halpern Decl. at ¶ 2; Halpern Decl. at ¶ 5. Specifically, Opposer's product offered in connection with the XYREM mark is **only** available through a

restricted distribution program, called the Xyrem Success Program. Id.

Under Opposer's Xyrem Success Program, Opposer's Xyrem product is **only** made available through the following procedures: (1) the prescriber must contact the XYREM CENTRAL PHARMACY, which will provide the prescriber with educational materials explaining the risks and proper use of sodium oxybate, and the details of the program; (2) once the prescriber has read the materials and returned the necessary form, the XYREM CENTRAL PHARMACY will ship educational materials to the patient; (3) once it is documented that the patient has read the materials, XYREM will be shipped to the patient; and (4) the Xyrem Success Program also includes provisions for detailed surveillance of the patients (patients are to be seen no less frequently than every 3 months and physicians are expected to report all serious adverse events to the manufacturer) and information to help minimize the risks of inadvertent use by others. Id.

Given the FDA's approval of Applicant's XIBROM name, the highly sophisticated purchasers of both parties' goods, the highly specialized nature of both parties' goods, the strict and limited channels of distribution for Opposer's Goods, the undisputed facts support a finding of no likelihood of confusion.

4. XYREM is a Weak Mark

Marks are categorized in order of decreasing distinctiveness, with arbitrary or fanciful marks considered the strongest type of mark and generic terms considered unprotectable as marks. AMF, Inc. v. Sleekcraft Boats, 599 F.2d. 349, 204 U.S.P.Q. 808 (9th Cir. 1979). In Alpha Industries, Inc. v. Alpha Steel Tube & Shapes ("Alpha Industries") 616 F.2d 440, 205 U.S.P.Q. 981 (9th Cir. 1980), the court stated that "a 'weak' mark is a mark that is a meaningful word in common usage or is merely a suggestive or descriptive trademark." Id. at 985. In Alpha Industries, both parties used marks containing the term "ALPHA." Nonetheless, the court determined that there was no likelihood of confusion between the marks because "the word ALPHA is in common usage and has meaning in the English language; that ALPHA occurs in widespread use as a trade name or trademark; and that ALPHA as part of a trademark or trade name is weak." Id.

This principle is also well-recognized by the Board and the courts. For example, in Genesco Inc. v. Tru Balance Corset, Inc., 152 U.S.P.Q. 198 (T.T.A.B. 1966), the Board determined that there was no likelihood of confusion between "PRIVATE LIFE" and "LIFE" for the identical types of women's undergarments. The Board reasoned that because "LIFE" was suggestive of foundational garments, there was no confusion between the marks. Id. at 199.

Likewise, in Industrial Adhesive Co. v. Borden Inc., 218 U.S.P.Q. 945, 951-52 (T.T.A.B. 1983), the Board found no likelihood of confusion between opposer's mark "BOND-PLUS" and applicant's mark "WONDER BOND PLUS" because opposer's mark was composed of common dictionary terms that were used in a suggestive manner.

Similarly, in Giorgio Beverly Hills Inc. v. Revlon Consumer Products Corp., 869 F. Supp. 176, 33 U.S.P.Q.2d 1465, 1467 (S.D.N.Y. 1994), the court determined that because the term "RED" had a long standing meaning, the mark's owner could not prevent a junior user from using a composite mark containing the term "RED" on identical goods.

Additionally, in Murray Corp. of America v. Red Spot Paint and Varnish Co., 280 F.2d 158, 126 U.S.P.Q. 391 (C.C.P.A. 1960), the court affirmed the PTO's determination that there was no confusion between the marks "EASY" and "EASYTINT" both for paints. In reaching this decision, the court stated that as the word "easy" has a descriptive or suggestive significance when applied to the goods, "it would be likely to be understood by purchasers as identifying or describing the merchandise itself, rather than the source thereof." The court noted that the registrant was not entitled to preempt all uses of the word "easy." Id. at 392. As such, the court concluded that even though the applicant's mark embodied the entire mark in the registrant's registration, there was no likelihood of confusion. Id. at 392-93.

Here, as is discussed above, it is apparent that Opposer selected a mark begin with the letter X (a fricative letter) to imply speed and the suffix REM to connote the fact that its goods are intended to assist with the patient obtaining proper REM sleep. As in the case referenced above, the purchasers of the Opposer's Goods would recognize the descriptive or suggestive significance of Opposer's Mark when applied to Opposer's Goods.

In Murray Corp. National Biscuit Co. v. Princeton Minding Co., Inc., 137 U.S.P.Q. 250, 253 (T.T.A.B. 1963), the Board determined that even though opposer had extensively advertised and used the PREMIUM mark as to acquire secondary meaning, the mark was only entitled to a narrow scope of protection, and, as such there was no likelihood of confusion between PREMIUM and PREMIUM POP for snack foods. In reaching its conclusion the Board stated: "[t]here can be no question on the record presented in this case but that the term "PREMIUM," notwithstanding its inherent connotation of high quality, has been so extensively advertised and otherwise used by opposer that it has acquired a secondary meaning as indicating origin in the opposer when applied to crackers or biscuits." Id. Similarly, Opposer cannot "claim that it created or cultivated" the mark's connotative suggestive meaning and is therefore only entitled to a narrow scope of protection.

Applicant notes that a search of the PTO's records revealed 71 active registrations and 76 active applications for marks beginning with the letter combinations XI, XY, ZY or ZI which include the wording "pharmaceutical" in the identification of goods, including the following registrations and allowed applications (printouts from the PTO's online database listing the active applications and registrations mentioned above are attached as Exhibit 4 to the Halpern Decl.): (1) U.S. Registration No. 2,144,141 for the mark ZYBAN for pharmaceutical preparations, namely, substances for the treatment and prevention of diseases of the **central nervous system** and to assist in the cessation of use of tobacco products (which predates Opposer's registrations); (2) U.S. Application No. 76/334,976 for the mark XIBALTA for pharmaceutical and medicinal preparation for the treatment of diseases and disorders of the **central nervous system**; (3) U.S. Registration No. 2,867,337 for the mark ZEBRAIC for medical diagnostic kits comprised of reagents for medical use in diagnosing and monitoring disease; (4) U.S. Registration No. 2,705,938 for the mark ZEEBRAL for pharmaceutical preparation for the treatment of **central nervous system disorders**; (5) U.S. Application No. 78/192,109 for the mark ZOBRAKE for pharmaceutical preparations for the treatment of cancer, auto immune disease, cardiovascular disorders, obesity; (6) U.S. Registration No. 1,702,392 for the mark ZITHROMAX for an antibiotic preparation; (7) U.S. Registration No. 2,851,060 for the mark XIRTAM for pharmaceutical preparations and substances

for the treatment of cancer, stroke, traumatic brain injury, cardiovascular diseases and disorders, metabolic diseases and disorders; antibacterial pharmaceuticals, antiviral preparations, anticoagulants and platelet aggregation inhibitors, antithrombotic agents; (8) U.S. Registration No. 2,895,228 for the mark XILIARX for pharmaceutical preparations for the treatment of disorders of the **central nervous system**, the immune system, the cardiovascular system, the respiratory system, the musculoskeletal system, the genitourinary system, for the treatment of inflammatory disorders, for the treatment of skin disorders, for the treatment of gastroenterological disorders, for the treatment of cancer, and for the treatment of eye disorders; (9) U.S. Registration No. 2,773,066 for the mark ZYZCALM for pharmaceutical preparations for preventing or curing diseases in humans, namely, for treating the muscular-skeletal system and the **nervous system**; dietetic substances, namely, diet capsules, diet pills, dietary food supplements; food for babies; medical plasters; materials for dressings, namely, medical dressings, surgical dressings, wound dressings; material for stopping teeth; dental wax; (10) U.S. Registration No. 2,517,404 for the mark ZICAM for pharmaceutical and homeopathic preparations for the relief of colds and allergy symptoms, specifically excluding preparations to assist in smoking cessation or to treat smoking-related conditions other than colds and allergy symptoms; (11) U.S. Registration No. 1,485,937 for the mark ZYTRON for pharmaceutical products, namely, formulations that aid in reducing pain and/or inflammation; (12) U.S. Application No. 78/036,790 for the mark ZILBRIX for vaccines for human use; (13) U.S. Registration No. 773,095 for the mark ZYLOPRIM for drug for the treatment of gout, leukemia and related conditions; (14) U.S. Registration No. 2,773,065 for the mark ZYZMYON for pharmaceutical preparations for preventing or curing diseases in humans, namely, for treating the muscular-skeletal system and the **nervous system**; dietetic substances, namely, diet capsules, diet pills, dietary food supplements; food for babies; medical plasters; materials for dressings, namely, medical dressings, surgical dressings, wound dressings; material for stopping teeth; dental wax; (15) U.S. Registration No. 2,574,061 for the mark XIGRIS for pharmaceutical preparation, namely, an antithrombotic agent, an anti-inflammatory agent, an anticoagulant agent and a pro-fibrinolytic agent; (16) U.S. Application No. 76/334,977 for the mark XIMBALTA for pharmaceutical

and medicinal preparations for the treatment of diseases and disorders of the **central nervous system**; (17) U.S. Registration No. 2,786,452 for the mark XIRELYS for pharmaceutical preparations for the treatment of hormonal related conditions; (18) U.S. Registration No. 2,479,307 for the mark ZYCAL for pharmaceutical preparations for the treatment of respiratory diseases, namely, antiallergic decongestant and antiasthmatic; (19) U.S. Application No. 78/313,109 for the mark ZYDRIVE for pharmaceutical preparations for the treatment and prevention of diabetes, incontinence, cardiovascular diseases, **central nervous system diseases and disorders**, stroke, cancer, inflammation and inflammatory diseases, respiratory and infectious diseases, auto-immune diseases, solid organ transplant rejection; pharmaceutical preparations, namely, antibiotics, anti-fungals, anti-virals and immunosuppressants; (20) U.S. Registration No. 2,418,989 for the mark ZYPHAGE for pharmaceutical products for prevention and treatment of diabetes and complications thereof; (21) U.S. Registration No. 2,157,636 for the mark ZYFLO for pharmaceutical preparations, namely, an anti-inflammatory; (22) U.S. Application No. 78/342,718 for the mark ZYMERYS for **pharmaceutical preparations for the treatment of diseases and disorders of the central nervous system**; (23) U.S. Registration No. 2,784,308 for the mark XINOD for pharmaceutical preparations and substances for the prevention and treatment of diseases and disorders of the respiratory system, **central nervous system**, peripheral nervous system, cardiovascular system, gastrointestinal system; pharmaceutical preparations and substances for use in pain control, arthritis, anesthesia, oncology, infection, inflammation, urology, gynecology; pharmaceutical preparations and substances for the treatment and prevention of diabetes; (24) U.S. Application No. 78/017,358 for the mark ZYLOD for pharmaceutical preparations, namely preparations for the treatment of infectious diseases; cancer; ophthalmologic conditions and diseases; **central nervous systems diseases and disorders**; Parkinson's disease; cardiovascular diseases and conditions; migraines; preparations for the treatment and symptoms of diabetes; preparations for the treatment of gynecologic disorders and diseases; hormonal preparations; analgesics, anti-inflammatory pharmaceutical preparations; (25) U.S. Registration No. 1,591,635 for the mark ZYMASE for pharmaceutical composition for treatment of chronic pancreatitis, pancreatectomy, cystic fibrosis, and steatorrhea from

diverse etiologies; (26) U.S. Registration No. 2,959,967 for the mark ZYVOX for pharmaceutical preparation, namely an antibiotic; (27) U.S. Registration No. 2,843,896 for the mark ZYMR for pharmaceutical preparations for the treatment of bacterial conjunctivitis; (28) U.S. Registration No. 2,072,867 for the mark ZYPREZA for pharmaceutical products, namely antipsychotics; (29) U.S. Registration No. 2,965,332 for the mark XIFAXAN for preparations for the treatment, prevention and/or alleviation of disorders of the gastrointestinal tract; (30) U.S. Registration No. 2,529,047 for the mark XIMDAN for pharmaceutical preparations for the treatment of cardiovascular diseases; (31) U.S. Registration No. 2,941,576 for the mark XILENTO for pharmaceutical preparations, namely, preparations for the treatment of immunological, oncological, neurological and cardiovascular diseases; (32) U.S. Registration No. 2,810,468 for the mark ZYLEMPO for pharmaceutical preparations and substances for the treatment of cancer, stroke, traumatic brain injury, cardiovascular diseases and disorders, metabolic diseases and disorders; antibacterial pharmaceuticals, antiviral preparations, anticoagulants and platelet aggregation inhibitors, antithrombotic agents; diagnostic preparations and reagents for medical use; (33) U.S. Registration No. 2,842,771 for the mark XIRATUSS for pharmaceutical preparation for the symptomatic relief of the cough and nasal congestion associated with the common cold; (34) U.S. Application No. 78/233,842 for the mark ZYFETOR for pharmaceutical preparations and substances for the treatment of diseases and disorders of the metabolic, genito-urinary and **central nervous systems**; (35) U.S. Application No. 78/075,872 for the mark ZYMTHER for pharmaceutical preparations for the treatment of respiratory and gastro-intestinal diseases and conditions; (36) U.S. Application No.78/145,051 for the mark ZYLEST for pharmaceutical preparations, namely preparations for the treatment of infectious diseases, cancer, ophthalmologic conditions and diseases, **central nervous systems diseases and disorders,** Parkinson's disease, cardiovascular diseases and conditions, migraines; pharmaceutical preparations for the treatment of diabetes; pharmaceutical preparations for the treatment of urological disorders; pharmaceutical preparations for gynecological uses, namely, for the treatment of menopausal diseases and disorders; pharmaceutical preparations for the treatment of urinary tract and bladder infections, analgesics, anti-inflammatory pharmaceutical

preparations; (37) U.S. Application No. 78/192,080 for the mark XINLAY for pharmaceutical preparations for the treatment of cancer, auto immune disease, cardiovascular disorders, obesity; (38) U.S. Registration No. 2,909,394 for the mark ZYRKAMINE for pharmaceutical preparations for the treatment of cancer; (39) U.S. Registration No. 2,363,608 for the mark ZYFUZET for pharmaceutical preparations and substances for the treatment of cancer; (40) U.S. Registration No. 2,862,527 for the mark XYSENZA for pharmaceutical preparations and substances for the treatment and prevention of cancer; (41) U.S. Registration No. 2,810,466 for the mark XYVONDA for pharmaceutical preparations and substances for the treatment of cancer, stroke, traumatic brain injury, cardiovascular diseases and disorders, metabolic diseases and disorders; antibacterial pharmaceuticals, antiviral preparations, anticoagulants and platelet aggregation inhibitors, antithrombotic agents; diagnostic preparations and reagents for medical use; (42) U.S. Application No. 78/122,779 for the mark ZIOPLA for pharmaceutical preparations for the treatment and prevention of cardiovascular diseases, **central nervous system diseases and disorders**, stroke, cancer, inflammation and inflammatory diseases, respiratory and infectious diseases, auto-immune diseases; (43) U.S. Registration No. 2,677,181 for the mark ZINDACLIN for pharmaceuticals and pharmaceutical preparations for use in the treatment of dermatological disorders; medicinal preparations for use in the treatment of dermatological disorders; drugs for use in the treatment of dermatological disorders; (44) U.S. Application No. 78/192,086 for the mark XYECLAVE for pharmaceutical preparations for the treatment of cancer, auto immune disease, cardiovascular disorders, obesity; (45) U.S. Registration No. 2,794,109 for the mark ZIPAFORM for pharmaceutical products for the prevention and treatment of diabetes and complications thereof; (46) U.S. Registration No. 2,758,944 for the mark XYPNA for pharmaceutical preparations and substances for use in the treatment of diseases and disorders of the alimentary tract and metabolism, blood and blood forming organs, the cardiovascular system, the musculoskeletal system, **the central nervous system**, the peripheral nervous system, the genitourinary system, the respiratory system; dermatological preparations; hormones for medical purposes; anti-infective preparations; anti-viral preparations; cytostatic preparations for use in the treatment of cancer; allergy medications; dietary food supplements for

medically restricted diets; (47) U.S. Registration No. 2,746,637 for the mark ZIMINO for pharmaceutical prescription drugs for the treatment of neurological, cardiovascular, respiratory or hormonal diseases and disorders; (48) U.S. Application No. 76/361,026 for the mark XYOCAM for pharmaceuticals, namely drugs for use in the treatment of cancer; (49) U.S. Application Serial No. 76/328,656 for the mark ZILERAN for pharmaceutical preparations for the treatment of depression and obsessive compulsive disorders; (50) U.S. Application 78/156,075 for the mark ZIMYCAN for dermatological pharmaceuticals; (51) U.S. Registration No. 2,905,408 for the mark XINNA for pharmaceutical preparation, namely hormonal preparations; (52) U.S. Registration No. 21,133,466 for the mark ZINACEF for antibiotic preparation for pharmaceutical and veterinary use; (53) U.S. Registration No. 1,959,144 for the mark ZINECARD for cardioprotective pharmaceutical for treating anthracycline induced cardiotoxicity; (54) U.S. Registration No. 1,831,849 for the mark ZIAC for cardiovascular pharmaceutical preparations; (55) U.S. Registration No. 2,574,270 for the mark ZINTREPID for pharmaceutical preparation, namely, a cholesterol absorption inhibitor; (56) U.S. Registration No. 2,479,307 for the mark XYZAL for pharmaceutical preparations for the treatment of respiratory diseases, namely antiallergic decongestant and antiasthmatic; and (57) U.S. Registration No. 2,339,603 for the mark ZYGARA for pharmaceutical preparations and substances used in the treatment of cancer. Printouts of these registrations and applications obtained from the PTO's online database are attached as Exhibit 5 to the Halpern Decl. and made of record. Printouts of Internet searches showing use of many of these marks and other marks beginning with the letters ZI, ZY, XI or XY and used in connection with pharmaceutical products are attached as Exhibit 6 to the Halpern Decl.

Applicant assumes that all of these registrations and applications were examined and approved by the PTO, despite the existence of each other (and Opposer's Mark), because the PTO acknowledges that even a slight variation in the goods and/or the marks is sufficient to preclude a likelihood of confusion. Furthermore, the coexistence of these applications and registrations on the PTO records and the coexistence of the marks in the marketplace indicates that medical and healthcare professionals as well as patients are likely to know that marks beginning with XI, XY, ZI or ZY are commonly used in

conjunction with different pharmaceutical products and different owners.

Likewise, the suggestive and weak nature of Opposer's Mark along with the widespread use and registration of similar marks by third parties supports the conclusion that Opposer's rights in Opposer's Mark are narrow and that given the differences in the goods, the channels of trade and the consumers of the goods, there are no issues of material fact regarding the lack of a likelihood of confusion between the parties' marks.

V. APPLICANT'S MARK DOES NOT DILUTE OPPOSER'S MARK

Opposer alleges in its Notice of Opposition that Applicant's mark dilutes the distinctive quality of the XYREM mark. Notice of Opposition ¶ 25. Moreover, Opposer has not and cannot establish that its mark is famous and distinctive, nor can Opposer establish that Applicant diluted any distinctive quality (if any) of Opposer's Mark. As the involved marks are not even likely to cause confusion, there is no genuine issue of material fact on this issue.

The standard to establish fame and distinctiveness under a dilution claim is much more rigorous than that required under a likelihood of confusion claim. I.P. Lund Trading ApS v. Kohler Co., 49 U.S. PQ.2d 1225, 1239 (1st Cir. 1998). In particular, in order to succeed in its dilution claim, Opposer must prove that its XYREM mark and Applicant's XIBROM mark are **substantially** similar. Luigino's, Inc. v. Stouffer Corp., 50 U.S.P.Q.2d 1047, 170 F.3d 827, 832 (8th Cir. 1999) ("Luigino's").

Opposer must also provide that its XYREM mark is so well known, distinctive and famous that it is part of the "select class of marks - those with such powerful consumer association that even - competing uses can impinge on their value." Avery Dennison Corp. v. Sumpton, 51 U.S. P.Q. 1801, 1809 (9th Cir. 1999). Clearly, Opposer's XYREM is not such a mark.

Moreover, unless the marks are **identical**, the "mere fact that consumers mentally associate the junior's user's mark with a famous mark is not sufficient to establish actionable dilution." Moseley v. V Secret Catalogue, Inc., 65 U.S. P.Q.2d 1801, 537 U.S. 418, 433 (S. Ct. 2003). Furthermore, as dilution is an "extraordinary remedy," the Board does not "resolve doubts in favor of the party claiming dilution." Toro Co. v. ToroHead, Inc., 61 U.S.P.Q.2d 1164, 1173-74 (T.T.A.B. 2001).

The Marks are Not Similar

In order to prevail on a dilution claim, the involved marks must be more than merely similar. Instead, Opposer must be able to show that the marks are identical or very substantially similar. It is undisputed that the marks are not identical. Moreover, as is discussed above, the undisputed facts also show that the marks XYREM and XIBROM are not even similar enough for a finding of a likelihood of confusion. Consequently, as a matter of law, Opposer's dilution claim fails.

The Board's decision in Toro Co. v. ToroHead, Inc., supra., supports this conclusion. In Toro Co. v. ToroHead, Inc, the Board held that the opposer's mark TORO and the applicant's mark TORO MR with a picture of the head of a bull were not sufficiently similar for finding dilution due to the differences in the marks. In reaching this holding the Board stated "we must find that the involved marks are more than merely similar; a party must show that the marks are identical or 'very or substantially similar.'"

Furthermore, the recent Board decision, Nike, Inc. v. Nikepal Int'l, Inc., Opposition No. 91124869 (April 21, 2005), while non-predecential, provides insight as to how similar marks must be. In the this decision, the Board found Nike's mark to be famous, and as such, entitled to substantial weight. Nonetheless, the Board concluded that the marks NIKE and NIKEPLA were not substantially similar enough for dilution purposes. Exhibit 7 to Halpern Decl. at ¶ 8. Likewise, the marks XYREM and XIBROM are not "very or substantially similar."

There is No Evidence that the Mark has Achieved Fame

While Opposer has alleged that it is the owner of several registrations containing the term XYREM, these registrations are very narrow in scope. Moreover, in considering whether or not a mark is famous and distinctive for dilution purposes, one of the factors is the degree of distinctiveness of the mark. As is discussed above, due to the common use of the "XY" letter in the names of pharmaceutical products, the recognized meaning of the letter X in connection with pharmaceuticals and the recognized meaning of the term REM, Opposer's mark is a weak mark.

Furthermore, in Opposer's response to Applicant's First Set of Interrogatories, Interrogatory No. 10, Opposer stated that its goods are intended for a niche market -- patients suffering from sleep disorders and cataplectic episodes. Opposer's Response to Applicant's Interrogatory No. 10, Exhibit 2 to Halpern Decl at ¶ 2. Applicant does not seek registration for goods within this niche. Opposer also stated that the parties' goods are not competitive.

Particularly relevant is Luigino's, supra, which involved Stouffer's low fat frozen food products under the mark LEAN CUISINE and Luigino's low fat frozen food product under the mark MICHELINA'S LEAN 'N TASTY. Luiginio brought a declaration judgment action. The district court granted Luiginio's summary judgment of non-infringement and no dilution.

On appeal, the court noted that the LEAN CUISINE mark was a strong mark and the two products at issue were in direct competition. Nonetheless, the court found that marks looked and sounded different, and had a difference in meaning. Furthermore, the court noted that it order to succeed on a dilution claim, "the marks must at least be similar enough that a significant segment of the target group of customers sees the two marks as essentially the same." Luigino's, 170 F.3d at 833. Accordingly, the court affirmed the district court's granting of non-infringement and no dilution.

As Opposer admitted the target groups of consumers of each party's goods are not the same, as a matter of law, Opposer's dilution claim must fail. Moreover, the marks are clearly not similar enough that a significant segment of a target group of customers would see the two marks as essentially the same.

Applicant's Mark Does Not dilute the Distinctive Quality of Opposer's Mark

Even if Opposer's Mark is found to be famous and distinctive, which due to its weak and suggestive nature, it cannot be found, and even if the marks are found to be very or substantially similar, which due to the differences in the marks, they cannot be found, Opposer's dilution claim would nonetheless fail because Applicant's Mark does not dilute the distinctive quality of Opposer's Mark. Many of the factors considered in determining whether a mark has been diluted are similar to those applied in the likelihood-of-confusion test, including similarity of marks, shared consumers, sophistication of the consumers and actual confusion. 15 U.S.C.A. §1125(c)(1).

As is discussed in detail above, neither the marks, nor the consumers of the goods are similar. Furthermore, the purchasers of the goods are sophisticated. Moreover, there have been no instances of actual confusion. Additionally, due to the existence of similar third-party marks and the inherent weakness of Opposer's Mark, it is undisputed that Applicant's Mark cannot "lessen the distinctive quality of Opposer's Mark." Consequently, as a matter of law, Opposer's dilution claim fails.

VI. CONCLUSION

On the basis of the facts and the law, as demonstrated above, Applicant has clearly shown that Applicant's Mark and Opposer's Mark are not so "related" that there is any likelihood of confusion between the marks, or that the trade or purchasing public will be deceived into believing that Applicant's Goods originate with or are otherwise authorized, licensed or sponsored by Opposer. Applicant has also clearly shown that Applicant's Mark does not and cannot dilute or cause a likelihood of dilution with Opposer's Mark.

Accordingly, Applicant requests that the Board grant summary judgment in dismissing this opposition proceeding and allowing Applicant's Application to proceed to registration.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 25, 2005

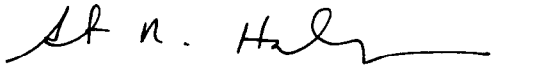
By: _____

Steven J. Nataupsky
Michael K. Friedland
Stacey R. Halpern
Tirzah Abé Lowe
2040 Main Street, 14th Floor
Irvine, California 92614
(949) 760-0404
efiling@kmob.com
Attorneys for Applicant,
ISTA Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing **MEMORANDUM IN SUPPORT OF ISTA PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT** upon Opposer's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on August 25, 2005, addressed as follows:

Stephen R. Baird
Troy E. Arnlund
WINTHROP & WEINSTINE, P.A.
225 South 6th Street, Suite #3500
Minneapolis, MN 55402



Stacey R. Halpern

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

Orphan Medical, Inc., Opposer, v. ISTA Pharmaceuticals, Inc., Applicant.	Opposition No.: 91,162,204

DECLARATION OF TOM MITRO IN SUPPORT OF ISTA PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT

I, Tom Mitro, declare as follows:

1. I am the Vice President of Sales and Marketing of ISTA Pharmaceuticals, Inc., ("Applicant") the owner of Application Serial No. 78/298,369 for the mark XIBROM ("Applicant's Application"). As Vice President of Sales and Marketing for Applicant, I have personal knowledge of the facts set forth below. If called upon and sworn as a witness, I could and would competently testify as set forth below.

2. I have been involved in the pharmaceutical industry for over 24 years, with a focus on business development, product acquisitions, and sales and marketing in the branded ophthalmic and dermatologic physician and managed care marketplaces. In June 2002, I became the Vice President of Sales and Marketing for Applicant. As Applicant's Vice President of Sales and Marketing, I am responsible for product strategy and market forecasts and management of the Applicant's sales and marketing department.

3. Prior to joining Applicant, I worked at Allergan, Inc., a specialty pharmaceutical company that develops and commercializes ophthalmology, neuromuscular, and dermatology products. During my tenure at Allergan, I held a number of sales, marketing and management positions that focused on the branded ophthalmic and dermatologic physician and managed care marketplaces. In addition, I

started and directed the sales and marketing activities at Pacific Pharma, a subsidiary of Allergan that focuses on the ophthalmic generic drug marketplace. Throughout my tenure at Allergan, I served as Vice President in three different business areas: Business Development, Sales and Marketing, and e-Business. Through these positions, I developed and managed the implementation of worldwide strategic sales and marketing plans, built three different sales forces and a marketing department, and launched numerous new prescription drug products. I also managed the North American business development efforts which completed the acquisition of three companies. I later assumed responsibility for the development and implementation of worldwide plans to maximize the use of the Internet for Allergan's business applications.

4. Applicant is a specialty pharmaceutical company focused on the development and commercialization of unique and uniquely improved ophthalmic products for serious conditions of the eye.

5. Applicant's XIBROM ophthalmic solution is used to treat postoperative inflammation in patients who have undergone cataract extraction. A cataract is the clouding of the normally clear, natural crystalline lens of the eye. The lens is composed of water and protein. The protein is arranged in a highly organized pattern that allows light to pass through it with minimal distortion. As a result, the lens appears virtually clear. The lens can become cloudy, blocking or scattering some light and preventing it from reaching the retina in sharp focus. This causes decreased vision. A patient suffering from cataracts may undergo cataract surgery. After cataract surgery, a patient may develop ocular inflammation. Applicant's XIBROM product is approved by the FDA to decrease such inflammation. The generic name for Applicant's XIBROM product is bromfenac sodium ophthalmic solution 0.09%.

6. Brand names (trademarks) for pharmaceutical products are selected in various manners. One of these methods is to select a trademark which suggests a function or feature of the product. Brand names beginning with the letters X, Y, and Z are popular in the pharmaceutical industry. In particular, the letter X is often used to connote strength or speed. Brand names beginning with the letter combinations XI, XY, ZI or ZY are also popular in the pharmaceutical industry.

7. In May 2004, Applicant submitted a New Drug Application (NDA) to the Food and Drug Administration for its XIBROM product. The goal of an NDA is to determine whether a drug is safe and effective in its proposed use(s), whether the benefits of the drug outweigh the risks, whether the drug's proposed labeling (package insert) is appropriate, and what it should contain, and whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. To minimize confusion between pharmaceutical product names, the FDA reviews brand names and rejects names that look or sound alike. Applicant received the FDA approval of its XIBROM product on March 28, 2005.

8. Applicant's XIBROM product can only be obtained with a prescription. Furthermore, Applicant's XIBROM product is not orally ingested. Instead, Applicant's XIBROM product is dispensed in a plastic squeeze bottle with a dropper tip and is topically applied by placing a one drop on to the outer surface of the patient's eyes, twice a day. On the prescription, the physician must designate the specific eye that will receive the Xibrom drop and the number of times per day the patient should apply Xibrom to the eye. A copy of a photograph of Applicant's packaging is attached hereto as Exhibit 1. Due to the eye dropper configuration of the bottle, it would be impossible for a patient to mistakenly ingest Applicant's product. Additionally, on both the box in which Xibrom is shipped and the bottle that contains Xibrom the words "For topical application in the eye" appear in bold print.

9. In addition to approving the XIBROM brand name for Applicant's product, the FDA requires that the established or official name, or in the absence of an official name, the common or usual name, appears on labels and labeling of pharmaceutical products.

10. Applicant's XIBROM product could not be used to treat diseases of the central nervous system, narcolepsy, fibromyalgia, insomnia, myositis or other sleep disorders. Such conditions are unrelated to cataract surgery or ocular inflammation caused by cataract surgery.

11. The ultimate consumer of a prescription pharmaceutical product (*i.e.*, the patient) does not make the purchasing decision by his/her own self, as they would with an over the counter (OTC) product. Rather, such prescription products must be selected and ordered by a physician and dispensed

only by a pharmacist after a prescription has been received. Each prescription must also include specific instruction as to the number of drops to apply each day and the eye onto which XIBROM should be applied. In Applicant's case, its XIBROM product would be selected and ordered by an ophthalmologist, a medical practitioner specializing in conditions, diseases and surgery of the eye. Due to the specific functions and purposes of Applicant's XIBROM product, it is unlikely that any other types of medical and/or healthcare professional would prescribe Applicant's XIBROM product.

I declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Dated: 8/22/05

By: _____
Tom Mtiro

1882603
082205

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing **DECLARATION OF TOM MITRO IN SUPPORT OF ISTA PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT** upon Opposer's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on August 25, 2005, addressed as follows:

Stephen R. Baird
Troy E. Arnlund
WINTHROP & WEINSTINE, P.A.
225 South 6th Street, Suite #3500
Minneapolis, MN 55402

Stacey R. Halpern

Exhibit 1

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

Orphan Medical, Inc., Opposer, v. ISTA Pharmaceuticals, Inc., Applicant.	Opposition No.: 91,162,204

DECLARATION OF STACEY R. HALPERN IN SUPPORT OF ISTA PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT

I, Stacey R. Halpern, declare as follows:

1. I am a partner with Knobbe, Martens, Olson & Bear, LLP, U.S intellectual property counsel for ISTA Pharmaceuticals, Inc. ("Applicant") in the above-identified Opposition proceeding. I have personal knowledge of the facts set forth below. If called upon and sworn as a witness, I could and would competently testify as set forth below.

2. On April 22, 2005, Applicant served Applicant's First Set of Interrogatories Nos. 1-47 ("Applicant's First Interrogatories") and Applicant's First Requests for Production of Documents and Things Nos. 1-80 ("Applicant's First Document Requests") (collectively hereinafter referred to as Applicant's First Set of Discovery Requests"). True and correct copies of Applicant's First Set of Discovery Requests are attached hereto as Exhibit 1.

3. On August 1, 2005, Opposer provided responses to Applicant's First Set of Discovery Requests. True and correct copies of Opposer's responses to Applicant's First Set of Discovery Requests are attached hereto as Exhibit 2. As portions of Opposer's responses to Applicant's First Interrogatories are designated "Confidential" and/or "Attorney's Eyes Only," such portions were redacted from the

attached copies. On August 3, 2005, Opposer provided documents responsive to Applicant's First Set of Document Requests. Attached hereto as Exhibit 3 are true and correct copies of documents produced by Opposer, Document Bates Nos. OM0012, OM0113, OM0142-0M0145, OM0175-OM0184, OM0264, OM0276, OM0341, OM0347-OM0355, OM0811, OM0834, OM3309-OM3312 and OM4107-OM04108.

4. As shown in Document Bates Nos. OM0175-OM0184 and OM4107-OM04108, which discuss narcolepsy and other sleep disorders, generally, sleep disorders affect the quality, duration, and onset of sleep. Rapid eye movement latency (the time it takes a person to achieve REM sleep) is typically affected in sleep disorder. This means that in narcolepsy, the REM sleep begins soon after the onset of sleep. Thus, in healthy individuals, the first REM sleep period occurs about 80 to 120 minutes after the onset of sleep. By contrast, in narcolepsy, the initial REM sleep period usually occurs within 15 minutes of the onset of sleep. In addition, narcolepsy patients will have two or more sleep onset REM periods during the multiple sleep latency test (MSLT) in the daytime, affecting the quality, duration, and onset of sleep. Medications, such as Opposer's XYREM product, act on some neurotransmitter systems to produce suppression of REM sleep and consequently improve the symptoms of sleep disorders.

5. Document Bates Nos. OM0012, OM0113, OM0142-0M0145, OM0264, OM0276, OM0341, OM0347-OM0355, OM0811, OM0834 and OM3309-OM3312, which discuss Opposer's XYREM product and the strict and limited conditions under which the FDA gave approval for Opposer to offer its product. Specifically, unlike most goods in the marketplace, Opposer was required to obtain FDA approval for its mark. Furthermore, the FDA's involvement does not end with approval of the name. Instead, the product is regulated by the FDA and cannot be sold without a prescription. In fact, unlike most pharmaceutical preparations, which can be filled at a consumer's local pharmacy or through mail order, Opposer's XYREM products can **only be** distributed by means of one third-party pharmacy. In fact, a condition of the FDA approving Opposer's XYREM drug was the requirement that Opposer's XYREM product not be sold at retail pharmacies, that a single third-party pharmacy be the **exclusive** distributor of the XYREM product, and that the pharmacy only sell the product under extremely strict guidelines.

6. On August 23, 2005, I conducted a search on the U.S. Patent and Trademark Office's ("PTO") online database. Attached as Exhibit 4 hereto are true and correct copies of the listings of live registrations and applications I found via this database showing marks beginning with the letters XI, XY, ZI or ZY in connection with pharmaceutical products. Attached as Exhibit 5 and made of record are true and correct copies of some of these registrations obtained from the PTO's online database.

7. Attached as Exhibit 6 hereto are true and correct copies of printouts of Internet searches providing information concerning various pharmaceutical products with names beginning with XY, XI, ZY or ZI, including some of the marks listed in Exhibits 4 and 5.

10. Attached as Exhibit 7 hereto is a true and correct copy of Nike, Inc. v. Nikepal Int'l, Inc., Opposition No. 91124869 (April 21, 2005).

I declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Dated: August 25, 2005

By: _____
Stacey R. Halpern

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing **DECLARATION OF STACEY R. HALPERN IN SUPPORT OF ISTA PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT** upon Opposer's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on August 25, 2005, addressed as follows:

Stephen R. Baird
Troy E. Arnlund
WINTHROP & WEINSTINE, P.A.
225 South 6th Street, Suite #3500
Minneapolis, MN 55402

Stacey R. Halpern

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

ORPHAN MEDICAL, INC., Opposer, v. ISTA PHARMACEUTICALS, INC. Applicant.	Opposition No.: 91162204

APPLICANT'S FIRST SET OF INTERROGATORIES NOS. 1-47

Pursuant to the Rules of Practice of the United States Patent and Trademark Office ("PTO"), and the applicable Federal Rules of Civil Procedure ("FRCP"), Opposer, Orphan Medical, Inc., is hereby required to answer separately and fully, in writing and under oath, each of the following Interrogatories.

DEFINITIONS

The following definitions and instructions shall apply to each of the Interrogatories herein:

1. The term "Opposer" shall mean Orphan Medical, Inc. and any present or former owner, officer, director, employee, servant, agent, attorney or other representative acting on his behalf, and shall include any predecessor, successor, affiliate parent company, wholly-owned or partially-owned subsidiary or other related company either within the United States or a foreign country.

2. The term "Applicant" shall mean ISTA Pharmaceuticals, Inc., and any present or former owner, officer, director, employee, servant, agent, attorney or other representative acting on his behalf, and shall include any predecessor, successor, affiliate parent company, wholly-owned or

EXHIBIT 1 PAGE 1 OF 34

partially-owned subsidiary or other related company either within the United States or a foreign country.

3. The term "you" shall mean the party or person to whom the Interrogatory is propounded, all agents, employees, servants, attorneys, and all other representatives, and persons over whom the person or party to whom the Interrogatory is propounded has the right to or does control or direct any activities.

4. The term "document" shall mean any tangible thing upon which information is or has been stored, recorded, or communicated, and any written, printed, typed and visually or aurally reproduced material of any kind, whether or not privileged, such as (by way of example and not by way of limitation) correspondence, letters, notes, memoranda, diaries, invoices, purchase orders, records, minutes, bills, contracts, agreements, orders, receipts, price lists, studies, drawings or sketches, tapes or discs capable of being mechanically read, films, pictures, photographs, electronic mail, advertising or promotional literature, operating manuals or instruction bulletins, voice recording, cables or telegrams, maps, charts, surveys, test data, HTML code, website pages and reports; every copy of every such writing or record where the original is not in the possession, custody or control of Opposer, and every copy of every such writing or record where such copy is not an identical copy of the original or where such copy contains any commentary that does not appear on the original.

5. The term "thing" shall mean all tangible objects of any type, composition, construction or nature.

6. The term "concerning" means relating to, referring to, describing, evidencing or constituting.

7. A document or thing "relating or referring" or which "relates" to any given subject

means any document or thing that comprises, constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any way pertinent to that subject, including, without limitation, documents concerning the preparation of other documents.

8. The term "communication(s)" includes the disclosure, transfer or exchange of information by any means, written, verbal, electronic or otherwise.

9. The term "person" shall include both natural persons and corporate or other business entities, whether or not in the employ of Opposer, and the acts and knowledge of a person are defined to include the acts and knowledge of that person's directors, officers, members, employees, representatives, agents and attorneys.

10. The terms "trademark" or "mark" include trademarks, service marks, collective marks, certification marks and trade names as defined in 15 U.S.C. § 1127.

11. The terms "all" and "each" shall be construed to include all and each.

12. The term "and" shall be construed to include "or" and *vice versa*, and shall be the logical equivalent of "and/or."

13. The use of the singular form of any word also includes the plural and *vice versa*.

14. The terms "Applicant's Mark" shall mean the mark that is the subject of U.S. Trademark Application Serial Number 78/298,369.

15. The terms "Applicant's Goods" shall mean the goods identified in U.S. Trademark Application Serial Number 78/298,369.

16. The terms "Opposer's Mark" shall mean and refer to all marks relied on by Opposer in the Notice of Opposition.

GENERAL INSTRUCTIONS

1. In multi-part Interrogatories, the separate parts of such Interrogatories are to be

read in context of the entire Interrogatory, but each part is to be answered separately.

2. All requests contained in the following Interrogatories to identify a person are to be answered by providing sufficient information to enable the undersigned to contact the person by telephone, mail, and to serve legal documents on such person. If such a person is a natural person, state his or her:

a) full name;

b) current business and residence addresses, including telephone numbers;

c) present employer, occupation and position;

d) a brief description of the job responsibilities of such person; and

e) a brief description of the responsibilities of such person with the pertinent organization if the person is other than a natural person by stating:

(1) its full name or designation;

(2) the legal classification of the entity (e.g. corporation, partnership, etc.), giving the state of incorporation where appropriate;

(3) the principal place of business;

(4) the current or last known address and telephone number of the organization; and

(5) any other information reasonably necessary to permit efficient contact with the organization.

3. If you claim that any information requested is privileged, please provide all information falling within the scope of the Interrogatory which is not privileged, and identify with sufficient particularity for purposes of a Motion to Compel a Response or Production of each item of information, document or thing, separately, with respect to which you claim a

privilege, and state:

a) the basis on which the privilege is claimed;

b) the author of the document;

c) each individual or other person to whom the document, or copy thereof, was sent or otherwise disclosed; and

d) the date of the document.

You are not requested to provide privileged information or information for which you claim privileged, but only to identify such information, document or thing.

4. Opposer's responses to the following Interrogatories are to be promptly supplemented to include subsequently acquired information in accordance with the requirements of Rule 26(e) of the FRCP.

INTERROGATORIES

INTERROGATORY NO. 1:

Identify any and all persons who have the most knowledge concerning Opposer's use of Opposer's Mark in the United States.

INTERROGATORY NO. 2:

Describe in detail the circumstances surrounding the selection of Opposer's Mark, and identify the person(s) with the most knowledge of the selection of Opposer's Mark.

INTERROGATORY NO. 3:

Describe in detail all goods and/or services in conjunction with which Opposer's Mark, or any variation thereof, has ever been used, or contemplated to be used, by Opposer in the United States.

INTERROGATORY NO. 4:

Identify all variations of Opposer's Mark ever used or contemplated to be used by Opposer and indicate the goods and/or services upon which each such variation was used or contemplated to be used.

INTERROGATORY NO. 5:

With respect to each of the goods and/or services identified in response to Interrogatory No. 3, state the date when Opposer commenced use of Opposer's Mark in connection with each such good and/or service in each state of the United States, and identify all persons with knowledge thereof.

INTERROGATORY NO. 6:

With respect to each of the goods and/or services identified in response to Interrogatory No. 3, state the quarterly revenue in the United States, by product or service provided, for each year from inception to the present.

INTERROGATORY NO. 7:

State the average sales price for each good and/or service identified in Interrogatory No. 3 sold or offered by Opposer under Opposer's Mark in the United States every year from the year that each such good or service was first sold or offered under Opposer's Mark to the present.

INTERROGATORY NO. 8:

With respect to each of the goods identified in response to Interrogatory No. 3, describe in detail the nature of the product, including the ailment(s) treated by the product and how it is taken by the ultimate user.

INTERROGATORY NO. 9:

Identify the generic name(s) and chemical names(s) of all active ingredients used in connection with each of the goods and/or services identified in response to Interrogatory No. 3.

INTERROGATORY NO. 10:

Identify each class of persons who purchase or use Opposer's goods and/or services under Opposer's Mark.

INTERROGATORY NO. 11:

With respect to each pharmaceutical product identified in response to Interrogatory No. 3, indicate which pharmaceutical products are obtainable by doctor's prescription only.

INTERROGATORY NO. 12:

With respect to each pharmaceutical product identified in response to Interrogatory No. 3, describe in detail the medical specialties of the doctors who prescribe the pharmaceutical product.

INTERROGATORY NO. 13:

With respect to each pharmaceutical product identified in the response to Interrogatory No. 3, state the percentage of doctors of each medical specialty who prescribe the pharmaceutical product.

INTERROGATORY NO. 14:

State whether Opposer is aware of any ophthalmologists who have prescribed products bearing Opposer's Mark.

INTERROGATORY NO. 15:

With respect to each of the goods and/or services identified in response to Interrogatory No. 3, describe in detail the channels of trade in the United States by which the goods and/or services of Opposer reach the ultimate user.

INTERROGATORY NO. 16:

Describe all plans made by Opposer to alter the channels of trade provided in the answer to the above Interrogatory in the future.

INTERROGATORY NO. 17:

Describe in detail the manner, including TV, radio, print, kiosks, etc., in which Opposer's Mark, or any variation thereof, is promoted and/or advertised in the United States.

INTERROGATORY NO. 18:

With respect to each of the goods and/or services identified in response to Interrogatory No. 3, describe in detail the target consumers of the goods and/or services of Opposer.

INTERROGATORY NO. 19:

Identify any and all persons who have the most knowledge concerning Opposer's promotion or marketing of Opposer's Mark in the United States.

INTERROGATORY NO. 20:

State the names of all the publications, including journals, in which advertisements or articles containing Opposer's Mark have appeared in the United States.

INTERROGATORY NO. 21:

State the names of any or all conferences or trade shows where Opposer promoted or presented information regarding the goods and/or services used in connection with Opposer's Mark.

INTERROGATORY NO. 22:

With respect to each of the conferences or trade shows identified in response to the previous Interrogatory, describe the year or years Opposer attended.

INTERROGATORY NO. 23:

With respect to each of the conferences or trade shows attended by Opposer, describe the class of persons who attend.

INTERROGATORY NO. 24:

State the amount expended for advertising and promotion of Opposer's Mark, or any variation thereof, in the United States on a quarterly basis for each year since inception.

INTERROGATORY NO. 25:

Identify any person who has publicly endorsed or promoted the goods and/or services provided under Opposer's Mark.

INTERROGATORY NO. 26:

Identify all advertising agencies, public relations agencies, marketing firms, or market research agencies which Opposer has used in connection with any goods and/or services offered in connection with Opposer's Mark and indicate the time period(s) during which such activities were conducted and each person that was responsible or consulted.

INTERROGATORY NO. 27:

Describe in detail every search, survey, study, or investigation conducted by or on behalf of Opposer in connection with Opposer's Mark, or any variation thereof.

INTERROGATORY NO. 28:

State the nature of the business conducted by Opposer and a brief business history of Opposer and of all companies related to Opposer.

INTERROGATORY NO. 29:

Describe in detail the research and development efforts you have undertaken for each of the goods and/or services identified in response to Interrogatory No. 3.

INTERROGATORY NO. 30:

State whether Opposer is aware of any medical link between narcolepsy and ocular disorders.

INTERROGATORY NO. 31:

Describe in reasonable detail the circumstances relating to how and when you first became aware of (i) Applicant and (ii) Applicant's Mark, including but not limited to the date of such awareness and the manner in which you became aware of such information, and identify each person who obtained such knowledge.

INTERROGATORY NO. 32:

Describe in detail all agreements and the parties thereto, which Opposer has entered or is contemplating entering into, relating to Opposer's Mark.

INTERROGATORY NO. 33:

If Opposer claims the benefit of any use of Opposer's Mark, or any variation thereof, by any predecessor-in-title or licensee, identify the predecessor-in-title or licensee and describe in detail the nature and extent of the predecessor's or licensee's use of the marks.

INTERROGATORY NO. 34:

Identify all licensed users of Opposer's Mark.

INTERROGATORY NO. 35:

Describe any period of time when Opposer discontinued use of Opposer's Mark in the United States since its initial adoption by Opposer, provide the reasons for such discontinuance, and, if applicable, provide the date and location of any resumption of use and the reason for such resumption of use.

INTERROGATORY NO. 36:

Describe all instances of actual or possible confusion, or any reports of such confusion, known to Opposer between Opposer's Mark and Applicant's Mark, including but not limited to, all persons with knowledge thereof.

INTERROGATORY NO. 37:

Describe in detail every instance in which Opposer has ever disclaimed any association with Applicant in connection with the use of Opposer's Mark, or any variation thereof.

INTERROGATORY NO. 38:

Describe in detail any adversarial proceeding (apart from the present proceeding) involving Opposer's Mark or any variation thereof.

INTERROGATORY NO. 39:

Describe in detail the nature of any objection received by Opposer to its use or registration of Opposer's Mark.

INTERROGATORY NO. 40:

Describe in detail the facts of every objection made by Opposer to the use or registration by others of any trademark or service mark believed by Opposer to be confusingly similar to Opposer's Mark, or any variation thereof (apart from the present proceeding).

INTERROGATORY NO. 41:

Identify any third-party trademarks or service marks known by Opposer which can employ the first syllable sound "ZĪ" in connection with pharmaceutical products, over-the-counter medications, vitamins or nutritional supplements, medical devices, medical services or the health industry (other than Applicant's Mark).

INTERROGATORY NO. 42:

Identify the companies deemed by Opposer to be its significant competitors.

INTERROGATORY NO. 43:

Identify each person whom Opposer expects to call as a witness to give evidence in this proceeding, and for each such person, state the subject matter and the substance of the facts on which such person is expected to testify; the substance of the facts and opinions to which each expert is expected to testify; and the grounds for each such opinion of each expert.

INTERROGATORY NO. 44:

Identify all third-party marks upon which Opposer will rely for any purpose in connection with this Opposition.

INTERROGATORY NO. 45:

Identify all facts supporting Opposer's contentions in his proceedings against Applicant's Mark.

INTERROGATORY NO. 46:

If you contend that the types of goods or services for which you have registration for Opposer's Mark are the same as Applicant's Goods covered by Applicant's Mark or offered by Applicant, explain how they are similar.

INTERROGATORY NO. 47:

Identify all persons who were consulted or had more than a clerical role in the preparation of the answers or responses to the foregoing interrogatories or in the obtaining of information in connection with these interrogatories or Applicant's First Set of Requests for Production of Documents and Things to Applicant or in the responses to Applicant's First Set of Requests for Admissions to Applicant, and state the nature and extent of participation of each such person.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 22, 2005

By: _____

Steven J. Nataupsky
Michael K. Friedland
Tirzah Abé Lowe
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404
Attorneys for Applicant,
ISTA Pharmaceuticals, Inc.

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EXHIBIT 1 ,PAGE 13 OF 34

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing Applicant's First Set of Interrogatories Nos. 1-47 upon Opposer's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid on April 22, 2005, addressed as follows:

Mr. Peter J. Gleekel
Winthrop & Weinstine, P.A
225 South Sixth Street, Suite 3500
Minneapolis, MN 55402-4629.

Tirzah Abé Lowe

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042205

EXHIBIT 1, PAGE 14 OF 34

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

ORPHAN MEDICAL, INC., Opposer, v. ISTA PHARMACEUTICALS, INC., Applicant.	Opposition No.: 91162204

APPLICANT'S FIRST REQUESTS FOR

PRODUCTION OF DOCUMENTS AND THINGS NOS. 1- 80

Pursuant to Rule 2.120(d) of the U.S. Patent and Trademark Office's ("PTO") Trademark Rules of Practice, 37 C.F.R. § 2.120(d), and Rule 34 of the Federal Rules of Civil Procedure ("FRCP"), Applicant, ISTA Pharmaceuticals, Inc. hereby requests that Opposer, Orphan Medical, Inc., produce the following documents and things for inspection and copying at the offices of Knobbe, Martens, Olson & Bear, 2040 Main Street, Fourteenth Floor, Irvine, California 92614, or such other place as may be agreed between the parties, within thirty (30) days of service hereof in accordance with Rule 2.120(a) of the PTO's Trademark Rules of Practice and FRCP 34. Alternatively, Opposer may fulfill his obligation to produce the requested documents by attaching complete and legible copies of the original documents to his written responses to Applicant's First Requests for Production of Documents and Things Nos. 1-80 ("Document Requests") prior to the service of the same upon Applicant. Opposer may be requested to supplement his responses from time to time as appropriate in accordance with FRCP 26(e).

DEFINITIONS

1. The term "Opposer" shall mean Orphan Medical, Inc. and any present or former owners, officers, directors, employees, servants, agents, attorneys or other representatives acting on his behalf, and shall include any parent corporation, or wholly-owned or partially-owned subsidiary, predecessor, successor, or affiliate either within the United States or a foreign country.

2. The term "Applicant" shall mean ISTA Pharmaceuticals, Inc., and any present or former owners, officers, directors, employees, servants, agents, attorneys or other representatives acting on its behalf, and shall include any parent corporation, or wholly-owned or partially-owned subsidiary, predecessor, successor, or affiliate either within the United States or a foreign country.

3. The term "you" shall mean the party or person to whom the Document Request is propounded, all agents, servants, attorneys, and all other representatives, and persons over whom the person or party to whom the Document Request is propounded has the right to or does control or direct any activities.

4. The term "document" shall mean the original and all copies (whether or not different from the original because of notes made on or attached to each copy or otherwise), including but not limited to written, printed, typed and visually or aurally reproduced material of any kind, whether or not privileged, such as (by way of example and not by way of limitation) letters, notes, memoranda, summaries, minutes, interoffice communications, invoices, purchase orders, records, bills, contracts, agreements, catalogs, websites, orders, receipts, drawings or sketches, photographs, tapes or discs capable of being electronically or mechanically read, advertising or promotional literature, operating manuals or instruction bulletins, cables or

telegrams, e-mail, microfilm, videotapes, tape or other recordings, test data and reports.

5. The term "thing" shall mean all tangible objects of any type, composition, construction or nature.

6. A document or thing "relating" or which "relates" to any given subject means any document or thing that comprises, constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any way pertinent to that subject, including, without limitation, documents concerning the preparation of other documents.

7. The term "person" shall include both natural persons and corporate or other business entities, whether or not in the employ of Opposer, and the acts and knowledge of a person are defined to include the acts and knowledge of that person's directors, officers, members, employees, representatives, agents and attorneys.

8. The term "concerning" means relating to, referring to, describing, evidencing or constituting.

9. The terms "trademark" or "mark" shall include trademarks, service marks, collective marks, certification marks and trade names as defined in 15 U.S.C. § 1127.

10. The terms "all" and "each" shall be construed to include all and each.

11. The term "and" shall be construed to include "or" and *vice versa*, and shall be the logical equivalent of "and/or."

12. The use of the singular form of any word also includes the plural and *vice versa*.

13. The terms "Applicant's Mark" shall mean the mark shown in U.S. Trademark Application Number 78/298,369.

14. The terms "Opposer's Mark" shall mean and refer to all marks relied on by Opposer in the Notice of Opposition.

GENERAL INSTRUCTIONS

1. If you claim that any document requested or any portion thereof is privileged, please provide all information on such document falling within the scope of the Document Request which is not privileged, and identify with sufficient particularity for purposes of a Motion to Compel a Response for Production of each item, document or thing, separately, with respect to which you claim a privilege, and state:

a) the basis on which the privilege is claimed;

b) the author of the document;

c) each individual or other person to whom the document or copy thereof was sent or otherwise disclosed;

d) the date of the document; and

e) the general subject matter of the document.

You are not requested to provide privileged documents or portions thereof for which you claim privilege, but only to identify such information, document or thing.

2. Opposer's responses to the following Document Requests are to be promptly supplemented to include subsequently acquired information in accordance with the requirements of Rule 26(e) of the FRCP.

3. If any document which you would have produced in response to any Document Request was, but is no longer, in your present possession or subject to your control or is no longer in existence, please state whether any such document is:

a) missing or lost;

b) destroyed;

c) transferred to others; and

d) otherwise disposed of and, in any such instance, set forth the surrounding circumstances in any authorization for such disposition and state the approximate date of any such disposition, and, if known, state also the present location and custodian of such document.

4. The documents produced pursuant to these Document Requests shall be separately produced for each paragraph of the Document Requests or, in the alternative, shall be identified as complying with the particular paragraph(s) of the Document Requests to which they are responsive.

REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS

REQUEST FOR PRODUCTION NO. 1:

All documents and things identified in response to Applicant's First Set of Interrogatories, segregated by Interrogatory number.

REQUEST FOR PRODUCTION NO. 2:

All documents and things consulted in preparing responses to Applicant's First Set of Interrogatories, segregated by Interrogatory number.

REQUEST FOR PRODUCTION NO. 3:

Representative samples of all documents and things referring or relating to Opposer's selection, adoption, development, or creation of Opposer's Mark, including, but not limited to, invoices, advertisements in any media, promotional materials in any media, brochures, catalogs, labels, tags, packaging, containers, point-of-sale displays, or websites, produced by or on behalf of Opposer.

REQUEST FOR PRODUCTION NO. 4:

Representative samples of all documents and things referring or relating to any variation of

Opposer's Mark and/or goods and/or services upon which such variations were used or Opposer plans to use Opposer's Mark, including, but not limited to, invoices, advertisements in any media, promotional materials including email advertisements and promotions, catalogs, brochures, tags, labels, packaging, containers, point of sale displays, or websites, produced by or on behalf of Opposer.

REQUEST FOR PRODUCTION NO. 5:

Representative samples of all documents and things referring or relating to Opposer's current use of Opposer's Mark in connection with goods in International Class 5, including, but not limited to, invoices, advertisements in any media, promotional materials including email advertisements and promotions, catalogs, brochures, tags, labels, packaging, containers, point of sale displays, or websites, produced by or on behalf of Opposer.

REQUEST FOR PRODUCTION NO. 6:

All documents and things sufficient to identify each person who participated in the adoption, development, creation, or selection of Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 7:

All documents and things sufficient to identify each mark considered by Opposer as an alternate mark to Opposer's Mark.

REQUEST FOR PRODUCTION NO. 8:

Representative samples of all documents and things referring or relating to, Opposer's past use, current use, or plans for future use of Opposer's Mark in connection with any goods or services.

REQUEST FOR PRODUCTION NO. 9:

All documents and things that concern, refer, or relate to Opposer's decision to apply to

register Opposer's Mark, or any variation thereof, with the PTO, any State Trademark Office, or any other state or federal agency or entity.

REQUEST FOR PRODUCTION NO. 10:

All documents and things concerning any inquiry or investigation made by or on behalf of Opposer with respect to any reference noted on each trademark search.

REQUEST FOR PRODUCTION NO. 11:

All documents and things concerning any opinion regarding Opposer's right to use Opposer's Mark.

REQUEST FOR PRODUCTION NO. 12:

All documents and things concerning any business, legal or other opinions regarding any mark consisting of or including the mark "XIBROM," or any variation thereof.

REQUEST FOR PRODUCTION NO. 13:

All documents and things sufficient to identify all goods and/or services Opposer offers or intends to offer under Opposer's Mark, or any variation thereof, including:

a) the nature and intended use of the products and/or services;

b) the projected date and nature of the first use of Opposer's Mark, or any variation thereof, for each of the products and/or services;

c) the projected date and nature of the first use of Opposer's Mark, or any variation thereof, in interstate commerce;

d) the present stage of development of each product and/or service;

e) the steps that have been taken toward the exploitation of Opposer's Mark, or any variation thereof, in connection with each product and/or service; and

f) your intent to use Opposer's Mark, or any variation thereof, in connection with each product and/or service.

REQUEST FOR PRODUCTION NO. 14:

All documents and things sufficient to identify the period or periods of use of Opposer's Mark, or any variation thereof, since the date of first use.

REQUEST FOR PRODUCTION NO. 15:

Representative samples of all invoices, purchase orders, sales reports, shipping orders, inventory reports, or other records concerning any sales or offerings of goods and/or services to any person or entity under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 16:

All documents and things, including financial, accounting and corporate records concerning:

a) your total income from the sale of Opposer's goods and/or services under Opposer's Mark; and

b) your projected income from the sale of Opposer's goods and/or services under Opposer's Mark.

REQUEST FOR PRODUCTION NO. 17:

All documents and things sufficient to establish the date of first use in commerce of Opposer's Mark, or any variation thereof, in connection with each good and/or service rendered under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 18:

All documents and things sufficient to show how Opposer uses or intends to use Opposer's Mark, or any variation thereof, including, but not limited to: advertising and advertising mockups

and proposals, promotional materials including emails and websites, catalogs, forms, letterhead, membership materials, purchase orders, press and/or media kits, point-of-purchase displays, and promotional goods and FDA submissions.

REQUEST FOR PRODUCTION NO. 19:

All documents and things sufficient to identify each channel of trade through which Opposer markets or intends to market his goods and/or services under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 20:

All documents and things sufficient to identify each type of media through which Opposer advertises and promotes or intends to advertise and promote goods and/or services under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 21:

All documents and things sufficient to identify each publication through which Opposer advertises and promotes or intends to advertise and promote goods and/or services under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 22:

Representative samples of all documents and things relating or referring to, or tending to show, the amount of money spent by any authorized user of Opposer's Mark for promotional activities or advertisements for Opposer's Mark.

REQUEST FOR PRODUCTION NO. 23:

Representative samples of all documents and things relating or referring to, or showing market research conducted by Opposer in connection with Opposer's Mark, including, but not limited to, surveys or statistics showing Opposer's target audience of consumers.

REQUEST FOR PRODUCTION NO. 24:

All documents and things concerning studies, tests, ratings or surveys in connection with the quality and performance of Opposer's Mark in connection with goods in International Class 5.

REQUEST FOR PRODUCTION NO. 25:

All documents and things concerning business plans, including but not limited to marketing plans, advertising plans, and business forecasts, for goods in International Class 5 in connection with Opposer's Mark.

REQUEST FOR PRODUCTION NO. 26:

All documents and things concerning your policies regarding retention, storage, filing and destruction of documents and things.

REQUEST FOR PRODUCTION NO. 27:

All documents and things concerning any efforts to enforce the rights in Opposer's Mark against any third persons.

REQUEST FOR PRODUCTION NO. 28:

All documents and things relating or referring to any search or investigation of records of the PTO or any other records or publications in connection with the decision to adopt, the adoption, use or application for registration of Opposer's Mark.

REQUEST FOR PRODUCTION NO. 29:

All documents and things relating or referring to the incorporation or creation of Opposer's company or any of his subsidiaries or related companies, including but not limited to copies of the incorporation documents signed by the Secretary of State of the state of incorporation for Opposer and for each of his subsidiaries or related companies.

REQUEST FOR PRODUCTION NO. 30:

All documents and things relating or referring to or showing ownership of any claimed predecessor-in-title to Opposer's Mark.

REQUEST FOR PRODUCTION NO. 31:

Representative samples of all documents and things relating or referring to plans for steps toward expansion by Opposer of the number of products or services in connection with which Opposer's Mark is used, or to alter the present channels of distribution, or to sell to persons other than Opposer's present purchasers or consumers.

REQUEST FOR PRODUCTION NO. 32:

Representative samples of all documents and things relating or referring to, or showing how Opposer's Mark has been and is being advertised or promoted in the U.S. since the date of its initial adoption to the present, including internal company memorandums, brochures, flyers, newspaper articles, advertisements (both print and electronic versions), magazine or trade journal articles, and radio or television advertisements.

REQUEST FOR PRODUCTION NO. 33:

Representative samples of documents referring or relating to or tending to show any current or anticipated advertisements or promotions in the U.S. of goods or services bearing Opposer's Mark or in association with Opposer's Mark, including internal company memorandums, brochures, flyers, newspaper articles, advertisements (both print and electronic versions), magazine or trade journal articles, and radio or television advertisements.

REQUEST FOR PRODUCTION NO. 34:

A sample of each product, label, tag, packaging, or container showing Opposer's use of Opposer's Mark since its initial adoption.

REQUEST FOR PRODUCTION NO. 35:

All documents and things sufficient to identify each trade and/or professional association through which Opposer promotes or intends to promote his goods and/or services under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 36:

All documents and things sufficient to identify each trade show through which Opposer promotes or intends to promote his goods and/or services under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 37:

All documents and things sufficient to identify each class of persons, including but not limited to, gender, age, ethnicity, and socioeconomic status, who purchase, prescribe, or use Opposer's goods and/or services provided under Opposer's Mark.

REQUEST FOR PRODUCTION NO. 38:

All documents sufficient to identify each public relations firm, advertising agency, and marketing firm that has been engaged to advertise or promote Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 39:

All communications between Opposer and any public relations firm, advertising agency, and/or marketing firm that has been engaged to advertise or promote Opposer's goods and/or services.

REQUEST FOR PRODUCTION NO. 40:

Each press release issued by or on behalf of Opposer which refers to Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 41:

Each press release issued by or on behalf of Opposer which refers to Opposer's goods and/or services.

REQUEST FOR PRODUCTION NO. 42:

Each unsolicited press mention, article or other story relating to Opposer and/or Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 43:

All advertisements in any magazine, newspaper or other printed publication, relating to Opposer and/or Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 44:

Each unsolicited press mention of Opposer's goods and/or services.

REQUEST FOR PRODUCTION NO. 45:

All documents and things sufficient to identify the approximate dollar amount expended annually by Opposer in advertising and promoting Opposer's Mark, or any variation thereof, from inception to the present.

REQUEST FOR PRODUCTION NO. 46:

All documents and things sufficient to identify each retail store which sells Opposer's goods and/or services.

REQUEST FOR PRODUCTION NO. 47:

All documents and things sufficient to identify each channel of distribution through which Opposer provides his goods and/or services.

REQUEST FOR PRODUCTION NO. 48:

All documents and things sufficient to identify the specific geographic area within which

Opposer has provided goods and/or services under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 49:

All documents and things sufficient to identify the specific geographic areas within which Opposer has promoted goods and/or services under Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 50:

All marketing plans referring or relating to Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 51:

All documents and things concerning the marketing, advertisement, and/or promotion of Opposer's goods and/or services, including any customer list or other materials identifying actual or prospective clients and customers.

REQUEST FOR PRODUCTION NO. 52:

All documents and things that refer or relate to any plans by Opposer to expand use of Opposer's Mark, or any variation thereof, or sales or distribution of the goods and/or services, including but not limited to expansion of marketing lines, customer base or geographical areas served.

REQUEST FOR PRODUCTION NO. 53:

All documents and things sufficient to identify on an annual basis the number of companies and people using goods and/or services offered in connection with Opposer's Mark, or any variation thereof, from Opposer's first use to the present.

REQUEST FOR PRODUCTION NO. 54:

All documents sufficient to identify the approximate annual sales in both units and dollars of all goods and/or services offered in connection with Opposer's Mark, or any variation thereof, from Opposer's first use until present.

REQUEST FOR PRODUCTION NO. 55:

All documents sufficient to identify the approximate annual sales in both units and dollars of all goods in International Class 5 offered in connection with Opposer's Mark, or any variation thereof, from Opposer's first use until present.

REQUEST FOR PRODUCTION NO. 56:

All documents and things relating or referring to any discontinuation of use of Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 57:

All documents and things in Opposer's possession, custody or control concerning, referring, or relating to Opposer's first awareness of any of Applicant's Marks.

REQUEST FOR PRODUCTION NO. 58:

All documents and things in Opposer's possession, custody, or control which refer or relate to Applicant, Applicant's Mark, or to any good and/or service of Applicant, including but not limited to Applicant's goods and/or services rendered under Applicant's Mark.

REQUEST FOR PRODUCTION NO. 59:

All documents and things evidencing, referring or relating to third-party use of Opposer's Mark, or any variation thereof, including, but not limited to, authorizations, assignments, licenses and agreements, including but not limited to, franchise agreements and manufacturing agreements, whether in draft form or executed.

REQUEST FOR PRODUCTION NO. 60:

All documents and things evidencing, referring or relating to any domain names registered, owned, previously owned, or contemplated which consist of or incorporate Opposer's Mark, or any variation thereof, and the dates of registration of the domain names, including, but not limited to,

Whois printouts, and documents referring or relating to the annual amount of expenditures for domain name registration and hosting services.

REQUEST FOR PRODUCTION NO. 61:

A copy of each market survey and other research documents including but not limited to surveys, polls, tests and focus group studies Opposer has conducted or plans to conduct directed to:

a) Opposer's goods and/or services rendered under Opposer's Mark, or any variation thereof;

b) Opposer's Mark, or any variation thereof, as perceived by purchasers and potential purchasers;

c) confusion between Opposer's Mark, or any variation thereof, and the mark or name of any other entity; or

d) possible use in this Opposition proceeding.

REQUEST FOR PRODUCTION NO. 62:

All unsolicited communications to Opposer that refer to Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 63:

All documents and things concerning any inquiry or investigation made by or on behalf of Opposer with respect to Applicant's Marks.

REQUEST FOR PRODUCTION NO. 64:

All documents and things which evidence, refer, or relate to any confusion, or the likelihood or possibility of confusion, between Opposer and Applicant, or between the goods and/or services offered, sold, or distributed by Applicant or Opposer, including but not limited to consumer statements, misdirected mail and inquiries as to affiliation.

REQUEST FOR PRODUCTION NO. 65:

All documents which evidence actual confusion with respect to any affiliation between Applicant and Opposer, including but not limited to misdirected mail and inquiries as to affiliation.

REQUEST FOR PRODUCTION NO. 66:

All communications intended for Applicant that were received by Opposer.

REQUEST FOR PRODUCTION NO. 67:

All documents and things referring or relating to or tending to show a disclaimer made by Opposer as to an association with Applicant.

REQUEST FOR PRODUCTION NO. 68:

All documents and things referring or relating to any adversarial proceeding involving Opposer's Mark, or any variation thereof, before the Trademark Trial and Appeal Board, Bureau of Customs, Federal Trade Commission, or any court.

REQUEST FOR PRODUCTION NO. 69:

All documents and things referring or relating to any objection raised to Opposer's use or registration of Opposer's Mark, or any variation thereof, by any third party.

REQUEST FOR PRODUCTION NO. 70:

All documents and things referring or relating to any objections made by Opposer to the use by others, of marks believed by Opposer to be confusingly similar to Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 71:

All documents and things sufficient to identify companies deemed by Opposer to be its competitors.

REQUEST FOR PRODUCTION NO. 72:

All documents and things which identify any third-party users of marks incorporating the initial letters "XI," "XY," ZI," or "ZY" or the initial sound "ZI."

REQUEST FOR PRODUCTION NO. 73:

All documents and things which support Opposer's allegations in his Notice of Opposition.

REQUEST FOR PRODUCTION NO. 74:

All documents and things submitted to the FDA in connection with the goods and/or services used in connection with Opposer's Mark.

REQUEST FOR PRODUCTION NO. 75:

All documents and things in connection with the research and development of the goods and/or services used in connection with Opposer's Mark, including any documents and things in connection with clinical trials.

REQUEST FOR PRODUCTION NO. 76:

For each expert whose opinion may be relied upon in this proceeding, each document concerning:

a) any opinions that may be presented in the Opposition;

b) the reason for such opinions;

c) any data or information considered by the witness in forming the opinions;

d) any exhibits used in support of or summarizing the opinions;

e) the compensation being paid to the witness; and

f) any cases in which the witness has testified at trial or by deposition from 1992 to date.

REQUEST FOR PRODUCTION NO. 77:

All documents and things that support your claim that there is a likelihood of confusion between Opposer's Mark, or any variation thereof, and Applicant's Mark.

REQUEST FOR PRODUCTION NO. 78:

All files maintained in connection with Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 79:

All documents and things bearing Opposer's Mark, or any variation thereof.

REQUEST FOR PRODUCTION NO. 80:

All advertisements, brochures, promotional materials and articles bearing Opposer's Mark, or any variation thereof.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 22, 2005

By: _____

Steven J. Nataupsky
Michael K. Friedland
Tirzah Abé Lowe
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404
Attorneys for Applicant,
ISTA Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing Applicant's First Requests For Documents and Things Nos. 1-80 upon Opposer's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid on April 22, 2005, addressed as follows:

Mr. Peter Gleekel
Winthrop & Weinstine, P.A.
225 South Sixth Street, Suite 3500
Minneapolis, MN 55402-4629

Tirzah Abé Lowe

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EXHIBIT 1, PAGE 34 OF 34

Contains Confidential and Attorneys' Eyes Only Information Subject to the Protective Order

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

ORPHAN MEDICAL, INC.,

Opposer,

v.

ISTA PHARMACEUTICALS, INC.,

Applicant.

Opposition No. 91162204
Mark: XIBROM
Serial No. 78/298,369
Filed: September 10, 2003
Published: August 31, 2004

RESPONSE TO APPLICANT'S REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS

TO: Applicant ISTA Pharmaceuticals, Inc., through its Attorneys, Steven J. Nataupsky, Esq., Michael K. Friedland, Esq. and Tirzah Abé Lowe, Esq., Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, California 92614.

COMES NOW, Opposer Orphan Medical, Inc. ("Orphan Medical") and as and for its Responses to Applicant's Requests for Production of Documents and Things states as follows:

GENERAL OBJECTIONS

1. The following responses are made by Orphan Medical without in any manner waiving or intending to waive:

a. All questions as to competency, relevancy, materiality, privilege and admissibility as evidence for any purpose, of the responses or subject matter thereof in any subsequent proceeding in this or any other action;

b. The right at any time to the use of any of said responses or subject matter, in any subsequent proceeding in this or in any other action;

c. The right to object on any ground at any time to a demand for further response to this or any other request for production of documents and things or other discovery procedures involving or relating to the subject matter of this Request for Production of Document and Things; and

d. The right at any time to revise, correct, add to, or clarify any of the responses herein.

2. Orphan Medical objects to each and every Request to the extent it seeks to discover information protected by work product or privilege, as defined by statute, or common law.

3. Orphan Medical objects to the extent any Request seeks production of documents not in the custody, possession or control of Orphan Medical.

4. Orphan Medical objects to the extent any Request seeks to impose an obligation to respond beyond that required by the Federal Rules of Civil Procedure and/or the Trademark Rules of Practice.

Subject to and without waiver of the foregoing General Objections, Orphan Medical responds and asserts specific objections in response to Applicant's First Request for Production of Documents and Things as follows:

REQUESTS AND RESPONSES FOR
PRODUCTION OF DOCUMENTS AND THINGS

REQUEST NO. 1: All documents and things identified in response to Applicant's First Set of Interrogatories, segregated by Interrogatory number.

RESPONSE: Orphan Medical objects to this Request to the extent it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or

attorney-client privilege. Orphan Medical objects to this request to the extent it seeks to impose burden otherwise not required by applicable rule. Subject to and without waiving these objections, any documents responsive to Request No. 1 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 2: All documents and things consulted in preparing responses to Applicant's First Set of Interrogatories, segregated by Interrogatory number.

RESPONSE: See response to Request No. 1.

REQUEST NO. 3: Representative samples of all documents and things referring or relating to Opposer's selection, adoption, development, or creation of Opposer's Mark, including, but not limited to, invoices, advertisements in any media, promotional materials in any media, brochures, catalogs, labels, tags, packaging, containers, point-of-sale displays, or websites, produced by or on behalf of Opposer.

RESPONSE: Orphan Medical objects to the phrases "relating" and "referring" on the grounds that they are overly broad, burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations. Orphan Medical further objects to the Request on the grounds that it is overbroad, unduly burdensome, is not relevant to any issue in this action, and is not reasonably calculated to lead to the discovery of relevant evidence. It is also improper to the extent that it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-client privilege. Orphan Medical objects to this request to the extent it seeks to impose burden otherwise not required by applicable rule. Subject to and without waiving these objections, any documents responsive to Request No. 2 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 4: Representative samples of all documents and things referring or relating to any variation of Opposer's Mark and/or goods and/or services upon which such variations were used or Opposer plans to use Opposer's Mark, including, but not limited to, invoices, advertisements in any media, promotional materials including email advertisements and

promotions, catalogs, brochures, tags, labels, packaging, containers, point of sale displays, or websites, produced by or on behalf of Opposer.

RESPONSE: Orphan Medical objects to the phrases "relating" and "referring" on the grounds that they are overly broad, burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations. Orphan Medical further objects to the Request on the grounds that it is overbroad, unduly burdensome, is not relevant to any issue in this action, and is not reasonably calculated to lead to the discovery of relevant evidence. Without waiving these objections Orphan Medical responds no such documents exist.

REQUEST NO. 5: Representative samples of all documents and things referring or relating to Opposer's current use of Opposer's Mark in connection with goods in International Class 5, including, but not limited to, invoices, advertisements in any media, promotional materials including email advertisements and promotions, catalogs, brochures, tags, labels, packaging, containers, point of sale displays, or websites, produced by or on behalf of Opposer.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence. Orphan Medical further objects to this Request to the extent it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-client privilege. Subject to and without waiving these objections, any documents responsive to Request No. 5 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 6: All documents and things sufficient to identify each person who participated in the adoption, development, creation, or selection of Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence. Orphan Medical further objects to this Request to the extent it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-

client privilege. Subject to and without waiving these objections, any documents responsive to Request No. 6 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel. Further, all individuals who were employees of Orphan Medical, Inc., at that time, participated in the product naming meeting.

REQUEST NO. 7: All documents and things sufficient to identify each mark considered by Opposer as an alternate mark to Opposer's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is overly broad, burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations, is not relevant to any issue in this action, and is not reasonably calculated to lead to the discovery of relevant evidence. Without waiving these objections Orphan Medical responds no such documents exist.

REQUEST NO. 8: Representative samples of all documents and things referring or relating to, Opposer's past use, current use, or plans for future use of Opposer's Mark in connection with any goods or services.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 8 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 9: All documents and things that concern, refer, or relate to Opposer's decision to apply to register Opposer's Mark, or any variation thereof, with the PTO, any State Trademark Office, or any other state or federal agency or entity.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant

evidence. Orphan Medical further objects to this Request to the extent it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-client privilege. Without waiving these objections, Opposer responds no such documents exist.

REQUEST NO. 10: All documents and things concerning any inquiry or investigation made by or on behalf of Opposer with respect to any reference noted on each trademark search.

RESPONSE: Orphan Medical objects to the Request on the grounds that it is vague, confusing, ambiguous, overbroad, subject to interpretation, is not relevant to any issue in this action, and is not reasonably calculated to lead to the discovery of relevant evidence.

REQUEST NO. 11: All documents and things concerning any opinion regarding Opposer's right to use Opposer's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence. Orphan Medical further objects to this Request to the extent it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-client privilege. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 12: All documents and things concerning any business, legal or other opinions regarding any mark consisting of or including the mark "XIBROM," or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence. Orphan Medical further objects to this Request to the extent it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-client privilege. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 13: All documents and things sufficient to identify all goods and/or services Opposer offers or intends to offer under Opposer's Mark, or any variation thereof, including:

a. the nature and intended use of the products and/or services;

b. the projected date and nature of the first use of Opposer's Mark, or any variation thereof, for each of the products and/or services;

c. the projected date and nature of the first use of Opposer's Mark, or any variation thereof, in interstate commerce;

d. the present stage of development of each product and/or service;

e. the steps that have been taken toward the exploitation of Opposer's Mark, or any variation thereof, in connection with each product and/or service; and

f. your intent to use Opposer's Mark, or any variation thereof, in connection with each product and/or service.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence. Orphan Medical further objects to this Request to the extent it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-client privilege. Subject to and without waiving these objections, any documents responsive to Request No. 13 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 14: All documents and things sufficient to identify the period or periods of use of Opposer's Mark, or any variation thereof, since the date of first use.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 14 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 15: Representative samples of all invoices, purchase orders, sales reports, shipping orders, inventory reports, or other records concerning any sales or offerings of goods and/or services to any person or entity under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 15 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 16: All documents and things, including financial, accounting and corporate records concerning:

a. your total income from the sale of Opposer's goods and/or services under Opposer's Mark; and

b. your projected income from the sale of Opposer's goods and/or services under Opposer's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see response to Interrogatory No. 6.

REQUEST NO. 17: All documents and things sufficient to establish the date of first use in commerce of Opposer's Mark, or any variation thereof, in connection with each good and/or service rendered under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 17 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 18: All documents and things sufficient to show how Opposer uses or intends to use Opposer's Mark, or any variation thereof, including, but not limited to: advertising and advertising mockups and proposals, promotional materials including emails and websites,

catalogs, forms, letterhead, membership materials, purchase orders, press and/or media kits, point-of-purchase displays, and promotional goods and FDA submissions.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 18 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 19: All documents and things sufficient to identify each channel of trade through which Opposer markets or intends to market his goods and/or services under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 19 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 20: All documents and things sufficient to identify each type of media through which Opposer advertises and promotes or intends to advertise and promote goods and/or services under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 20 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel. Further, Orphan Medical uses

its website at www.orphan.com to advertise and promote the goods offered under Opposer's mark.

REQUEST NO. 21: All documents and things sufficient to identify each publication through which Opposer advertises and promotes or intends to advertise and promote goods and/or services under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 21 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 22: Representative samples of all documents and things relating or referring to, or tending to show, the amount of money spent by any authorized user of Opposer's Mark for promotional activities or advertisements for Opposer's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 23: Representative samples of all documents and things relating or referring to, or showing market research conducted by Opposer in connection with Opposer's Mark, including, but not limited to, surveys or statistics showing Opposer's target audience of consumers.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence.

REQUEST NO. 24: All documents and things concerning studies, tests, ratings or surveys in connection with the quality and performance of Opposer's Mark in connection with goods in International Class 5.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 25: All documents and things concerning business plans, including but not limited to marketing plans, advertising plans, and business forecasts, for goods in International Class 5 in connection with Opposer's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence.

REQUEST NO. 26: All documents and things concerning your policies regarding retention, storage, filing and destruction of documents and things.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 27: All documents and things concerning any efforts to enforce the rights in Opposer's Mark against any third persons.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 27 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 28: All documents and things relating or referring to any search or investigation of records of the PTO or any other records or publications in connection with the decision to adopt, the adoption, use or application for registration of Opposer's Mark.

RESPONSE: Orphan Medical objects to the phrases "relating" and "referring" on the grounds that they are overly broad, burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations. Orphan Medical further objects to the Request on the grounds that it is overbroad, unduly burdensome, is not relevant to any issue in this action, and is not reasonably calculated to lead to the discovery of relevant evidence. It is also improper to the extent that it could be interpreted to apply to documents protected from disclosure by the work product doctrine and/or attorney-client privilege. Subject to and without waiving these objections, any documents responsive to Request No. 28 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 29: All documents and things relating or referring to the incorporation or creation of Opposer's company or any of his subsidiaries or related companies, including but not limited to copies of the incorporation documents signed by the Secretary of State of the state of incorporation for Opposer and for each of his subsidiaries or related companies.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence.

REQUEST NO. 30: All documents and things relating or referring to or showing ownership of any claimed predecessor-in-title to Opposer's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, Orphan Medical responds no such documents exist.

REQUEST NO. 31: Representative samples of all documents and things relating or referring to plans for steps toward expansion by Opposer of the number of products or services in

connection with which Opposer's Mark is used, or to alter the present channels of distribution, or to sell to persons other than Opposer's present purchasers or consumers.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 31 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 32: Representative samples of all documents and things relating or referring to, or showing how Opposer's Mark has been and is being advertised or promoted in the U.S. since the date of its initial adoption to the present, including internal company memorandums, brochures, flyers, newspaper articles, advertisements (both print and electronic versions), magazine or trade journal articles, and radio or television advertisements.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 32 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel. Further, such documents are a matter of public record and can be researched utilizing Lexis/Nexis search engines. Applicant has equal access to these records and can easily identify and print which news publications or articles in which they are interested.

REQUEST NO. 33: Representative samples of documents referring or relating to or tending to show any current or anticipated advertisements or promotions in the U.S. of goods or services bearing Opposer's Mark or in association with Opposer's Mark, including internal company memorandums, brochures, flyers, newspaper articles, advertisements (both print and electronic versions), magazine or trade journal articles, and radio or television advertisements.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 33 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 34: A sample of each product, label, tag, packaging, or container showing Opposer's use of Opposer's Mark since its initial adoption.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 34 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 35: All documents and things sufficient to identify each trade and/or professional association through which Opposer promotes or intends to promote his goods and/or services under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see response to Interrogatory No. 21.

REQUEST NO. 36: All documents and things sufficient to identify each trade show through which Opposer promotes or intends to promote his goods and/or services under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying

interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 36 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel. See response to Interrogatory No. 21.

REQUEST NO. 37: All documents and things sufficient to identify each class of persons, including but not limited to, gender, age, ethnicity, and socioeconomic status, who purchase, prescribe, or use Opposer's goods and/or services provided under Opposer's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see Opposer's answers to Interrogatories 10, 12, 13, 15, and 18.

REQUEST NO. 38: All documents sufficient to identify each public relations firm, advertising agency, and marketing firm that has been engaged to advertise or promote Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see Opposer's answer to Interrogatory 26.

REQUEST NO. 39: All communications between Opposer and any public relations firm, advertising agency, and/or marketing firm that has been engaged to advertise or promote Opposer's goods and/or services.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence.

REQUEST NO. 40: Each press release issued by or on behalf of Opposer which refers to Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 40 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 41: Each press release issued by or on behalf of Opposer which refers to Opposer's goods and/or services.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 41 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 42: Each unsolicited press mention, article or other story relating to Opposer and/or Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 42 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 43: All advertisements in any magazine, newspaper or other printed publication, relating to Opposer and/or Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 43 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 44: Each unsolicited press mention of Opposer's goods and/or services.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 44 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 45: All documents and things sufficient to identify the approximate dollar amount expended annually by Opposer in advertising and promoting Opposer's Mark, or any variation thereof, from inception to the present.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see response to Interrogatory No. 24.

REQUEST NO. 46: All documents and things sufficient to identify each retail store which sells Opposer's goods and/or services.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, Orphan Medical responds that the goods offered under the XYREM mark are not sold in retail stores, as that term, "retail stores", is understood.

REQUEST NO. 47: All documents and things sufficient to identify each channel of distribution through which Opposer provides his goods and/or services.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Further, Orphan Medical objects to this Request on the grounds that it requests confidential information and/or trade secrets of Orphan Medical. Subject to and without waiving these objections, see response to Interrogatory No. 15.

REQUEST NO. 48: All documents and things sufficient to identify the specific geographic area within which Opposer has provided goods and/or services under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, Opposer responds that the goods are not limited to the geographic area in which they are provided or offered.

REQUEST NO. 49: All documents and things sufficient to identify the specific geographic areas within which Opposer has promoted goods and/or services under Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying

interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see response to Request No. 48.

REQUEST NO. 50: All marketing plans referring or relating to Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations, is duplicative of Request No. 25 and is not reasonably calculated to lead to the discovery of relevant evidence. See also response to Request No. 25.

REQUEST NO. 51: All documents and things concerning the marketing, advertisement, and/or promotion of Opposer's goods and/or services, including any customer list or other materials identifying actual or prospective clients and customers.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, undefined and subject to varying interpretations, duplicative of Request Nos. 32, 35, 36 and 43 and is not reasonably calculated to lead to the discovery of relevant evidence. Orphan Medical further objects to this request on the grounds that it violates patient confidentiality.

REQUEST NO. 52: All documents and things that refer or relate to any plans by Opposer to expand use of Opposer's Mark, or any variation thereof, or sales or distribution of the goods and/or services, including but not limited to expansion of marketing lines, customer base or geographical areas served.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, duplicative, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Further, Orphan Medical objects to this Request on the grounds it request confidential information or trade secrets of Orphan Medical. Subject to and without waiving these objections, see response to Document Request No. 31.

THIS PAGE CONTAINS ATTORNEYS' EYES ONLY INFORMATION

REDACTED

REQUEST NO. 55: All documents sufficient to identify the approximate annual sales in both units and dollars of all goods in International Class 5 offered in connection with Opposer's Mark, or any variation thereof, from Opposer's first use until present.

RESPONSE: See response to Request No. 54.

REQUEST NO. 56: All documents and things relating or referring to any discontinuation of use of Opposer's Mark, or any variation thereof.

RESPONSE: No such documents exist.

REQUEST NO. 57: All documents and things in Opposer's possession, custody or control concerning, referring, or relating to Opposer's first awareness of any of Applicant's Marks.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist; see response to Interrogatory No. 31.

REQUEST NO. 58: All documents and things in Opposer's possession, custody, or control which refer or relate to Applicant, Applicant's Mark, or to any good and/or service of Applicant, including but not limited to Applicant's goods and/or services rendered under Applicant's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 58 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 59: All documents and things evidencing, referring or relating to third-party use of Opposer's Mark, or any variation thereof, including, but not limited to, authorizations, assignments, licenses and agreements, including but not limited to, franchise agreements and manufacturing agreements, whether in draft form or executed.

RESPONSE: No documents exist.

REQUEST NO. 60: All documents and things evidencing, referring or relating to any domain names registered, owned, previously owned, or contemplated which consist of or incorporate Opposer's Mark, or any variation thereof, and the dates of registration of the domain names, including, but not limited to, Whois printouts, and documents referring or relating to the annual amount of expenditures for domain name registration and hosting services.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 60 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 61: A copy of each market survey and other research documents including but not limited to surveys, polls, tests and focus group studies Opposer has conducted or plans to conduct directed to:

a. Opposer's goods and/or services rendered under Opposer's Mark, or any variation thereof;

b. Opposer's Mark, or any variation thereof, as perceived by purchasers and potential purchasers;

c. confusion between Opposer's Mark, or any variation thereof, and the mark or name of any other entity; or

d. possible use in this Opposition proceeding.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence.

REQUEST NO. 62: All unsolicited communications to Opposer that refer to Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying

interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 63: All documents and things concerning any inquiry or investigation made by or on behalf of Opposer with respect to Applicant's Marks.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 64: All documents and things which evidence, refer, or relate to any confusion, or the likelihood or possibility of confusion, between Opposer and Applicant, or between the goods and/or services offered, sold, or distributed by Applicant or Opposer, including but not limited to consumer statements, misdirected mail and inquiries as to affiliation.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 65: All documents which evidence actual confusion with respect to any affiliation between Applicant and Opposer, including but not limited to misdirected mail and inquiries as to affiliation.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 66: All communications intended for Applicant that were received by Opposer.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying

interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 67: All documents and things referring or relating to or tending to show a disclaimer made by Opposer as to an association with Applicant.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 68: All documents and things referring or relating to any adversarial proceeding involving Opposer's Mark, or any variation thereof, before the Trademark Trial and Appeal Board, Bureau of Customs, Federal Trade Commission, or any court.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 68 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 69: All documents and things referring or relating to any objection raised to Opposer's use or registration of Opposer's Mark, or any variation thereof, by any third party.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, no such documents exist.

REQUEST NO. 70: All documents and things referring or relating to any objections made by Opposer to the use by others, of marks believed by Opposer to be confusingly similar to Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, any documents responsive to Request No. 70 that exist and are in the possession, custody or control of Orphan Medical will be produced at a mutually convenient time and place to be agreed upon by counsel.

REQUEST NO. 71: All documents and things sufficient to identify companies deemed by Opposer to be its competitors.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see response to Interrogatory No. 42.

REQUEST NO. 72: All documents and things which identify any third-party users of marks incorporating the initial letters "XI," "XY," ZI," or "ZY" or the initial sound "ZI."

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations, and is not reasonably calculated to lead to the discovery of relevant evidence, and further, such information is in the public domain and equally available to Applicant. Without waiving this objection Orphan Medical responds no such documents exist.

REQUEST NO. 73: All documents and things which support Opposer's allegations in his Notice of Opposition.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence.

Subject to and without waiving these objections, see responses to Requests above and Opposer's Answers to Applicant's Interrogatories.

REQUEST NO. 74: All documents and things submitted to the FDA in connection with the goods and/or services used in connection with Opposer's Marks.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence.

REQUEST NO. 75: All documents and things in connection with the research and development of the goods and/or services used in connection with Opposer's Mark, including any documents and things in connection with clinical trials.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Further, Orphan Medical objects to this Request on the grounds that it requests confidential information and/or trade secrets of Orphan Medical.

REQUEST NO. 76: For each expert whose opinion may be relied upon in this proceeding, each document concerning:

a. any opinions that may be presented in the Opposition;

b. the reason for such opinions;

c. any data or information considered by the witness in forming the opinions;

d. any exhibits used in support of or summarizing the opinions;

e. the compensation being paid to the witness; and

f. any cases in which the witness has testified at trial or by deposition from 1992 to date.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence.

Subject to and without waiving these objections, discovery is ongoing. Orphan Medical will disclose this information when available.

REQUEST NO. 77: All documents and things that support your claim that there is a likelihood of confusion between Opposer's Mark, or any variation thereof, and Applicant's Mark.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see responses to Requests herein.

REQUEST NO. 78: All files maintained in connection with Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see responses contained herein.

REQUEST NO. 79: All documents and things bearing Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see responses contained herein.

REQUEST NO. 80: All advertisements, brochures, promotional materials and articles bearing Opposer's Mark, or any variation thereof.

RESPONSE: Orphan Medical objects to this Request on the grounds that it is over broad, unduly burdensome, vague, confusing, ambiguous, undefined and subject to varying

interpretations and is not reasonably calculated to lead to the discovery of relevant evidence. Subject to and without waiving these objections, see responses contained herein.

Dated: August 1, 2005

WINTHROP & WEINSTINE, P.A.

By: _____
Peter J. Gleekel, #149834
Stephen R. Baird, #0214024
Samuel T. Lockner, #0341095

225 South Sixth Street
Suite 3500
Minneapolis, MN 55402
Phone: (612) 604-6400
Fax: (612) 604-6800

Attorneys for Opposer Orphan Medical, Inc.

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

ORPHAN MEDICAL, INC.,

Opposer,

v.

ISTA PHARMACEUTICALS, INC.,

Applicant.

Opposition No. 91162204
Mark: XIBROM
Serial No. 78/298,369
Filed: September 10, 2003
Published: August 31, 2004

ANSWERS TO APPLICANT'S FIRST SET OF INTERROGATORIES NOS. 1-47

TO: Applicant ISTA Pharmaceuticals, Inc., through its Attorneys, Steven J. Nataupsky, Esq., Michael K. Friedland, Esq. and Tirzah Abé Lowe, Esq., Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, California 92614.

COMES NOW Opposer Orphan Medical, Inc. ("Opposer") as and for its Answers to Applicant ISTA Pharmaceuticals, Inc.'s ("Applicant") First Set of Interrogatories Nos. 1-47 states as follows:

GENERAL OBJECTIONS

Opposer generally objects to the Interrogatories of Applicant to the extent those Interrogatories seek answers or information protected by any privilege, including but not limited to, the work product privilege and the attorney/client privilege, and to the extent they seek information or answers not properly discoverable under the Federal Rules of Civil Procedure and/or the Trademark Rules of Practice. Opposer also objects to the Interrogatories to the extent

they seek information regarding the use, advertising or other related activities regarding Opposer's mark outside the United States.

Without waiving these objections and subject to any of the objections set forth below, Opposer submits the following as its Answers to Applicant's First Set of Interrogatories:

ANSWERS TO INTERROGATORIES

INTERROGATORY NO. 1: Identify any and all persons who have the most knowledge concerning Opposer's use of Opposer's Mark in the United States.

ANSWER: Pam Stahl, VP of Commercial Operations; Catherine M. Gendreau, Senior Product Manager and Mark D. Perrin, former Executive VP and Chief Commercial Officer.

INTERROGATORY NO. 2: Describe in detail the circumstances surrounding the selection of Opposer's Mark, and identify the person(s) with the most knowledge of the selection of Opposer's Mark.

ANSWER: See response to Interrogatory No. 1. Additionally, the Mark was selected by said persons following discussions concerning the same.

INTERROGATORY NO. 3: Describe in detail all goods and/or services in conjunction with which Opposer's Mark, or any variation thereof, has ever been used, or contemplated to be used, by Opposer in the United States.

ANSWER: Opposer identifies the goods and services used in conjunction with the respective marks as more fully set forth below and, generally, in the medical fields of neurology and psychiatry.

MARK	GOODS/SERVICES	DATE OF FIRST USE
1-866-XYREM88 (#2,774,178)	Providing information at the request of patients and physicians by means of telephone regarding the safe and appropriate use and distribution of medications used to treat sleep disorders (Class 44)	08/12/2002
XYREM (#2,249,959)	Pharmaceutical preparation for the treatment of narcolepsy (Class 5).	02/24/1999

MARK	GOODS/SERVICES	DATE OF FIRST USE
XYREM (#78/400,994)	Drug delivery devices (Class 10).	ITU
XYREM (#2,860,730)	Pharmaceutical preparations for the treatment of diseases of the central nervous system a variety of conditions, symptoms and diseases, namely, narcolepsy, fibromyalgia, insomnia and myositis (Class 5).	02/24/1999
XYREM (sodium oxybate) ORAL SOLUTION & Design (#2,952,351)	Pharmaceutical preparations for use in the treatment of sleep disorders (Class 5).	10/07/2002
XYREM & Design (#2,472,156)	Pharmaceutical preparation for the treatment of narcolepsy (Class 5).	02/23/1999
XYREM & Design (color) (#2,423,880)	Pharmaceutical preparation for the treatment of narcolepsy (Class 5).	02/23/1999
XYREM PATIENT SUCCESS PROGRAM SERVICES (#2,848,521)	Providing telephone support services to patients regarding the safe and appropriate used and distribution of mediations used to treat sleep disorders; providing medical information via telephone and in the form of written educational materials to patients in connection with the safe and appropriate use and distribution of medication for the treatment of sleep disorders (Class 44).	09/23/2002
XYREM PHYSICIAN SUCCESS PROGRAM (#2,860,905)	Providing telephone support services to physicians regarding the safe and appropriate use and distribution of medications used to treat sleep disorders; providing medical information via telephone and in the form of written educational materials to physicians in connection with the safe and appropriate use and distribution of medication for the treatment of sleep disorders (Class 44).	09/23/2002

MARK	GOODS/SERVICES	DATE OF FIRST USE
XYREM SUCCESS PROGRAM (#2,867,332)	Providing telephone support services to physicians regarding the safe and appropriate use and distribution of medications used to treat sleep disorders; providing medical information via telephone and in the form of written educational materials to physicians in connection with the safe and appropriate use and distribution of medication for the treatment of sleep disorders (Class 44).	09/23/2002

INTERROGATORY NO. 4: Identify all variations of Opposer's Mark ever used or contemplated to be used by Opposer and indicate the goods and/or services upon which each such variation was used or contemplated to be used.

ANSWER: See Response to Interrogatory No. 3 above.

INTERROGATORY NO. 5: With respect to each of the goods and/or services identified in response to Interrogatory No. 3, state the date when Opposer commenced use of Opposer's Mark in connection with each such good and/or service in each state of the United States, and identify all persons with knowledge thereof.

ANSWER: *See* response to Interrogatory No. 3 above.

REDACTED

REDACTED

INTERROGATORY NO. 7: State the average sales price for each good and/or service identified in Interrogatory No. 3 sold or offered by Opposer under Opposer's Mark in the United States every year from the year that each such good or service was first sold or offered under Opposer's Mark to the present.

ANSWER: Opposer objects to this Interrogatory on the grounds that it is overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence.

INTERROGATORY NO. 8: With respect to each of the goods identified in response to Interrogatory No. 3, describe in detail the nature of the product, including the ailment(s) treated by the product and how it is taken by the ultimate user.

ANSWER: The ailments treated by the Xyrem product are identified as follows: cataplexy and narcolepsy; hypersomnia; insomonia; fibromyalgia pain; sleep disorders / disburbances; other. The medication is orally ingested. Other indications and delivery methods are contemplated.

INTERROGATORY NO. 9: Identify the generic name(s) and chemical names(s) of all active ingredients used in connection with each of the goods and/or services identified in response to Interrogatory No. 3.

ANSWER: Sodium oxybate; gamma hydroxybutyrate.

INTERROGATORY NO. 10: Identify each class of persons who purchase or use Opposer's goods and/or services under Opposer's Mark.

ANSWER: Persons who are likely to purchase or use the good offered under Opposer's Mark are patients suffering from sleep disorders and cataplectic episodes. Future purchasers may include patients suffering from other neurological and psychiatric conditions.

INTERROGATORY NO. 11: With respect to each pharmaceutical product identified in response to Interrogatory No. 3, indicate which pharmaceutical products are obtainable by doctor's prescription only.

ANSWER: All pharmaceutical products offered under the XYREM Marks are obtainable by doctors' prescription only.

INTERROGATORY NO. 12: With respect to each pharmaceutical product identified in response to Interrogatory No. 3, describe in detail the medical specialties of the doctors who prescribe the pharmaceutical product.

ANSWER: The medical specialties of the doctors who prescribe Xyrem include: neurologists (23%); physicians specializing in pulmonology (16%); sleep medicine specialists (16%); psychiatrists (15%); internists (10%); general practitioners (8%); physicians specializing in pain management (5%) and others (6%).

INTERROGATORY NO. 13: With respect to each pharmaceutical product identified in the response to Interrogatory No. 3, state the percentage of doctors of each medical specialty who prescribe the pharmaceutical product.

ANSWER: See Response to Interrogatory #12 above.

INTERROGATORY NO. 14: State whether Opposer is aware of any ophthalmologists who have prescribed products bearing Opposer's Mark.

ANSWER: Yes, Dr. Mir Tabasum prescribed Xyrem through July 8, 2005.

INTERROGATORY NO. 15: With respect to each of the goods and/or services identified in response to Interrogatory No. 3, describe in detail the channels of trade in the United States by which the goods and/or services of Opposer reach the ultimate user.

ANSWER: Opposer's goods are distributed to patients by means of a third-party that facilitates the dispensing and distribution of the product. Opposer has entered into an Amended and Restated Services Agreement with Express Scripts Specialty Distribution Services, Inc. for this purpose. Other distribution channels may be used in the future, should the FDA approve such channels. Also, *see* documents produced.

REDACTED

INTERROGATORY NO. 17: Describe in detail the manner, including TV, radio, print, kiosks, etc., in which Opposer's Mark, or any variation thereof, is promoted and/or advertised in the United States.

ANSWER: Opposer objects to this interrogatory on the grounds that it is overbroad, and unduly burdensome. Subject to and without waiving those objections, *see* documents produced.

INTERROGATORY NO. 18: With respect to each of the goods and/or services identified in response to Interrogatory No. 3, describe in detail the target consumers of the goods and/or services of Opposer.

ANSWER: The targeted consumers of the goods and services offered under Opposer's Mark are presently patients with sleep disorders, their prescribing physicians, and the restrictive central pharmacy distribution system but may expand in the future to include patients with other neurologic or psychiatric conditions, their prescribing physicians, and the FDA authorized distribution channels.

INTERROGATORY NO. 19: Identify any and all persons who have the most knowledge concerning Opposer's promotion or marketing of Opposer's Mark in the United States.

ANSWER: *See* response to Interrogatory No. 1.

INTERROGATORY NO. 20: State the names of all the publications, including journals, in which advertisements or articles containing Opposer's Mark have appeared in the United States.

ANSWER: *See* summary of publications produced.

INTERROGATORY NO. 21: State the names of any or all conferences or trade shows where Opposer promoted or presented information regarding the goods and/or services used in connection with Opposer's Mark.

ANSWER: *See* table entitled Xyrem Exhibit History Since 2002 and documents produced.

INTERROGATORY NO. 22: With respect to each of the conferences or trade shows identified in response to the previous Interrogatory, describe the year or years Opposer attended.

ANSWER: *See* response to Interrogatory No. 21.

INTERROGATORY NO. 23: With respect to each of the conferences or trade shows attended by Opposer, describe the class of persons who attend.

ANSWER: The class of persons who attend the trade shows referenced herein are physicians.

REDACTED

THIS PAGE CONTAINS ATTORNEYS' EYES ONLY AND CONFIDENTIAL INFORMATION

REDACTED

INTERROGATORY NO. 25: Identify any person who has publicly endorsed or promoted the goods and/or services provided under Opposer's Mark.

ANSWER: *See* list of Trained Speakers and Speakers Response Rate lists produced.

REDACTED

INTERROGATORY NO. 27: Describe in detail every search, survey, study, or investigation conducted by or on behalf of Opposer in connection with Opposer's Mark, or any variation thereof.

ANSWER: None.

INTERROGATORY NO. 28: State the nature of the business conducted by Opposer and a brief business history of Opposer and of all companies related to Opposer.

ANSWER: Orphan Medical is a pharmaceutical firm dedicated to patients with inadequately treated or uncommon diseases and, which acquires, develops and markets products of high medical value that address inadequately treated or uncommon diseases within selected market segments. Jazz Pharmaceuticals, Inc., which acquired Orphan Medical in late June 2005, is a pharmaceutical company focused on helping patients by meeting unmet medical needs in neurology and psychiatry with important and innovative therapeutic products. As to the business history of Opposer, that aspect of the Interrogatory is objected to on the grounds that it is irrelevant and not likely to lead to the discovery of admissible evidence. *See* also Answer to Interrogatory No. 32.

INTERROGATORY NO. 29: Describe in detail the research and development efforts you have undertaken for each of the goods and/or services identified in response to Interrogatory No. 3.

ANSWER: Opposer objects to this Interrogatory on the grounds that it is irrelevant and not likely to lead to the discovery of admissible evidence.

INTERROGATORY NO. 30: State whether Opposer is aware of any medical link between narcolepsy and ocular disorders.

ANSWER: Opposer is not aware of any medical links between narcolepsy and ocular disorders.

INTERROGATORY NO. 31: Describe in reasonable detail the circumstances relating to how and when you first became aware of (i) Applicant and (ii) Applicant's Mark, including but not limited to the date of such awareness and the manner in which you became aware of such information, and identify each person who obtained such knowledge.

ANSWER: Opposer first became aware of Applicant and their Marks through the review of the *Official Gazette*.

INTERROGATORY NO. 32: Describe in detail all agreements and the parties thereto, which Opposer has entered or is contemplating entering into, relating to Opposer's Mark.

ANSWER: Opposer objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome and not likely to lead to the discovery of relevant evidence. Subject to and without waiving these objections, on or about June 24, 2005 Jazz Pharmaceuticals acquired Orphan Medical, Inc. Pursuant to that transaction Jazz Pharmaceuticals became the ultimate owner of Opposer's marks. *See* also Answer to Interrogatory No. 15.

INTERROGATORY NO. 33: If Opposer claims the benefit of any use of Opposer's Mark, or any variation thereof, by any predecessor-in-title or licensee, identify the predecessor-in-title or licensee and describe in detail the nature and extent of the predecessor's or licensee's use of the marks.

ANSWER: None.

INTERROGATORY NO. 34: Identify all licensed users of Opposer's Mark.

ANSWER: Opposer objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome and not likely to lead to the discovery of relevant evidence. Subject to and without waiving these objections, Express Scripts Specialty Distribution Services, Inc. *See* documents produced.

INTERROGATORY NO. 35: Describe any period of time when Opposer discontinued use of Opposer's Mark in the United States since its initial adoption by Opposer, provide the reasons for such discontinuance, and, if applicable, provide the date and location of any resumption of use and the reason for such resumption of use.

ANSWER: None.

INTERROGATORY NO. 36: Describe all instances of actual or possible confusion, or any reports of such confusion, known to Opposer between Opposer's Mark and Applicant's Mark, including but not limited to, all persons with knowledge thereof.

ANSWER: To date, Opposer is not aware of any instances of confusion between Opposer's and Applicant's Marks; however, to date, Applicant's Mark is not yet on the market.

INTERROGATORY NO. 37: Describe in detail every instance in which Opposer has ever disclaimed any association with Applicant in connection with the use of Opposer's Mark, or any variation thereof.

ANSWER: None.

INTERROGATORY NO. 38: Describe in detail any adversarial proceeding (apart from the present proceeding) involving Opposer's Mark or any variation thereof.

ANSWER: Opposer objects on the grounds that this Interrogatory is irrelevant, not likely to lead to the discovery of admissible evidence, overly broad and is available to Applicant through public records. Subject thereto, Opposer has initiated opposition proceedings summarized as follows:

Caption	Infringing Mark / Application / Domain name
Orphan Medical Inc. v. Novartis, AG (Opposition No. 01157204)	XILEP
Orphan Medical v. Matsu North America, Inc.	ZIDEX / ZYDEX
Orphan Medical v. Aventis Pasteur (Opp. No. 91/155,988)	ZYRAB
Orphan Medical v. Pharmacia Corp. (Opp. No. 125,153)	XYNAM
Orphan Medical v. Dupont Pharmaceuticals Company	XYVEL
Orphan Medical Inc. v. Alan John Holton [National Arbitration Forum]	xyrem.org and xyrem.net
Orphan Medical Inc. v. Bobby Charlton [National Arbitration Forum]	xyrem.com

See also documents produced.

INTERROGATORY NO. 39: Describe in detail the nature of any objection received by Opposer to its use or registration of Opposer's Mark.

ANSWER: None.

INTERROGATORY NO. 40: Describe in detail the facts of every objection made by Opposer to the use or registration by others of any trademark or service mark believed by Opposer to be confusingly similar to Opposer's Mark, or any variation thereof (apart from the present proceeding).

ANSWER: *See* response to Interrogatory No. 38 above and documents produced.

INTERROGATORY NO. 41: Identify any third-party trademarks or service marks known by Opposer which can employ the first syllable sound "ZĪ" in connection with pharmaceutical products, over-the-counter medications, vitamins or nutritional supplements, medical devices, medical services or the health industry (other than Applicant's Mark).

ANSWER: Opposer objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome, subject to varying interpretations and not likely to lead to the discovery of relevant evidence. Further, the information sought is in the public domain and equally available and as accessible to Applicant as to Opposer.

INTERROGATORY NO. 42: Identify the companies deemed by Opposer to be its significant competitors.

ANSWER: Opposer objects to this Interrogatory on the grounds that it is vague and not likely to lead to the discovery of relevant evidence. Subject to and without waiving those objections, stimulants are prescribed in narcolepsy to reduce daytime sleepiness and sleep attacks during the day. There are several commercially available stimulants. As these products are also an approved indication for narcolepsy, Opposer considers them as competitors. These products include: Modafinil, sold by Cephalon; methylphenidate, sold by McNeil Consumer and Specialty Pharmaceuticals, Celltech, Mallinckrodt and Novartis; and amphetamines sold by Shire, Ovation and GSK.

Additionally, Selective Seratonin Reuptake Inhibitors (SSRIs), such as Prozac® (fluoxetine hydrochloride manufactured by Eli Lilly) and Zoloft® (sertraline hydrochloride sold by Pfizer) have been reported to reduce episodes of cataplexy. Other antidepressants such as Effexor XR® (venlafaxine hydrochloride sold by Wyeth Pharmaceuticals) have been used to treat cataplexy patients. Sedatives and hypnotics such as Ambien® (zolpidem tartrate sold by Sanofi) and Sonata® (zaleplon sold by King Pharmaceuticals) have played an important role in the treatment of disrupted nocturnal sleep and insomnia. Lunesta™ (eszcopiclone sold by Sepracor) is now commercially available as a sleep aid.

INTERROGATORY NO. 43: Identify each person whom Opposer expects to call as a witness to give evidence in this proceeding, and for each such person, state the subject matter and the substance of the facts on which such person is expected to testify; the substance of the facts and opinions to which each expert is expected to testify; and the grounds for each such opinion of each expert.

ANSWER: Opposer objects to this Interrogatory on the grounds that it is premature; discovery is ongoing and Opposer will supplement this response.

INTERROGATORY NO. 44: Identify all third-party marks upon which Opposer will rely for any purpose in connection with this Opposition.

ANSWER: Opposer objects to this Interrogatory on the grounds that it is unclear, vague and ambiguous; subject to and without waiving this objection Opposer replies there are none.

INTERROGATORY NO. 45: Identify all facts supporting Opposer's contentions in his proceedings against Applicant's Mark.

ANSWER: *See* Opposer's Opposition.

INTERROGATORY NO. 46: If you contend that the types of goods or services for which you have registration for Opposer's Mark are the same as Applicant's Goods covered by Applicant's Mark or offered by Applicant, explain how they are similar.

ANSWER: Opposer objects to this Interrogatory on the grounds it is unclear, vague and ambiguous; without waiving their objections, Opposer states that the goods under which both Applicant's and Opposer's Marks are offered are pharmaceutical medications prescribed by physicians.

INTERROGATORY NO. 47: Identify all persons who were consulted or had more than a clerical role in the preparation of the answers or responses to the foregoing interrogatories or in the obtaining of information in connection with these interrogatories or Applicant's First Set of Requests for Production of Documents and Things to Applicant or in the responses to Applicant's First Set of Requests for Admissions to Applicant, and state the nature and extent of participation of each such person.

ANSWER: Pam Stahl, Catherine Gendreau, Kate Stephany and Cherie Johnson with assistance of counsel.

AS TO ANSWERS:

ORPHAN MEDICAL, INC.

By: _____
Carol A. Gamble
Its Vice President

Subscribed and sworn to before
me this 1 day of ~~July~~ August, 2005.

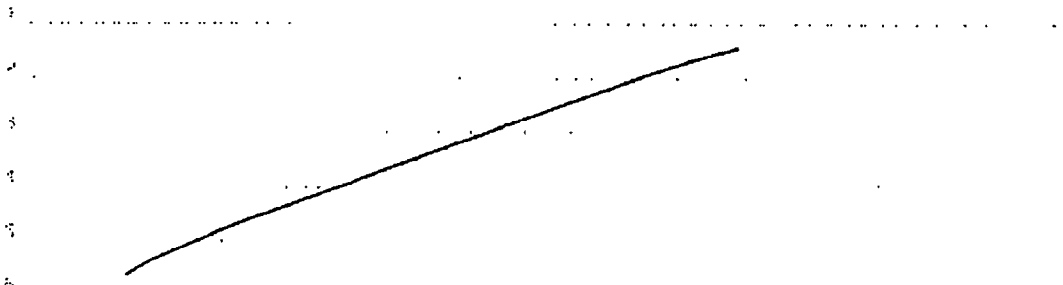
_____ 8/1/05
(see attached)

CALIFORNIA JURAT WITH AFFIANT STATEMENT

State of California

County of Santa Clara } ss.

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–5 to be completed only by document signer[s], *not* Notary)



Signature of Document Signer No. 1

Signature of Document Signer No. 2 (if any)

Subscribed and sworn to (or affirmed) before me on this

1 (Date) day of August (Month), 2005 (Year) by

(1) Carol Gamble (Name of Signer),

☑ Personally known to me
☐ Proved to me on the basis of satisfactory evidence to be the person who appeared before me (.) (,)

(and

(2) _____ (Name of Signer),

☐ Personally known to me
☐ Proved to me on the basis of satisfactory evidence to be the person who appeared before me.)

KATHY E. HONNERT
Commission # 1405914
Notary Public - California
San Mateo County
My Comm. Expires Apr 12, 2007

Kathy E. Honnert
Signature of Notary Public

Place Notary Seal Above

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Further Description of Any Attached Document

Title or Type of Document: Answers to Applicant's First set of Interrogatories Nos 1-47

Document Date: _____ Number of Pages: 13

Signer(s) Other Than Named Above: —

RIGHT THUMBPRINT OF SIGNER #1	RIGHT THUMBPRINT OF SIGNER #2
Top of thumb here	Top of thumb here

AS TO OBJECTIONS:

Dated: August 1, 2005

WINTHROP & WEINSTINE, P.A.

By: _____

Peter J. Gleekel, #149834
Stephen R. Baird, #0214024
Samuel T. Lockner, #0341095

225 South Sixth Street
Suite 3500
Minneapolis, MN 55402
Phone: (612) 604-6400
Fax: (612) 604-6800

Attorneys for Opposer Orphan Medical, Inc.

2294913v2

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

In the matter of Application Ser. No.: 78/298,369
Filed: September 10, 2003
For the mark: XIBROM
Published in the Trademark Official Gazette on August 31, 2004

ORPHAN MEDICAL, INC.,

Opposer,

v. Opposition No. 91162204

ISTA Pharmaceuticals, Inc.,

Applicant.

AFFIDAVIT OF SERVICE

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

I, Hesper Lovejoy of the County of Hennepin, the State of Minnesota, being duly sworn, says that on the 1st day of August, 2005, she served a copy of the following:

1. Answers to Applicant's First Set of Interrogatories Nos. 1-47; and
2. Response to Applicant's Requests for Production of Documents and Things

upon Tirzah Abe Lowe, Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, Fourteenth Floor, Irvine, CA 92614

by mailing via U.S. mail to said person(s) a copy thereof, enclosed in an envelope, postage prepaid, directed to said person(s) at the last-known address stated above.

Hesper Lovejoy

Subscribed and sworn to before me this
1st day of August, 2005.

Notary Public
2166502v5

ELIZABETH H. MULVANEY
NOTARY PUBLIC-MINNESOTA
My Commission Expires Jan. 31, 2010

- You can get Xyrem® only by prescription. You must get it from one central pharmacy. Before you use Xyrem®, your doctor should teach you about the safe and effective use of this medicine. You cannot get the medicine until you have read the information the pharmacy will send you about Xyrem®.

What is Xyrem®?

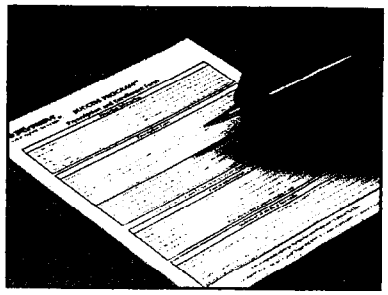
Xyrem® is a brand of medicine used to reduce the number of cataplexy (weak or paralyzed muscles) attacks in patients with narcolepsy. Xyrem® is a controlled drug. This means anyone who misuses, sells, or distributes it may be prosecuted under federal and state law. You must not share it with anyone else.

XYREM® (sodium oxybate) oral solution

SUCCESS PROGRAM℠

for patients

1. How do I obtain Xyrem®?



Who will fill Xyrem® prescriptions?

All Xyrem® prescriptions will be processed by one Central Pharmacy.

What does the Central Pharmacy do?

The Central Pharmacy will provide four main services to you.

They will:

- Provide patient counseling, dispense and ship your Xyrem®
- Work with your insurance plan to facilitate coverage.
- Collect information about the safety of Xyrem® Your name and any problems with Xyrem® you report will be recorded.
- Provide information about Xyrem® at 1-866-XYREM88℠ (1-866-997-3688).

How does the Central Pharmacy dispense Xyrem®?

- Your doctor sends the Xyrem® prescription directly to the Central Pharmacy.
- The Central Pharmacy contacts you to confirm the location of, and who will sign for, delivery of your Xyrem® as well as any insurance details.
- Xyrem® will be shipped via an overnight courier.
- When the courier arrives you, or someone you designate, must sign for the Xyrem®

What will I receive?

In each Xyrem® carton you receive, there will be one bottle of Xyrem, a liquid measuring device, 2 dosing cups with child resistant caps and a printed medication guide. Your shipment may include more than one carton of Xyrem®

When will I receive Xyrem®?

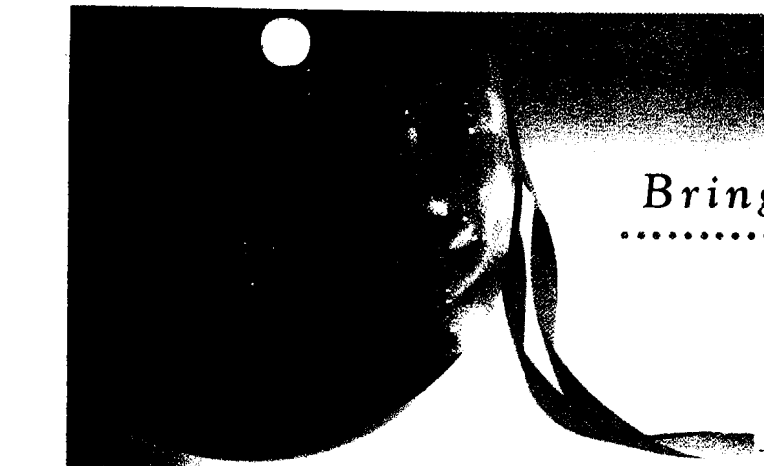
The Central Pharmacy will call you to arrange a convenient time and location for delivery.

Could my local pharmacy provide Xyrem®?

No. The use of a Central Pharmacy is designed to reduce any diversion or illicit use of Xyrem® However, in some cases, you may be able to have the courier deliver Xyrem® to your local pharmacy for later collection.

Will insurance pay for my Xyrem®?

In most cases, YES. A reimbursement specialist from the Central Pharmacy will contact you and your insurance plan to facilitate benefits.



Bring back the laughter

XYREM® (sodium oxybate) oral solution

SUCCESS PROGRAM℠

How Do I Prescribe Xyrem?

Xyrem is available only through the Xyrem Success Program.℠ To obtain Success Program℠ materials call the Xyrem Central Pharmacy at 1-866-XYREM88℠ (1-866-997-3688)

- Carefully read the Xyrem Success Program℠ information and materials for physicians
- Complete the Xyrem Prescription and Enrollment form
- Fax completed Prescription and Enrollment form to the Central Pharmacy at 1-866-470-1744

EXHIBIT 3, PAGE 3 OF 13

OM0142

XYREM® (sodium oxybate) oral solution

Bring back the laughter

Xyrem Success Program[SM]

1.866.XYREM88[SM] *(1-866-977-3688)*

"A single source for all your Xyrem Services"

Educational Materials

- Patients & Physicians/Health Care Providers receive educational materials on the safe and appropriate use of Xyrem

Reimbursement Services

- Participation in prescription plans nationwide
- Reimbursement specialists dedicated to obtaining prescription insurance coverage for your patients
- Expertise with Patient Assistance Programs

Pharmacy Services

- Specially-trained Xyrem Pharmacists provide quality care to your patients
- Medical information services for narcolepsy & Xyrem
- Pharmacists available for counseling with medication questions 24 hours a day/7 days a week
- Federal Express overnight delivery of Xyrem directly to patient

EXHIBIT 3, PAGE 4 OF 43

Bring back the laughter

Xyrem Success Program℠ Easy Steps

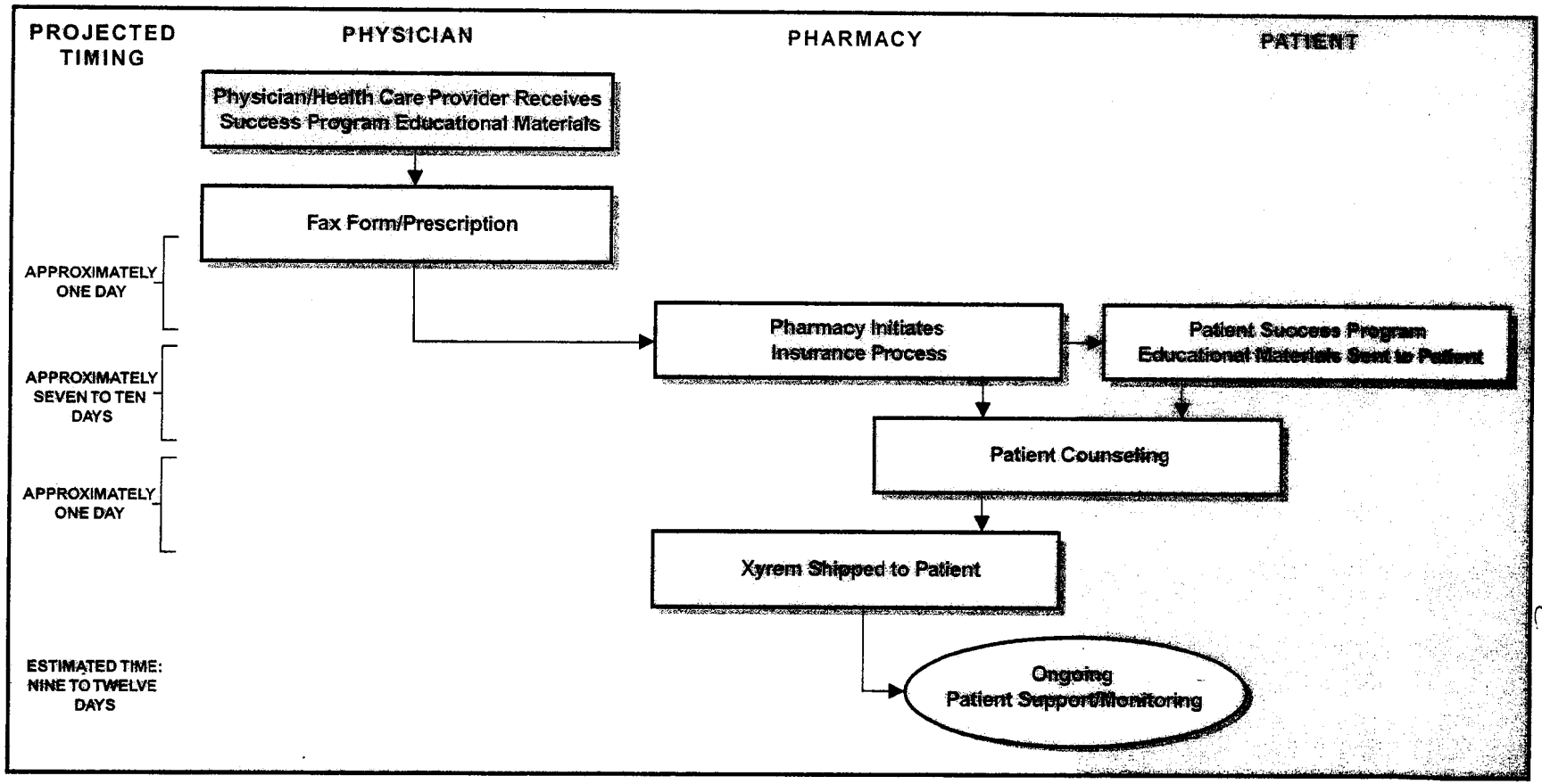


EXHIBIT 3, PAGE 5 OF 43

XYREM® (sodium oxybate) oral solution
SUCCESS PROGRAM℠

Prescribing Requirements

- Each of your Xyrem patients will receive educational materials to ensure proper preparation and dosing
- Patients are to be advised of, and comply with, the requirements of the Xyrem Success Program℠ for patients in order to receive Xyrem
- Physicians are urged to see and evaluate patients every 3 months and to rewrite prescriptions for Xyrem at least every 3 months
- Physicians are also urged to complete the "Xyrem Post Marketing Patient Evaluation" form at the 3-month and 6-month visits

XYREM® (sodium oxybate) oral solution

EXHIBIT 3 PAGE 6 OF 43

INTRODUCTION

Cataplexy is the second most common and most specific symptom of narcolepsy. Narcolepsy is an uncommon, complex sleep disorder associated with a deficit in the neurotransmitter hypocretin resulting in "impaired control of the boundaries that normally separate the state of wakefulness from REM and non-REM sleep."[1] As such, narcolepsy is characterized by the primary symptoms of excessive daytime sleepiness, fragmented nighttime sleep and abnormal manifestations of REM sleep phenomena including cataplexy, sleep paralysis and hypnagogic hallucinations.[2]

Cataplexy may be the least understood symptom of narcolepsy. Cataplexy is defined as sudden, transient, bilateral skeletal muscle weakness, occurring as an abnormal response to strong emotions such as laughter, anger or embarrassment. Cataplectic attacks are thought to arise from an imbalance between excitatory and inhibitory motor systems at times of strong emotional input, possibly due to a deficiency of the excitatory neurotransmitter hypocretin.[3,4]

Attacks of cataplexy are described as partial or complete. Partial cataplexy is restricted to loss of tone in specific muscle groups and commonly manifests as slurred speech, sagging jaw, drooping head or buckling knees. Complete cataplexy involves loss of tone in all postural muscles, usually resulting in complete collapse. Accordingly, cataplectic attacks cause considerable distress and inconvenience to narcoleptic patients.

To date, there has been no approved treatment for this serious, debilitating symptom. Untreated cataplexy is associated with significant physical and psychological morbidity. Patients with cataplexy are reported to suffer from a greater incidence of accidents in the home and workplace and there is a considerable risk to personal safety while driving or operating machinery. There is also a profound effect on social function. Substantial evidence exists suggesting that, without effective treatment, narcoleptics attempt to manage their cataplexy by controlling or suppressing their emotions (adopting a flat affect) or simply avoiding social or other situations known to precipitate attacks. As a result, narcoleptics may be mislabeled as bored, disinterested or unintelligent. Thus, there is a profound medical need to treat this poorly understood symptom.

It is against this background that Xyrem® (sodium oxybate) oral solution has been developed. Xyrem is the first FDA-approved product proven to be effective for the treatment of cataplexy associated with narcolepsy.

The approval of Xyrem is based primarily on two blinded, randomized, placebo-controlled studies: Trial 1 and Trial 2. Data from Trial 1 indicates that the administration of Xyrem at doses of 6 and 9g per night for four weeks resulted in a median percent reduction in cataplexy attacks of 49% and 69%, respectively. This decrease in cataplexy attacks was accompanied by meaningful clinical benefit. In blinded investigator ratings of their narcolepsy disease status, 80% of the 9g Xyrem patients were rated as "very much improved" or "much improved" compared to 32% of placebo patients ($p = 0.0014$). Data from Trial 2 indicates that anti-cataplectic activity was safely and effectively maintained long term following a mean of 21 months therapy. Analysis of safety data from Trial 1 indicates that the adverse events reported more frequently than with placebo were dizziness (23%), headache (20%), nausea (16%), pain (12%), somnolence (9%), sleep disorder (9%), confusion (7%), infection (7%), vomiting (6%) and urinary incontinence (5%).[5]

The responsible use of Xyrem as an anti-cataplectic agent requires consideration of some important safety issues. The active ingredient in Xyrem is sodium oxybate, the sodium salt of gamma-hydroxybutyrate (GHB). GHB is known to be a CNS depressant and to have abuse potential. The use of GHB at or above therapeutic doses has been associated with confusion, depression and other neuropsychiatric

events. Thus, Xyrem should not be administered with alcohol or other CNS depressants. Illicitly manufactured GHB has been abused, particularly among young adults and has been associated with adverse events including seizures, respiratory depression and profound decreases in level of consciousness with instances of coma and death. In consideration of these issues, Xyrem is made available under a Risk Management Program including distribution from a single, central pharmacy. In addition, patients administered Xyrem should be monitored for treatment-emergent adverse events, particularly reports of respiratory or CNS depression, urinary incontinence, confusion, depression and sleepwalking.

This monograph provides detailed information on the efficacy and safety of Xyrem as a treatment for cataplexy. In addition, it provides a brief review of the pathophysiology and clinical features of cataplexy associated with narcolepsy, including a detailed description of cataplexy, as well as summary data on the chemistry, pharmacology and clinical pharmacokinetics of sodium oxybate.

Cataplexy is the defining symptom of the disease narcolepsy — a chronic, disabling, sleep disorder afflicting approximately 140,000 of the U.S. population.[1] Cataplexy is generally described as sudden episodes of bilateral muscle weakness triggered by emotions such as laughter, anger or embarrassment. Cataplexy attacks can cause significant social embarrassment and may adversely affect personal safety. Untreated symptoms of cataplexy may seriously affect relationships, education and employment potential. Since there is no known cure for cataplexy, treatment focuses on controlling this symptom and enabling patients to return to full personal and professional lives. In response to the unmet medical need for new treatments to effectively control cataplexy, Orphan Medical has developed Xyrem® (sodium oxybate) oral solution — the first FDA-approved product proven to be effective for the treatment of cataplexy associated with narcolepsy.

CATAPLEXY: CLINICAL FEATURES

DEFINITION & PRESENTATION

The term "cataplexy" is derived from Greek and means "to strike down" and was first used by Adie to describe the sudden loss of muscle tone often experienced by patients with narcolepsy. Daniels provided a vivid description of cataplexy in 1934: "A state of helplessness into which a narcoleptic patient may be precipitated by emotional stress; he is not unconscious but a mass of toneless muscles; and he promptly recovers, none the worse for the experience."[7] More generally, cataplexy is defined as *sudden episodes of bilateral skeletal muscle weakness triggered by intense emotions.*

Cataplexy is an extremely variable symptom, both in frequency and severity. Clinically, episodes of cataplexy may range from a subjective sensation of muscle weakness to complete muscle atonia and collapse. The most common presentation is found between these two extremes and is known as partial cataplexy. The most commonly affected muscle regions for partial cataplexy are those of the face and neck but may also include legs and knees, head and shoulders, or arms and hands. A combination of sagging jaw and inclined head, often with slight buckling of the knees is the most frequent presentation of cataplexy. Although the extraocular muscles are not generally involved, the palpebral muscles may be affected and less severe presentations may consist of blurred vision or slurred speech.[8]

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Complete or full cataplexy involves atonia of most skeletal muscles, generally excluding the extraocular muscles and diaphragm. This renders the patient helpless and immobile, but with breathing and consciousness maintained. Attacks of complete cataplexy often follow a distinct pattern, taking several moments to complete (see Case Study). In rare, extreme cases, complete attacks may last up to 30 minutes.[8] During such long episodes, patients with narcolepsy may fall asleep or experience hypnagogic hallucinations.[9]

Laughter is the most common emotion triggering cataplexy, while other causes can include anger, annoyance, embarrassment, grief, surprise, elation, joy and even sexual arousal. Positive emotions are reported to trigger an attack of cataplexy in up to 93% of patients with narcolepsy. For some patients, even the memory of a happy moment may cause a cataplectic episode.[10]

The frequency of cataplexy varies widely among narcoleptics but is generally stable for each patient. The frequency varies from many episodes each day to occasional attacks.[2] In a series of 130 patients with narcolepsy, 75% reported at least one attack of cataplexy per day; 69% reported one to four attacks per day and 5.3% suffered from more than four attacks per day.[8]

In patients with narcolepsy, the symptom of cataplexy is rarely the only manifestation of the disease. Excessive daytime sleepiness (EDS) is

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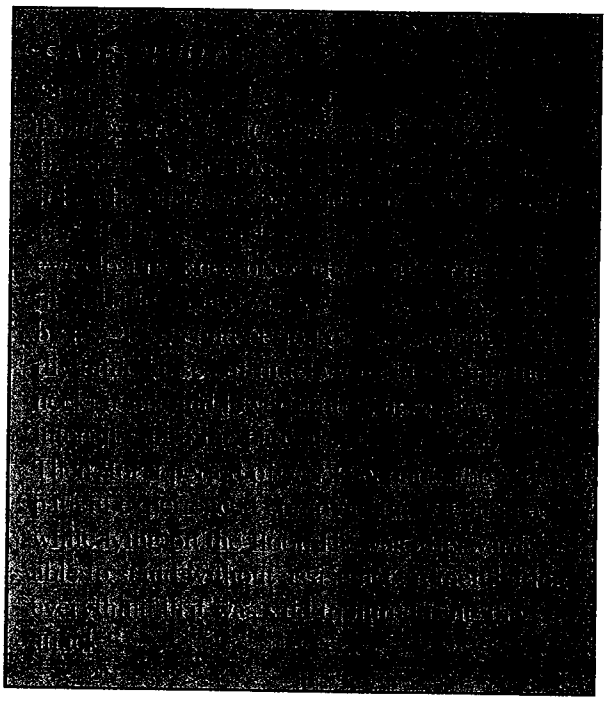
Table 1. Symptoms Associated With Narcolepsy and the Range of Reported Frequencies [2,9,11]

Symptoms	Incidence
Excessive Daytime Sleepiness	100%
Cataplexy	60–90%
Hypnagogic Hallucinations	15–80%
Sleep Paralysis	17–80%
Fragmented Nighttime Sleep	60–90%
Automatic Behaviors	40–50%

always present and is described as a continuous, fluctuating sleepiness that periodically becomes irresistible, resulting in involuntary naps or "sleep attacks."[2] Patients with cataplexy more frequently present with ancillary symptoms of narcolepsy, such as hypnagogic and hypnopompic hallucinations, sleep paralysis, fragmented nighttime sleep and sleep attacks.[10] The prevalence of these symptoms in a narcoleptic population is shown in Table 1.

Most frequently, the symptoms of narcolepsy appear between the ages of 15 and 30 with onset after age 55 uncommon. In a series of 130 narcoleptics, the average age of onset for men and women was 24.5 and 25.8 years respectively.[8] In 34 patients, cataplexy developed along with excessive daytime sleepiness; in 46 patients the onset of cataplexy was within five years after disease onset and after 6 to 10 years in 26 patients. In one patient, cataplexy did not occur until 31 years after the initial symptoms of narcolepsy began.[8]

Once present, cataplexy remains persistent with only minor fluctuations in severity.[2] Reports that cataplexy declines over time may represent patient adaptation and avoidance of situations known to trigger cataplexy.[7]



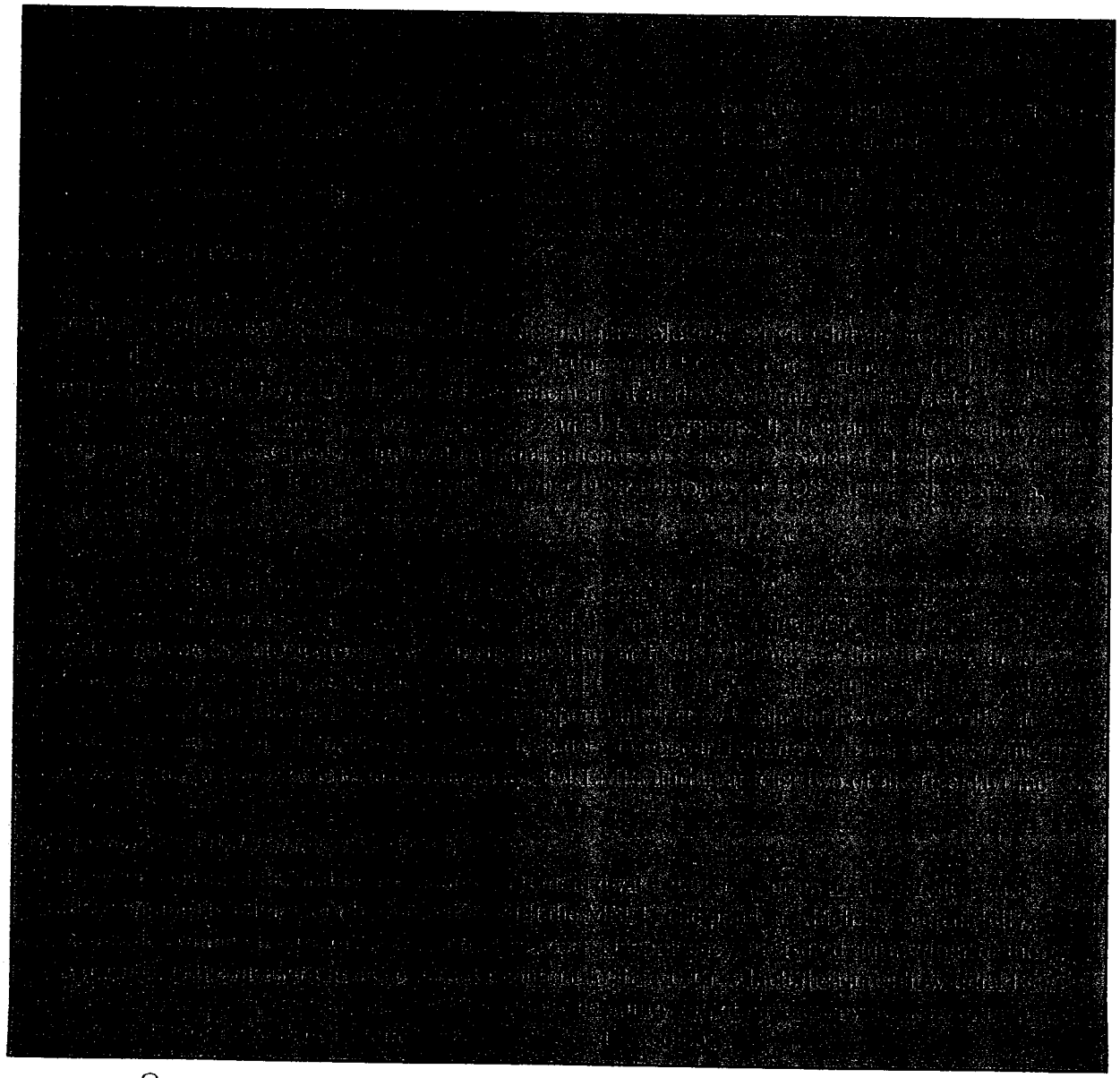
DIAGNOSIS

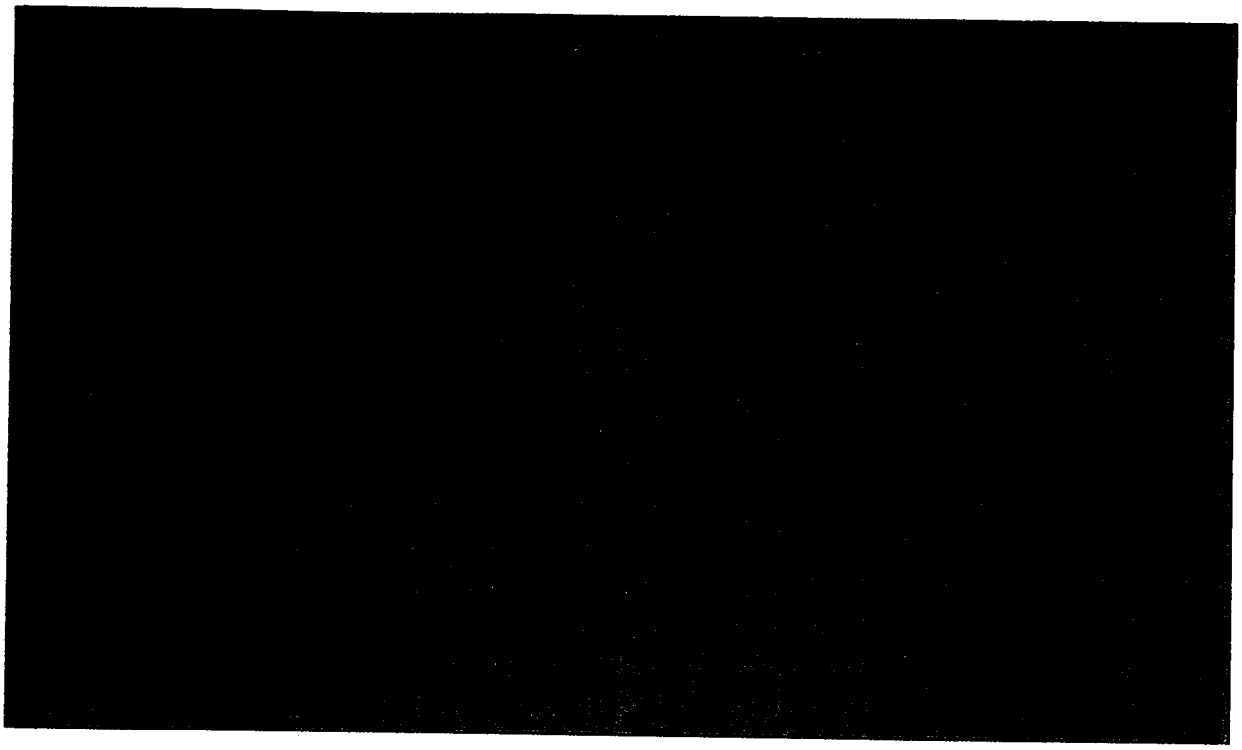
The varied presentation of the narcoleptic, described above, may sometimes make accurate diagnosis problematic. Cataplexy is the most specific symptom of narcolepsy and, ***when coupled with excessive daytime sleepiness, is considered by some to be diagnostic for narcolepsy.*** As indicated above, a high percentage of narcoleptics may experience cataplexy; although there is considerable debate regarding the actual prevalence of this symptom

of narcolepsy. This stems directly from the diagnostic dilemma arising from the fact that attacks of cataplexy are rarely observed by the clinician who must instead rely on patient histories. Given the subjective nature of mild forms of cataplexy, these can often be misleading.[10] Recently, a validated questionnaire has been developed to assist in the identification of cataplexy. It has been suggested that the proper use of this diagnostic tool, consisting of 51 cataplexy-related questionnaire items, may reveal cataplexy in approximately 90% of narcoleptic patients.[10]

For the clinician, the differential diagnosis of narcolepsy is extensive and must include periodic limb movement disorder, obstructive sleep apnea, upper airway resistance syndrome and idiopathic hypersomnia, to name a few. The differential diagnosis of cataplexy includes epilepsy.

Appropriate diagnostic tests are listed next.





PATHOPHYSIOLOGY

As cataplexy is a primary symptom of narcolepsy, it is essential to briefly review the pathophysiology of narcolepsy, prior to a more detailed discussion of cataplexy. A rapidly accumulating body of research suggests that most human narcolepsy is due to a loss of hypocretin-containing neurons, most probably as a result of an autoimmune process.

Hypocretin is a recently-discovered neurotransmitter that appears to have important roles in sleep-wake regulation, neuroendocrine stasis, autonomic regulation and control of feeding behavior.[4] The cell bodies of hypocretin-containing neurons are located in the postero-lateral hypothalamus and have widespread projections within the CNS. Two active peptides have been identified: hypocretin-1 and hypocretin-2. With respect to sleep, the dominant activities of the hypocretin system appear to be maintenance of the waking state and suppression of entry into REM sleep ("gating"). Specific effects may include excitation of "REM-off" neurons and modulation of cholinergic "REM-on" neurons under the influence of circadian rhythm.[13] It is thought that hypocretin may exert many of its effects through its interactions with cholinergic, catecholaminergic and amino acid transmitters.[14,15]

In many humans with narcolepsy, analysis of cerebrospinal fluid indicates the concentration of hypocretin-1 is extremely low in comparison to normal controls.[16] Furthermore, postmortem examinations of brains from patients with narcolepsy using immunocytochemical methods and *in situ* hybridization have revealed a 85–95% decrease in hypocretin-containing cells and greatly diminished hypocretin mRNA.[3,4] This cell loss is highly specific as melanin-concentrating hormone neurons, normally intermingled with hypocretin-containing neurons, remain unaffected.[4]

A possible autoimmune role is suggested by the observation that approximately 90% of patients with cataplexy are positive for the Human Leukocyte Antigen (HLA) DQB1 *0602 subtype, compared to 12–35% of the general population.[2] However, since most people with such haplotypes do not develop narcolepsy, other external precipitating factors may be involved.

CATAPLEXY

Cataplexy is an abnormal suppression of skeletal (postural) muscle activity. In unaffected individuals, this motor suppression occurs during normal REM sleep. However, in narcoleptic patients with cataplexy, this inhibition occurs abnormally outside the context of sleep and manifests as a cataplectic attack. The mechanisms underpinning this pathology are described in detail below and necessitate a brief review of REM-sleep and motor activities. They are illustrated graphically in Figure 1.

Mechanism of REM Sleep Atonia

During REM sleep, brain motor systems are highly activated, at levels comparable to or even exceeding those occurring during active waking states.[17] The activity of these systems does not normally result in movement during REM sleep because, simultaneously, there is a corresponding activation of a motor inhibitory system[18] and an inactivation of a motor facilitatory system.[19] The net result is a profound reduction of tone in most muscles, classically described as REM sleep atonia. Some muscles are not subject to this loss of tone, including the diaphragm and extraocular muscles. These latter muscles have near-normal tone during REM sleep, resulting in the characteristic eye movements that give REM sleep its name.[20] Thus, normal REM sleep is characterized clinically by muscle atonia and rapid eye movement.

The neurons in the motor facilitatory system are located in the locus coeruleus of the pons and in the raphe nuclei along the midline of the brainstem, respectively. These neurons release norepinephrine and serotonin onto motor neurons, increasing their activity. During REM sleep, these norepinephrine and serotonin neurons are inhibited by neurons containing gamma-aminobutyric acid (GABA). These GABA neurons are activated by the pontine REM sleep generator. The facilitatory and inhibitory stems are interconnected such that electrical stimulation of the inhibitory region in the medulla will shut off the facilitatory system in the pons.[21]

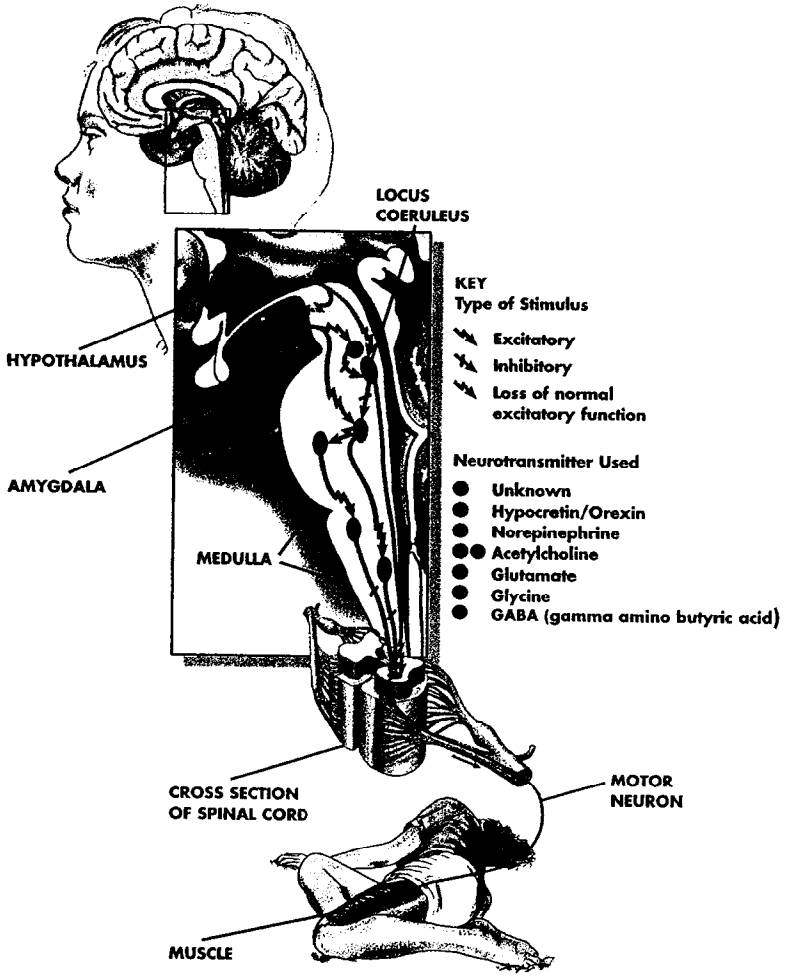
The inhibitory system, responsible for the muscle tone suppression of REM, causes the release of the inhibitory amino acids glycine and GABA onto motor neurons. These inhibitory amino acids are believed to originate in interneurons in the spinal cord and in neurons in the medulla. These neurons are, in turn, under the influence of neurons in the pons and midbrain which are selectively activated during REM sleep by the pontine REM sleep generator mechanisms.[22]

Cataplexy and Hypocretin

Cataplexy is associated with the loss of hypocretin neurons.[3,4] Hypocretin release is usually maximal during periods of normal wakefulness[23] and is believed to increase muscle tone through activation of the facilitatory system .[14] In the absence of sufficient levels of hypocretin, the balance of motor excitation and inhibition elicited by emotional stimuli is altered, causing inactivation of the facilitatory system and activation of the inhibitory system. The net result is a decrease in muscle tone resulting in cataplexy in narcoleptic patients.[15,24]

Animal studies have shown that cataplexy results from the occurrence of the REM sleep activity pattern during periods of wakefulness. Studies in narcoleptic dogs revealed that, prior to and throughout cataplexy attacks, neurons in

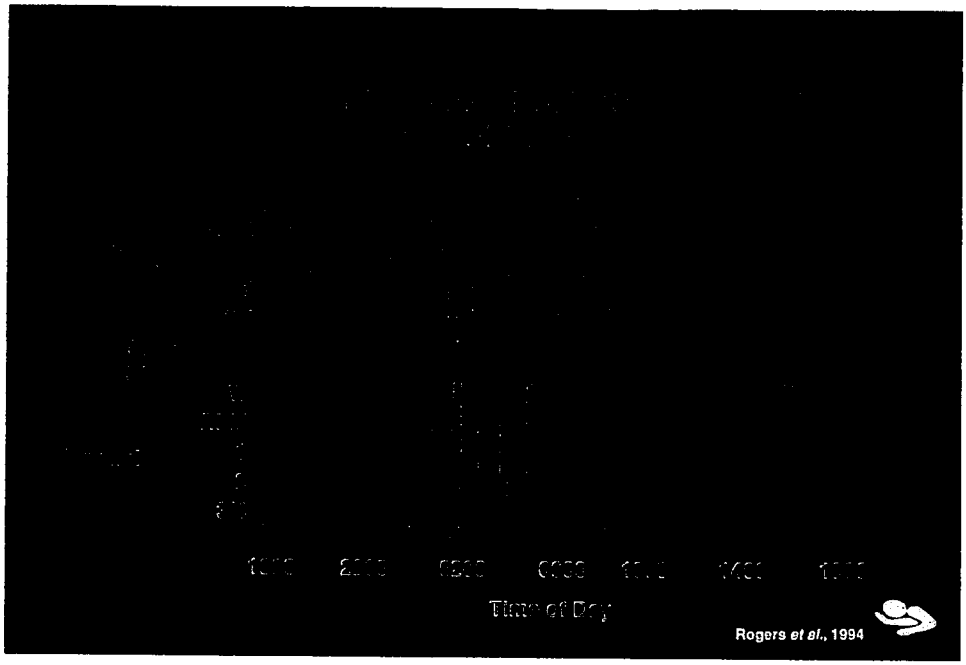
Figure 1. The Neuronal Systems Involved in the Pathogenesis of Cataplexy[24]



the medullary inhibitory region (normally active only during REM sleep) became highly active, even though the animal remained awake during the attack.[18] At the same time, noradrenergic neurons in locus coeruleus that normally never become inactive during wakefulness, abruptly and completely cease discharge.[25] These cataplectic episodes are triggered by emotional stimuli and may be mediated by connections between the amygdala (a brain center for emotional integration) and the facilitatory and inhibitory systems.[26]

Conversely, when the muscle tone suppression system is not properly activated in REM sleep, motor expression appears, resulting in the REM sleep behavior disorder. These patients often injure themselves or bed partners. Interestingly, REM sleep behavior disorder is more common in narcolepsy, presumably because in narcoleptics the system not only goes on inappropriately in waking, but also goes off inappropriately in REM sleep.[27]

Figure 2. Narcoleptic Versus Normal Sleep Architecture Assessed by 24-Hour Polysomnography
(reprinted with permission from the National Sleep Foundation)



Summary
In summary, cataplexy results from the occurrence of inappropriate REM sleep motor atonia during periods of wakefulness and an underlying deficit of hypocretin. This deficiency results in an imbalance between excitatory and inhibitory motor systems which, following strong emotional stimuli, cascades down multiple neuronal pathways to produce an abnormal, transient reduction in muscle tone.

From a therapeutic perspective, changes in the sensitivity of receptors of any of these systems, changes in the basal discharge rate of any of the neuronal groups involved or changes in the hypocretin release by surviving hypocretin neurons could all have a major effect upon cataplexy. It is not yet known which of these neuronal connections and systems mediate the effects of sodium oxybate on cataplexy.

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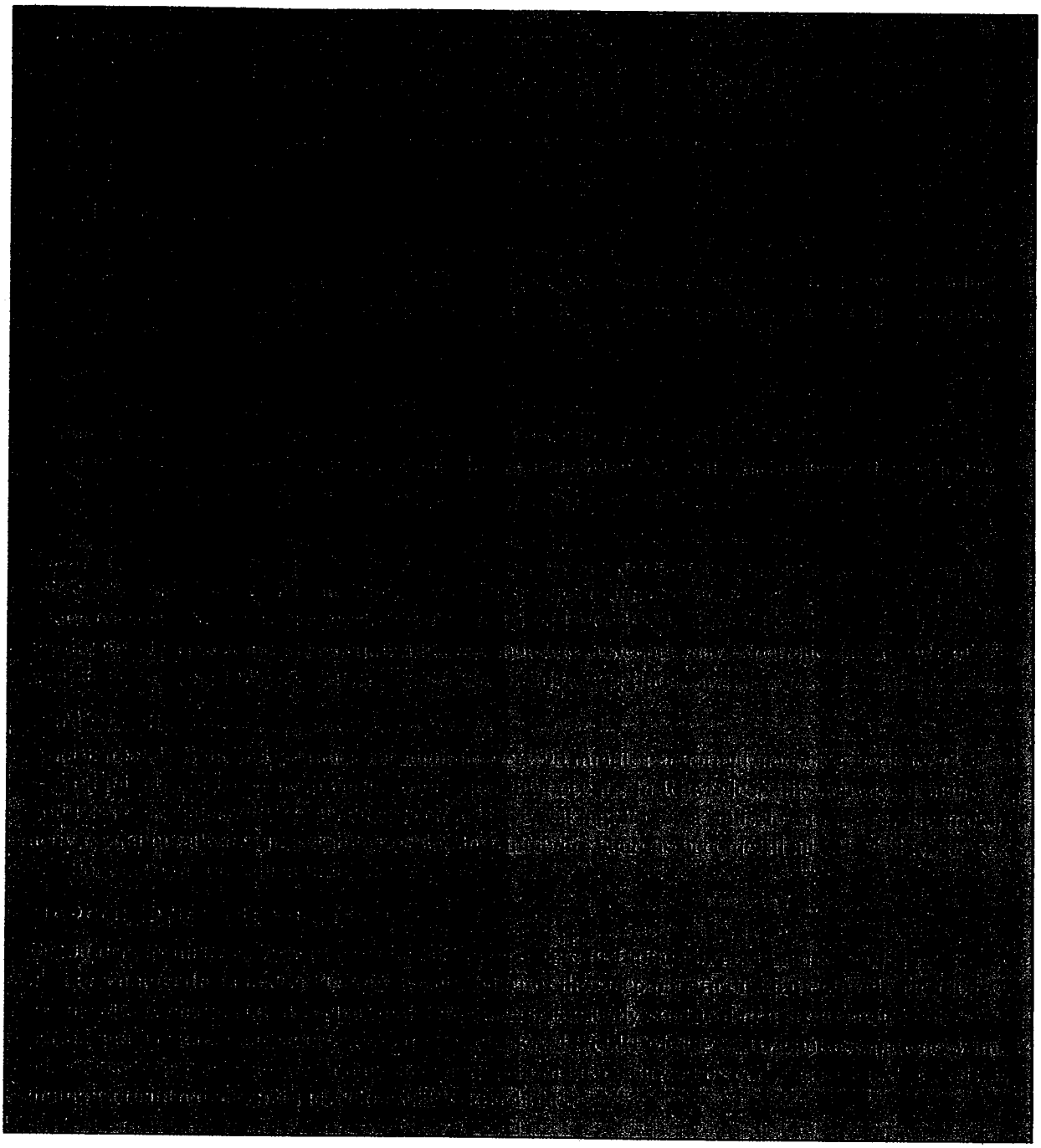

- Explain that Xyrem is only available through a specialized distribution program
- Ask the patient to call the Xyrem Patient Success Program℠ for assistance: 1-866-XYREM88℠ (1-866-997-3688)
- Advise that once their doctor orders the prescription through the special restricted distribution system, it will be shipped directly to the patient

and to rewrite prescriptions for Xyrem at least every 3 months. Physicians are also urged to complete the Xyrem Post Marketing Patient Evaluation form at the 3-month and 6-month visits.

The Central Pharmacy process

The Central Pharmacy provides safe, secure, and convenient home delivery of Xyrem directly to patients. After receiving the physician's prescription, the Xyrem Central Pharmacy will contact the physician's office to confirm prescription details and collect additional information, if needed. The Central Pharmacy will then send the Xyrem Success Program℠ materials, including an instructional video, directly to the patient. Patients are then contacted to confirm that the materials have been read and the details of delivery. During that call, the Central Pharmacy will also reinforce preparation, administration, and storage instructions, and introduce the professional information telephone service, which is available 24 hours a day, 7 days a week. The Central Pharmacy will then dispense and ship Xyrem directly to the patient or their designee, and contact the patient's insurance provider to verify benefits and eligibility. Finally, the Central Pharmacy will refill prescriptions and maintain a patient and prescriber registry to ensure safe and effective distribution.

Concluding Remarks

Cataplexy associated with narcolepsy is a very challenging disease. We are confident that you'll find Xyrem helpful in meeting the needs of your patients.

Important Points to Remember About Xyrem

- Must be prescribed on a specified Xyrem prescription form available only through the Xyrem Success Program℠ (Xyrem is distributed through a single Central Pharmacy)
- Must be taken at bedtime in two equally divided doses

  –First dose: taken while patient is sitting in bed, immediately before lying down to sleep

  –Second dose: patient should be awakened 2½ to 4 hours later and Xyrem taken before continuing sleep
- Must be taken several hours after a meal, since food significantly decreases the bioavailability of Xyrem
- Should *not* be taken with alcohol, sedative hypnotics, or other CNS depressants
- Must be titrated in increments of 1.5 g from the recommended starting nightly dose of 4.5 g
- Must be kept in a safe place, out of reach of children
- Xyrem has abuse potential

In addition, you should:

- Evaluate patients' progress on Xyrem every 3 months
- Counsel patients as fully as possible about the use and misuse of Xyrem

With the help of all healthcare professionals, narcolepsy patients with cataplexy who need this unique medication will have access to it—*safely and lawfully*. We at Orphan Medical, Inc., will always be happy to answer any questions you or your patients might have about Xyrem. Please consult the Prescribing Information and/or call the Xyrem Success Program℠ at 1-866-XYREM88℠ (1-866-997-3688).

XYREM® (sodium oxybate) oral solution CIII

EXHIBIT 2 PAGE 14 OF 43

Bring back the laughter

XYREM® (sodium oxybate) oral solution

SUCCESS PROGRAM℠

How Do I Prescribe Xyrem?

Xyrem is available only through the Xyrem Success Program.℠ To obtain Success Program℠ materials call the Xyrem Central Pharmacy at 1-866-XYREM88℠ (1-866-997-3688)

- Carefully read the Xyrem Success Program℠ information and materials for physicians
- Complete the Xyrem Prescription and Enrollment form
- Fax completed Prescription and Enrollment form to the Central Pharmacy at 1-866-470-1744

XYREM® (sodium oxybate) oral solution

OM0341

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-196

Orphan Medical
Attention: Dayton Reardan, Ph.D.
Vice President, Regulatory Affairs
13911 Ridgedale Drive, Suite 250
Minnetonka, MN 55305

Dear Dr. Reardan:

Please refer to your new drug application (NDA) dated September 30, 2000, received October 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xyrem® (sodium oxybate) Oral Solution.

We acknowledge receipt of your submissions dated May 8 and 28; June 6; July 1, 12 and 15, 2002. Your submission of May 16, 2002 constituted a complete response to our April 9, 2002 action letter.

This new drug application provides for the use of Xyrem® Oral Solution for the treatment of cataplexy associated with narcolepsy.

We also refer to your March 12, 2002, correspondence requesting review of Xyrem® Oral Solution under the provisions of Subpart H for restricted distribution. Therefore, as previously agreed, we have reviewed this application under the restricted distribution regulations contained in 21 CFR 314.500 (Subpart H) to assure safe use of the product.

Finally, we refer to the July 17, 2002, teleconference between representatives of Orphan Medical Inc. and this division during which the final language of the labeling text was agreed upon.

We have completed the review of this application, including the Xyrem® Risk Management Program, as amended, and have concluded that adequate information has been presented to approve Xyrem® (sodium oxybate) Oral Solution under 21 CFR 314 Subpart H. Accordingly, the application is approved under the provisions of 21 CFR 314, Subpart H. Approval is effective on the date of this letter. Marketing of this drug product and related activities are to be in accordance with the substance and procedures of all FDA regulations and the specific restrictions on distribution and use described below.

Xyrem® Risk Management Program

We remind you that Xyrem is being approved with a Risk Management Program (RMP) that must include each of the following components:

1) Implementation of a restricted distribution program for Xyrem.
2) Implementation of a program to educate physicians and patients about the risks and benefits of Xyrem, including critical information necessary for the safe use and handling of the drug.
3) Filling of the initial prescription only after the prescriber and patient have received and read the educational materials.
4) Maintenance of a registry of all patients and a record of all prescribers.

The RMP, as described in the attached documents, adequately addresses each of these requirements. Any proposed change in the RMP must be discussed with FDA prior to its institution. FDA will determine whether the proposed change is subject to FDA approval before implementation. We expect your continued cooperation to resolve any problems regarding the RMP that may be identified following approval of this NDA.

Medication Guide

As previously communicated to you in our December 13, 2001, letter, we have determined that Xyrem® poses a serious and significant public health concern requiring distribution of a Medication Guide. This Medication Guide is necessary to help prevent serious adverse effects due to Xyrem® pursuant to 21 CFR Part 208.1 (c)(1).

In accordance with 21 CFR Part 208, Orphan Medical is responsible for ensuring that:

- A Medication Guide for Xyrem® is available for every patient who is dispensed a prescription for Xyrem®.
- The label of each carton container of Xyrem® include a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom Xyrem® is dispensed.
- The label of each container includes a statement about how the Medication Guide is dispensed.

Post Marketing Commitments

You have made a commitment to conduct the following post marketing studies, as specified in your submission dated July 1, 2002, and our telephone conversation of July 12, 2002:

1. *Description:* conduct a drug interaction study to evaluate the pharmacokinetics of Xyrem® when administered concomitantly with a proton pump inhibitor in normal human volunteers.

   Protocol Submission: within three months of FDA approval of the NDA
   Study Start: within three months of FDA approval of the protocol
   Final Report: within six months of study initiation

2. *Description:* conduct a clinical study in subjects with respiratory compromise.

   Protocol Submission: within three months of FDA approval of the NDA
   Study Start: within three months of FDA approval of the protocol
   Final Report: completion of the study within 12 months of initiation with the final report three months following completion of the study.

3. *Description:* assess the post marketing safety of Xyrem in a prospective cohort of one thousand (1,000) patients prescribed Xyrem by evaluating physician-filed adverse event data sheets; each patient will be assessed for at least 6 months.

   Submission of Plans: within one month of approval
   Start Date: immediately upon treatment of any patient
   Reports to FDA: every three months from time of approval

Clinical protocols should be submitted to your IND for this product and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a summary of the status of each commitment in your annual report to this NDA. The summary should include expected study completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies. The number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

The final printed labeling (FPL) must be identical to the enclosed agreed upon labeling text for the Product Information Insert and Medication Guide. The immediate container and carton labels must be identical to those submitted on January 8, 2002. Marketing the product with FPL text that is not identical to the agreed upon approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-196." Approval of this submission by FDA is not required before the labeling is used.

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must directly submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement to the Division of Drug Marketing, Advertising and Communications. Please submit all

proposed materials in draft or mock up form, not final print and send one copy to the Division of Neuropharmacological Drug Products. We acknowledge your agreement to submit the reprint with the citation Sleep 2002; 25:42-49, under 21 U.S.C. § 360aaa.

We have approved an expiration date of 36 months for this drug product.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80, 314.81, 314.520, 314.550 and 314.560.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures:
Professional Labeling
Patient Medication Guide
Risk Management Plan
Post Marketing Evaluation Program
Physician and Patient Educational Programs

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Temple
7/17/02 04:57:49 PM

Xyrem® Risk Management Program

I. As a condition of approval, the requirements of your Risk Management Program include the following, with the details of the Program set out below in III.

- Implementation of a restricted distribution program for Xyrem
- Implementation of a program to educate physicians and patients about the risks and benefits of Xyrem, including support via ongoing contact with patients and a toll-free Helpline
- Filling of the initial prescription only after the prescriber and the patient have received and read the educational materials
- Maintain patient and prescribing physician registries

II. You have also agreed to the following:

- The bulk drug will be manufactured at a single site.
- The drug product will be manufactured at a single site.
- Following manufacture the drug product will be stored at a facility compliant with Schedule III regulations, where a consignment inventory will be maintained.
- The inventory will be owned by Orphan Medical, Inc., and the facility will be managed by a central pharmacy which will maintain the consignment inventory.
- Xyrem® will be distributed and dispensed through a primary and exclusive central pharmacy (which you have represented will contract with Orphan Medical to fulfill this function). Orphan Medical has a designated back-up distributor. Xyrem® will NOT be stocked in retail pharmacy outlets.

III. Risk Management Program Details

A. Dispensing

You will ensure that Xyrem is dispensed in the following manner:

- Prescriptions will be communicated by facsimile or other convenient method by the physician, or the physician's office, to the central pharmacy.
- Upon receipt of a prescription the central pharmacy will contact the prescribing physician and/or the physician's office and
  - Identify physician's name, license and DEA registration
  - Verify the prescription
  - Obtain patient insurance information
- The central pharmacy will then verify that the physician is eligible to prescribe Xyrem® by consulting the National Technical Information Services (NTIS). This stage of verification will include confirming that the physician has an active DEA number and will check on whether any actions are pending against the physician.

- If the physician is a first-time prescriber of Xyrem® the pharmacy will then ship, if the physician does not already have them, comprehensive printed materials to that physician; these materials (see Xyrem Physician Success Program℠ below) also contain information regarding the proper handling of the drug with an outline of precautions to be taken against diversion.
- You have agreed that if a patient has prescription drug coverage, the central pharmacy will then contact the patient's insurance company to obtain coverage. The central pharmacy will notify the patient of his/her approval status.
- All patient registry information will be verified before the initial prescription can be filled.
- Comprehensive printed and video materials (see Xyrem Patient Success Program℠ below) that also contain information regarding the proper handling of the drug with an outline of precautions to be taken against diversion will be provided to the patient in advance of the shipment.
- Prior to Xyrem® being shipped to a patient for the first time, the central pharmacist will confirm with the patient by telephone that the patient has read the educational materials contained in the Xyrem Patient Success Program℠. That confirmation will be recorded by the central pharmacist.
- Once approval has been established, the central pharmacy will verify the patient's home address and availability for shipping, and arrange shipment through Federal Express or a similar carrier.
- The patient may provide the name of a designee to the central pharmacy who is authorized to accept shipment of Xyrem® when the patient is unable to do so. This designee must be 18 years of age or older.
- Receipt of the initial drug shipment will be ensured through the following:
    - A phone call by the pharmacy to the patient, no more than 1 business day after the shipment has been delivered, to verify that the medication has been received; and
    - The courier service's own tracking system for shipments
- The package will be sent under condition that if the patient, or his/her designee is unavailable to accept a shipment of Xyrem® and execute the required receipt after two delivery attempts, the package will be returned to the pharmacy.
- You have agreed that, if a shipment is lost, an investigation will be launched to find it.
- If required by the patient's insurance company, the product may be shipped by the central pharmacy to another pharmacy for patient pick-up. The sponsor anticipates that this will be an unusual occurrence, and has a mechanism for verifying the second pharmacy's ability to protect against diversion of sodium oxybate before shipping the drug there through NTIS and State Boards of Pharmacy.

- Prescription refills will be permitted in the number specified in the original prescription. In addition, you have agreed that:
    - If a prescription refill is requested by the patient prior to the anticipated due date, such refills will be questioned by the pharmacist.
    - A lost, stolen, destroyed, or spilled prescription/supply will be documented and the prescription replaced to the extent necessary to honor the original prescription (e.g., a destroyed or spilled bottle will reduce the prescription refill amount). The pharmacist has the discretion to grant or not grant refill requests under those circumstances and at a

minimum will contact the prescribing physician to determine if the physician has any special concerns in regard to that refill request. New supplies of Xyrem® will be sent to the patient only if the pharmacist and physician are in agreement.

- Repeat instances of lost, stolen, destroyed, or spilled prescriptions/supplies will be flagged for monitoring and future instances thoroughly questioned.
- The first prescription will be limited to a one month's supply of Xyrem®.
- Following further contact between the pharmacy and patient, and verification that the patient understands the material in the Xyrem Patient Success Program℠, supplies of Xyrem® that are intended to last longer than a month may be shipped.
- The quantity of drug shipped to the patient with each refill may also be regulated based on the requirements of the patient's health insurance plan and the terms of the prescription itself.
- It is anticipated that the majority of patients will receive only one month's shipment at a time.
- Patients will never receive more than 3 months' supply of Xyrem® per shipment.
- Prescriptions for Xyrem® will be rewritten at least every 3 months

B. Registries

- Every patient and prescribing physician will be registered with the central pharmacy in a secure database. The database will contain the physician's name, address, telephone and facsimile numbers, DEA and state license numbers and prescribing frequency. The database will be made available for review by federal and state agencies upon request. From this database it will be possible to obtain the following information:
  - Prescriptions by physician specialty
  - Prescriptions by patient name
  - Prescriptions by volume (frequency)
  - Prescriptions by dose

C. Xyrem Post-Marketing Evaluation Program

- You have agreed that that the prescriber will be urged to see and evaluate his or her patients every 3 months. In addition, you will urge prescribers to submit reports of all serious adverse reactions to Orphan Medical every 3 months initially with the longer term reporting requirements to be negotiated with the Agency.

- At each visit subsequent to the initial prescription visit, you have agreed that the prescriber will be urged to query the patient for potential adverse events associated with Xyrem use, as well as document any suggestion of inappropriate Xyrem use (e.g., premature requests for refills). To assist

the prescriber in this assessment, evaluation forms are included with the physician Xyrem Success Program℠, which are to be completed by the prescriber at Month 3 and Month 6 of a patient's course of therapy. It is of utmost importance that the prescriber fill out this form as completely as possible.

D. Drug Product Kit

Every box of Xyrem® shipped to the patient will contain all the items below:.

- The drug product, a clear solution, in a 180 mL amber bottle with a closure mechanism that is child-resistant
- The Press-In-Bottle-Adapter (PIBA Well) which will be inserted into the bottle by the pharmacist
- An Exacta-Med Dispenser® which allows the patient to withdraw the appropriate dose of drug
- Two child-resistant dosing cups, one for each of 2 nightly doses.
- A package insert and Medication Guide

E. Education materials

1. Xyrem Physician Success Program℠

This program consists of printed material(s) to educate physicians about the features of Xyrem®. When a physician prescribes the drug for the first time, the physician must verify that he/she has read these materials before the medication will be sent to the patient.

2. Xyrem Patient Success Program℠

This program consists of a videotape and printed educational material. The patient will receive this material prior to the first shipment of drug. The central pharmacist will not ship the product unless the patient has confirmed to the pharmacist that he or she has read the educational materials.

Version 4

Important Points to Remember About Xyrem

- Must be prescribed on a specified Xyrem Prescription form available only through the Xyrem Success Program℠
- Distributed through a single Central Pharmacy
- Must be taken in 2 equally divided doses, at bedtime and 2½ to 4 hours later
  - First dose: taken while patient is sitting in bed, immediately before lying down to sleep
  - Second dose: patient should be awakened 2½ to 4 hours later and Xyrem taken before returning to sleep
- Must be taken several hours after a meal (food significantly decreases the bioavailability of Xyrem)

Xyrem
(sodium oxybate) oral solution

XYREM® (sodium oxybate) oral solution

Bring back the laughter

How to Prescribe Xyrem

Before prescribing Xyrem

Physicians must acknowledge having read the Xyrem Success Program℠ and use the special prescription form provided with the Xyrem Success Program.

Prescribing requirements

- All physicians must verify that each patient for whom Xyrem has been prescribed has been educated about Xyrem preparation, dosing, and scheduling. Patients are to be advised of, and comply with, the requirements of the Xyrem Success Program for Patients in order to receive Xyrem.
- Physicians are urged to see and evaluate each patient every 3 months and to re-write prescriptions at least every 3 months.

Physicians are also urged to complete the Xyrem Post Marketing Patient Evaluation form (which is included in the Physician Xyrem Success Program) at the 3 and 6 month visits after initiation of Xyrem therapy. This program evaluates the patient for specific adverse events of interest (reports of vomiting, incontinence, sleepwalking, confusion or convulsions), provides a mechanism for reporting other adverse events, and documents any evidence of inappropriate use of Xyrem.

Prescribing procedure

The physician should complete the Xyrem Prescription and Enrollment form included in the Xyrem Success Program for Physicians materials. The completed prescription form and all subsequent prescriptions should be faxed to the Xyrem Central Pharmacy at 1-866-470-1744.

The Central Pharmacy

The Central Pharmacy provides safe, secure, and convenient home delivery to patients.

After receiving the physician's prescription, the Xyrem Central Pharmacy will:

- Contact the physician or the physician's office to confirm prescription details and collect additional information, if needed.
- Send the Xyrem Success Program materials directly to the patient.
- Contact the patient's insurance provider to verify benefits and eligibility.
- Contact patients to confirm that the materials have been read and the details of delivery. During that call, the Central Pharmacy will also reinforce preparation, administration, and storage instructions, and introduce the professional information telephone service, which is available 24 hours a day, 7 days a week.
- Dispense and ship Xyrem directly to the patient, or the patient's designee.
- Maintain a patient and prescriber registry.
- Refill prescriptions.

chance of dozing during various daytime activities. Routine situations include reading, watching television, attending meetings and talking with another person.
Excessive Daytime Sleepiness – The principle symptom of narcolepsy, described as a continuous, subjective feeling of sleepiness, which may also be associated with irresistible attacks of sleep.

F

G

H

HLA DQB1 *0602 – A specific human leukocyte antigen found with high frequency in narcolepsy patients. It is also found in a minority of non-narcoleptics.

Hypersomnolence – Excessive sleepiness or drowsiness.

Hypocretin – a recently-discovered neurotransmitter that appears to have important roles in sleep-wake regulation, neuroendocrine stasis, autonomic regulation and control of feeding behavior. A deficiency of hypocretin-containing neurons is thought to be the underlying pathophysiology of narcolepsy.
Hypnagogic hallucinations – vivid, often frightening, dream-like images and sounds experienced at sleep onset, usually accompanied by fear and anxiety; a characteristic feature of narcolepsy.

I

J

K

L

M

Maintenance of Wakefulness Test (MWT) – The MWT measures the ability of a patient to remain awake during a series of 20-minute periods while reclining in a quiet, dimly lit room. The point at which the patient falls asleep is determined by EEG recordings. Mean sleep latency, measured during four or more nap periods, is the measure of sleepiness. The MWT measures the ability of patients to stay awake. An inability to stay awake for more than 12 minutes is suggestive of narcolepsy.

Multiple Sleep Latency Test (MSLT) – The MSLT is the primary test for the diagnosis of narcolepsy. This test assesses two major components of narcolepsy: hypersomnolence and sleep onset REM periods (SOREMPs), which occur in narcolepsy but are otherwise uncommon. The mean sleep latency, or time to sleep onset, provides evidence for hypersomnolence. Using an EEG to record sleep onset during normal waking hours, it consists of four or five 20-minute nap opportunities at two-hour intervals. Normally, sleep latency is greater than 10 minutes and REM sleep does not occur. Patients with narcolepsy typically fall asleep in 5 minutes or less and will display SOREMPs during at least two of the five daytime nap periods.

N

Narcolepsy – An uncommon, complex sleep disorder where a deficit in the neuro transmitter hypocretin results in "impaired control of the boundaries that normally separate the state of wakefulness from REM and non-REM sleep." As such, narcolepsy is characterized by the primary symptoms of excessive daytime sleepiness, fragmented nighttime sleep and abnormal manifestations of REM sleep phenomena including cataplexy, sleep paralysis and hypnagogic hallucinations.

NON-REM SLEEP – Usually divided into four stages.
Stage 1
Approximately five minutes are spent in Stage 1 sleep while making the transition from wakefulness into light (Stage 2) sleep. During this period, sleepers lose awareness of their surroundings although they are easily awakened.

Stage 2
Stage 2 is considered the first stage of true sleep. This stage is characterized by light sleep of 30-45 minutes duration, initially. During this time respiration and heart rate slow and brain electrical activity becomes irregular. About half the night may be spent in Stage 2, and if woken during this period sleepers report feeling moderately refreshed.

Stages 3 and 4
These stages are jointly identified as deep or slow-wave sleep and are most prominent in the first third of the night. Decreases in blood pressure, slower pulse rates and more regular breathing occur. These physiological changes are accompanied by the characteristic delta waves (large, slow brain waves) on EEG. It is believed the body repairs itself during this deep (restorative) sleep. Depending upon age, a sleeper may experience up to 20% of total sleep time as slow-wave sleep.

O

P

Patient Diaries – A means of recording daily symptoms and drug experience.
Polysomnographic (PSG) Testing – The PSG continuously records normal and abnormal physiological activity during an entire night. A typical PSG montage includes an electroencephalogram (EEG), electro-oculogram (EOG), electrocardiogram (ECG), continuous pulse oximetery and leg movements. It documents the adequacy of sleep, including the frequency, duration and total amounts of Stage 1-2, Stage 3-4 (slow-wave sleep) and REM sleep. It will also indicate whether other etiologies of EDS, such as sleep apnea, are present.

Q

R

Rebound Cataplexy – An increase in the frequency and severity of cataplexy attacks following abrupt discontinuation of antidepressants. In its most severe form, this is known as status cataplecticus.

REM Latency – The length of time between the onset of sleep and the first REM sleep period, used as an aid in the diagnosis of narcolepsy. REM latency is less than 20 minutes in approximately 50% of narcoleptics compared to about 90 minutes in normal individuals.

REM SLEEP – Approximately three to five times per night or every 90 minutes, a normal sleeper experiences several minutes of REM sleep during which dreaming occurs. In REM sleep, the activity of many brain systems equals or exceeds those when in active waking; however, muscle atonia prevents motor activity and noradrenergic, serotonergic and histaminergic neurons become silent. REM sleep makes up about 20% of total sleep time.

S

Serotonin-Selective Reuptake Inhibitors (SSRIs) - A class of antidepressants known to have anticataplectic properties. Fluoxetine and paroxetine are examples of SSRIs.

SF-36® Health Survey – A 36 question short-form survey used to measure health-related quality of life, generally regarded as the standard for patient-reported health outcomes assessment.

Sleep Architecture – A general term for the onset, continuity, frequency and duration of various sleep stages occurring during the course of nighttime sleep, measured using nocturnal polysomnography.

Sleep Cycle – A repeating pattern of sleep stages. Normal individuals experienced four to five sleep cycles during the course of a normal 8-hour sleep period.

Sleep Latency – The length of time between lying down and falling asleep. Measured during the Multiple Sleep Latency Test, as an aid in the diagnosis of narcolepsy. Narcoleptics usually have a sleep latency of less than 10 minutes.

XYREM® (sodium oxybate) oral solution

Bring back the laughter

How to Obtain Xyrem

The Xyrem Central Pharmacy will provide safe, secure and convenient home delivery of Xyrem to patients.

Xyrem is available only through the Xyrem Central Pharmacy. You cannot fill your prescription for Xyrem at your local chain or mail order pharmacy.

After your doctor has prescribed Xyrem and you have had time to review your Xyrem Success Program[SM] materials, the Central Pharmacy will contact you to confirm that you have read them. They will then confirm Xyrem delivery, review the preparation, dosing and storage instructions and obtain insurance information.

The Central Pharmacy will also provide access to a healthcare professional to answer your Xyrem questions 24 hours a day/7 days a week at 1-866-XYREM88[SM] (1-866-997-3688).

If you are taking Xyrem, it is recommended that you should be evaluated by your doctor every 3 months.

ORPHAN MEDICAL

Dedicated to patients with uncommon diseases®

Home | Healthcare Professionals | Disease Overview | Xyrem Overview | Xyrem Clinical Trial 1 | Xyrem Clinical Trial 2 | Xyrem Safety Profile | Xyrem Dosing and Administration | Xyrem Success Program for Physicians | How to Prescribe Xyrem | Important Information for Healthcare Professionals | Patient Resources | Xyrem Bibliography | Xyrem US Prescribing Information | Request Information About Xyrem | Glossary | Patients | Disease Overview | Xyrem Success Program for Patients | How to Obtain Xyrem | Xyrem Patient Medication Guide | Reimbursement Information | Patient Resources | Ongoing Xyrem Clinical Trials | Contact Us | Clinical Trial Investigator Form | Clinical Trial Patient Volunteer Form | Media | Site Map

The information in this Web site should not be used as a substitute for consultations with physicians or other health care professionals. Health care related questions should be referred to physicians or other health care professionals.

FDA Drug Approvals
Profiles of the latest drugs approved by the Food and Drug Administration.

Health Library

New FDA Drug Approvals

Xyrem™ (sodium oxybate or gamma hydroxybutyrate, also known as GHB)

Date Approved: July 17, 2002

Description of Xyrem™:

- Used for treating a small population of patients with narcolepsy who experience episodes of cataplexy, a condition characterized by weak or paralyzed muscles.

Important Information about Vioxx™:

- Because of safety concerns associated with the use of the drug, the distribution of Xyrem will be tightly restricted.
- FDA approved Xyrem based on the results of two controlled clinical trials that showed that use of the drug reduced the number of cataplectic attacks compared to placebo. About 85 percent of these patients were also treated with central nervous system stimulants. A total of 448 patients were treated with Xyrem in clinical trials. Xyrem must be taken at bedtime and then again 2 1/2 to 4 hours after the beginning of sleep.
- Due to serious concerns and adverse events associated with the use of Xyrem, including some events that resulted in death, FDA has worked with the drug's manufacturer, Orphan Medical Inc., to design a comprehensive risk management program. The program includes limited distribution, physician education, patient education, the creation of a patient and physician registry, and detailed patient surveillance. Under the program, prescribers and patients will be able to obtain the product only through a single centralized pharmacy. The pharmacy will send Xyrem to patients only after their doctors have provided instruction on the safe and effective use of the drug and after the patients have read the information provided about the drug. Doctors will also be urged to see their patients at least every three months. Doctors are also expected to report all serious adverse events to the manufacturer by calling 1-877-67-Xyrem (1-877-679-9736.)

Possible Side Effects of Xyrem™:

- Side effects associated with Xyrem include confusion, depression, nausea, vomiting, dizziness, headache, bedwetting, and sleepwalking. Abuse of Xyrem could also lead to dependence, i.e, craving for the medicine, and severe withdrawal symptoms.

Where to find more information about Xyrem:™:

- Visit the FDA web site at http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01157.html.

Last updated: August 7, 2002
Written & edited by: Ron Wozny, VHA/LaurusHealth.com
Medical Review by: Rockhill Communications
Source of Material: The above information was obtained from the U.S. Food & Drug Administration, U.S. Public Health Service and Deptartment of Health & Human Services, at http://www.fda.gov.

Mission Hospital • 27700 Medical Center Road • Mission Viejo, California 92691-6426 • (949) 364-1400

EXHIBIT 3, PAGE 34 OF 43

OM0595

EXHIBIT 3, PAGE 35 OF 43

Xyrem (sodium oxybate), produced by Orphan Medical. On April 10, 2002, Orphan Medical received notice from the FDA that it is prepared to approve Xyrem but only under special conditions. Why? Because sodium oxybate is also gamma hydroxybutyrate, or GHB, better known as the "date-rape" drug. On the street, GHB is used to incapacitate someone, usually for sexual assault. The drug is colorless and odorless, and its taste is easily masked by putting it in a drink. It knocks the victim unconscious for a few hours and often causes amnesia about what happened, too.

The FDA and law enforcement officials have been naturally concerned about bottles of Xyrem making their way to the street for criminal sale and use. It has been classified as a Schedule I (most restricted) controlled substance. Before approving Xyrem, the FDA required Orphan Medical to devise a risk management program. The result is a special distribution system in which all prescriptions for Xyrem will be filled by one central pharmacy. This limits the chain of people who handle the drug and who receive bottles of it.

Future research

In studies of Xyrem, people with cataplexy often experienced dramatic reductions in the number of spells they had each day. In an effort to relieve or reduce narcolepsy as well, companies are now looking to develop medications that either replace hypocretin or mimic its effects. There is some discussion about narcolepsy being an autoimmune disorder resulting in the destruction of the brain cells that produce hypocretin, so future research will no doubt explore this.

Information for this article was taken from:

- Foreman, J. "A new dawn in therapies for illness tied to narcolepsy." The Boston Globe, April 9, 2002.
- Okun, M. L., Lin, L., Pelin, Z., Hong, S., & Mignot, E. (2002). Clinical aspects of narcolepsy-cataplexy across ethnic groups. Sleep Vol. 25 No. 1, pp 27-35.
- "Orphan Medical Receives FDA Approvable Letter for Xyrem." Press release, April 10, 2002, from Orphan Medical. Available online.
- Siegel, J. M. Narcolepsy. Scientific American, January 2000. Available online

October 2002

North Carolina Board of Pharmacy
Newsletter ON THE WEB

FDA Approves Xyrem for Cataplexy Using Centralized Distribution

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Related Information: N/A

The US Food and Drug Administration (FDA) approved Xyrem (sodium oxybate or gamma hydroxybutyrate, also known as GHB) for treating patients with narcolepsy who experience episodes of cataplexy, a condition characterized by weak or paralyzed muscles. Because of safety concerns associated with the use of the drug, Xyrem will only be available through a restricted-distribution program.

Under the Xyrem Success Program created by the drug's manufacturer, Orphan Medical, Inc. and PDA, prescribers and patients will be able to obtain the Schedule III controlled substance only through a single centralized pharmacy. The pharmacy will send Xyrem to patients only after their doctors have provided instruction on the safe and effective use of the drug and after the patients have read the information provided about the drug. Physicians will also be urged to see their patients at least every three months and are also expected to report all serious adverse events to the manufacturer by calling I-866/Xyrem-88. A Medication Guide, a special patient information brochure required by the FDA, further advises patients about proper use, administration, and disposal of the drug. Patients who have further questions are advised to talk to their physician or to call the central pharmacy at the toll-free number.

In the early 1990s, prior to development by Orphan Medical, GHB was marketed purporting to be a dietary supplement for enhancing athletic performance and sexual activity, and for inducing sleep. It was also abused as a recreational drug and is well-known for use in date rape. As a result of a number of serious adverse events, including death, FDA intervened to prohibit the marketing of GHB.

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OM0731

FDA approves version of date-rape drug to treat rare disease, but under severe sales restrictions

LAURAN NEERGAARD, AP Medical Writer
Thursday, July 18, 2002

URL: sfgate.com/article.cgi?file=/news/archive/2002/07/18/financial0359EDT0026.DTL

(07-18) 00:59 PDT WASHINGTON (AP) --

A version of the date-rape drug GHB significantly helps a dangerous complication of the sleep disorder narcolepsy, the government ruled in deciding that certain patients now can buy it.

But the Food and Drug Administration's approval of the version named Xyrem late Wednesday came with some of the most severe restrictions ever imposed on a medicine. The agency's move, nevertheless, carves out a single medical use for an otherwise illegal chemical.

Throughout the 1990s, the government had cracked down on illegal GHB use -- abused as a party drug, sex and athletic enhancer and, because it can knock people out, a date-rape drug. Several dozen deaths are blamed on the chemical. But GHB was hard to stop because it was easy for people to mix up with some common chemicals.

Now the maker of the FDA-approved version, Orphan Medical Inc., will have to balance how to get GHB to patients who need it while at the same time not letting it fall into the wrong hands.

"No system, I believe, is foolproof, but there will be very close tabs" kept on every GHB shipment, said Dr. Russell Katz, FDA's neurologic drugs chief.

Narcolepsy is marked by recurring episodes in which patients suddenly fall asleep from a few seconds to an hour. GHB doesn't treat that symptom. However, anywhere from 20,000 to 50,000 narcolepsy patients also suffer cataplexy, a muscle-weakness complication that can cause them to collapse without warning.

Orphan Medical's version of GHB, to be sold under the brand name Xyrem, marks the first FDA-approved treatment for cataplexy. Studies suggest Xyrem (pronounced Zy-rem) could reduce cataplexy attacks by up to 70 percent.

Originally developed as a surgical anesthetic, GHB was pulled off the market because of side effects: it depresses breathing and can cause coma, even kill.

Then in 1990, some companies began selling it as a dietary supplement, and use as a recreational drug took off. Colorless and odorless, it made headlines when people slipped it into drinks, knocking out victims who often had no memory of what happened.

By the mid-90s, the government had declared any GHB use outside of FDA-sanctioned clinical trials illegal. A 2000 law toughened penalties so abusers or distributors could face a prison term. The Drug Enforcement Administration has blamed GHB for at least 58 deaths and 5,700 recorded overdoses since 1990.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-196

Orphan Medical
Attention: Dayton Reardan, Ph.D.
Vice President, Regulatory Affairs
13911 Ridgedale Drive, Suite 250
Minnetonka, MN 55305

RECEIVED
JUL 29 2002
D.T. REARDAN

Dear Dr. Reardan:

Please refer to your new drug application (NDA) dated September 30, 2000, received October 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xyrem® (sodium oxybate) Oral Solution.

We acknowledge receipt of your submissions dated May 8 and 28; June 6; July 1, 12 and 15, 2002. Your submission of May 16, 2002 constituted a complete response to our April 9, 2002 action letter.

This new drug application provides for the use of Xyrem® Oral Solution for the treatment of cataplexy associated with narcolepsy.

We also refer to your March 12, 2002, correspondence requesting review of Xyrem® Oral Solution under the provisions of Subpart H for restricted distribution. Therefore, as previously agreed, we have reviewed this application under the restricted distribution regulations contained in 21 CFR 314.500 (Subpart H) to assure safe use of the product.

Finally, we refer to the July 17, 2002, teleconference between representatives of Orphan Medical Inc. and this division during which the final language of the labeling text was agreed upon.

We have completed the review of this application, including the Xyrem® Risk Management Program, as amended, and have concluded that adequate information has been presented to approve Xyrem® (sodium oxybate) Oral Solution under 21 CFR 314 Subpart H. Accordingly, the application is approved under the provisions of 21 CFR 314, Subpart H. Approval is effective on the date of this letter. Marketing of this drug product and related activities are to be in accordance with the substance and procedures of all FDA regulations and the specific restrictions on distribution and use described below.

Xyrem® Risk Management Program

We remind you that Xyrem is being approved with a Risk Management Program (RMP) that must include each of the following components:

1) Implementation of a restricted distribution program for Xyrem.
2) Implementation of a program to educate physicians and patients about the risks and benefits of Xyrem, including critical information necessary for the safe use and handling of the drug.
3) Filling of the initial prescription only after the prescriber and patient have received and read the educational materials.
4) Maintenance of a registry of all patients and a record of all prescribers.

The RMP, as described in the attached documents, adequately addresses each of these requirements. Any proposed change in the RMP must be discussed with FDA prior to its institution. FDA will determine whether the proposed change is subject to FDA approval before implementation. We expect your continued cooperation to resolve any problems regarding the RMP that may be identified following approval of this NDA.

Medication Guide

As previously communicated to you in our December 13, 2001, letter, we have determined that Xyrem® poses a serious and significant public health concern requiring distribution of a Medication Guide. This Medication Guide is necessary to help prevent serious adverse effects due to Xyrem® pursuant to 21 CFR Part 208.1 (c)(1).

In accordance with 21 CFR Part 208, Orphan Medical is responsible for ensuring that:

- A Medication Guide for Xyrem® is available for every patient who is dispensed a prescription for Xyrem®.
- The label of each carton container of Xyrem® include a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom Xyrem® is dispensed.
- The label of each container includes a statement about how the Medication Guide is dispensed.

Post Marketing Commitments

You have made a commitment to conduct the following post marketing studies, as specified in your submission dated July 1, 2002, and our telephone conversation of July 12, 2002:

1. *Description:* conduct a drug interaction study to evaluate the pharmacokinetics of Xyrem® when administered concomitantly with a proton pump inhibitor in normal human volunteers.

   Protocol Submission: within three months of FDA approval of the NDA
   Study Start: within three months of FDA approval of the protocol
   Final Report: within six months of study initiation

2. *Description:* conduct a clinical study in subjects with respiratory compromise.

   Protocol Submission: within three months of FDA approval of the NDA
   Study Start: within three months of FDA approval of the protocol
   Final Report: completion of the study within 12 months of initiation with the final report three months following completion of the study.

3. *Description:* assess the post marketing safety of Xyrem in a prospective cohort of one thousand (1,000) patients prescribed Xyrem by evaluating physician-filed adverse event data sheets; each patient will be assessed for at least 6 months.

   Submission of Plans: within one month of approval
   Start Date: immediately upon treatment of any patient
   Reports to FDA: every three months from time of approval

Clinical protocols should be submitted to your IND for this product and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a summary of the status of each commitment in your annual report to this NDA. The summary should include expected study completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies. The number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled 'Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

The final printed labeling (FPL) must be identical to the enclosed agreed upon labeling text for the Product Information Insert and Medication Guide. The immediate container and carton labels must be identical to those submitted on January 8, 2002. Marketing the product with FPL text that is not identical to the agreed upon approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-196." Approval of this submission by FDA is not required before the labeling is used.

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must directly submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement to the Division of Drug Marketing, Advertising and Communications. Please submit all

proposed materials in draft or mock up form, not final print and send one copy to the Division of Neuropharmacological Drug Products. We acknowledge your agreement to submit the reprint with the citation Sleep 2002; 25:42-49, under 21 U.S.C. § 360aaa.

We have approved an expiration date of 36 months for this drug product.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80, 314.81, 314.520, 314.550 and 314.560.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures:
Professional Labeling
Patient Medication Guide
Risk Management Plan
Post Marketing Evaluation Program
Physician and Patient Educational Programs

bending of limbs or unusual body positions, assuring complete relaxation and then allowing him or her to recover naturally. Cataplexy for some can be so instantaneous that there is no time to prepare for safety, and injury may occur. Obviously, potentially life threatening situations should be avoided unless cataplexy is fully controlled.

Question: How is a diagnosis of narcolepsy determined?
Answer: Excessive daytime sleepiness (EDS) is often the first symptom to appear, and, for some, the primary symptom of narcolepsy. However, EDS is also a symptom of various other medical conditions. Cataplexy, on the other hand, is unique to narcolepsy. The combination of EDS and cataplexy allow for a textbook diagnosis of narcolepsy. Even when cataplexy is present, laboratory tests may still be needed to confirm diagnosis and determine a treatment plan. The usual diagnostic procedure includes an overnight polysomnogram (PSG or sleep study) to rule out other causes of EDS and to determine the presence of unusual REM patterns. This is followed by the Multiple Sleep Latency Test (MSLT), or daytime nap test, which measures rapidity of sleep onset and how quickly REM sleep follows. The MSLT is the most widely accepted diagnostic test for narcolepsy. In addition, a genetic blood test has been developed which measures certain antigens often found in people who have a predisposition to narcolepsy. Positive results suggest a predisposition, but do not prove the presence of narcolepsy. This test is sometimes used when the diagnosis is in question. A new test is currently in use at a limited number of research facilities, which measures the level of hypocretin in cerebrospinal fluid (CSF). The absence of detectable hypocretins can confirm the presence of narcolepsy/cataplexy, but normal levels of hypocretin cannot rule out the disorder.

Question: How is narcolepsy treated?
Answer: The goal is to decrease EDS and reduce occurrences of cataplexy using minimal medication. EDS and cataplexy must be treated separately. Traditionally, central nervous system stimulants (i.e., Ritalin, Dexedrine, etc.) have been used for EDS. In 1999, Provigil or Modafinil was the first stimulant approved for treatment of EDS associated with narcolepsy. Tricyclic antidepressants (i.e., Vivactil, Tofranil, etc.) and serotonin reuptake inhibitors have traditionally been used for treatment of cataplexy and other REM symptoms. Most recently, the antidepressants Effexor (a serotonin and norepinephrine reuptake inhibitor), and Strattera (a norepinephrine reuptake inhibitor) are showing excellent results in alleviating cataplexy and reducing other REM symptoms. In 2002, a new drug, Xyrem or sodium oxybate, was approved for the safe and effective treatment of cataplexy. In addition to drug therapy, 2 or 3 short naps during the day may help control sleepiness and maintain alertness. Proper diet and regular exercise may also help. Additionally, some report benefits from alternative remedies, such as herbs and acupuncture. Continuing doctor-patient communication is essential. Equally important is educating family, friends, teachers, and co-workers about narcolepsy. Joining a support group is recommended.

Question: What research is being conducted?
Answer: Sleep scientists, at present, are focusing on genetics, neurotransmitters, and the autoimmune system. Researchers also believe that other factors, such as viral and bacterial agents, abrupt changes in wake-sleep cycles, illnesses, accidents, stressors, and even hormonal changes, may act as triggers which determine whether or not someone with a genetic predisposition to narcolepsy will eventually develop the disorder.

Question: What are the long-term problems of narcolepsy?
Answer: The consequences of narcolepsy may be many and far-reaching. Cataplexy may interfere with physical activities, and efforts to avoid emotions may lead to social withdrawal. Sleep attacks and cataplexy in public are embarrassing and can cause serious social difficulties. Inability to work and/or drive may result in loss of independence, financial difficulties and various other problems. In these situations, a person can easily lose touch with others and become depressed.

What is the Narcolepsy Network?
We are a national non-profit corporation founded in 1986 to **CARE*** for people living with Narcolepsy.
***Communication, Advocacy, Research, and Education**

- The Network offers support and encouragement to Narcolepsy Support Groups around the country. Narcolepsy Network, Inc. will help to form and sustain Support Groups through advice, materials and networking with other successful groups and individual leaders.
- The Network offers a website-based communications link through which you can ask questions and seek guidance and help both in finding out if you have narcolepsy and in managing your symptoms.
- The Network publishes a quarterly newsletter and educational material about Narcolepsy and coexisting sleep disorders. These publications, available from Narcolepsy Network, Inc., cover subjects from explaining Narcolepsy to children to issues like work and school accommodations and driving with Narcolepsy.
- Narcolepsy Network, Inc. sponsors an annual conference that brings together people with Narcolepsy and those on the cutting edge of Narcolepsy research to discuss the newest advances in the recognition, diagnosis and treatment of Narcolepsy and other sleep disorders. The conference welcomes people with Narcolepsy, family, friends and other caregivers to the conferences. Each year the conference is held in a different part of the country to allow participants from all parts of the U.S. to attend.

NARCOLEPSY NETWORK, INC.
10921 Reed Hartman Hwy, Suite 117
Cincinnati, Ohio 45242
Tel (513) 891-3522; Fax (513)891-3836
E-mail: narnet@narcolepsynetwork.org
www.narcolepsynetwork.org

(Revised 02/04)

NARCOLEPSY

Questions and Answers

NARCOLEPSY NETWORK, INC.

Please detach or copy and return to:
NARCOLEPSY NETWORK, INC.
10921 Reed Hartman Hwy., Suite 117
Cincinnati, Ohio 45242
Tel (513) 891-3522; Fax (513) 891-3836
E-mail: narnet@narcolepsynetwork.org

NAME _____
ADDRESS _____
CITY _____
STATE _____ ZIP _____
PHONE _____
E-mail _____
MEMBERSHIP DUES:
- ☐ $35 Individual
- ☐ $75 Sleep Professional
- ☐ $150 -Sleep Center/Medical Facility

DONATION INCLUDED: $ _____
A receipt will be sent for all tax deductible donations.
SUPPORT GROUP INFORMATION:
- ☐ I would like to find a support group in my area
- ☐ I would like to help in starting a support group
- ☐ I am a member of the following support group:

Name of group _____
Contact Person _____
City/State _____
Phone _____
E-mail _____
INTEREST IN NARCOLEPSY NETWORK
- ___ I have narcolepsy
- ___ Family member has narcolepsy
- ___ Friend has narcolepsy
- ___ I am a Sleep Medicine Professional

Facility _____
Position _____
You _ MAY _ MAY NOT give my name to others seeking support and/or contacts through Narcolepsy Network.

Note: Membership includes a quarterly newsletter, a copy of "Narcolepsy: A Guide to Understanding", and a list of available educational materials.

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OM4108

Question: What is narcolepsy?
Answer: Narcolepsy is a neurological sleep disorder that can begin at any age and continues throughout life. The onset typically occurs during the teens or early twenties but it can also appear later in life. Predisposition to it seems to be hereditary. It is believed to affect approximately 1 in every 2000 people of both sexes and all races. It is not degenerative; therefore, people with narcolepsy can expect to live a normal life span.

Question: What causes narcolepsy?
Answer: Much has been learned since 1998, when researchers discovered the two brain chemicals called hypocretins (aka orexins). These neurotransmitters are involved in the regulation of the sleep/wake cycle as well as other bodily functions (e.g., blood pressure and metabolism). Research has shown that the majority of hypocretin-producing cells, located in the hypothalamus, have been destroyed in the brains of those who develop narcolepsy and cataplexy. Scientists currently believe that narcolepsy with cataplexy is caused by this loss of hypocretins, and theorize that narcolepsy without cataplexy is likely caused by a defect in the transmission or use of one or both hypocretins. Further research is needed to determine why these hypocretin cells are destroyed and to identify the exact cause(s) of narcolepsy without cataplexy.

Question: What are the symptoms?
Answer: There are five primary symptoms:
- **Excessive Daytime Sleepiness** (EDS), which includes daytime sleep attacks that may occur with or without warning and which may be uncontrollable; persistent drowsiness, which may continue for prolonged periods of time; and micro-sleeps, or fleeting moments of sleep, which may intrude into the waking state.
- **Cataplexy**, the second major symptom of narcolepsy, is a sudden loss of voluntary muscle control, usually triggered by emotions such as laughter, surprise, fear or anger. Cataplexy may occur more frequently during times of stress or fatigue. The cataplectic attack may involve only a slight feeling of weakness and limp muscles (i.e., sagging facial muscles, a nodding head, buckling knees, loss of arm strength, garbled speech), or it may result in immediate and total body collapse, during which the person may appear unconscious, but is actually awake and alert. These attacks may last from a few seconds up to several minutes. Cataplectic episodes are related to the loss of muscle tone usually associated with the normal dreaming stage of sleep called rapid eye movement (REM); as a protection against acting out one's dreams, the muscles become immobile or paralyzed.
- **Disrupted or fragmented nighttime sleep,** involves multiple periods of arousal.

The other two primary symptoms are:
- **Hypnagogic hallucinations** - vivid, realistic, and often frightening dreams; and
- **Sleep paralysis** - a temporary inability to move.

Either one or both of these can occur during the transition between sleep and wakefulness, while the brain is neither fully awake nor fully asleep.

Question: Are there any other symptoms?
Answer: The following secondary or auxiliary symptoms may appear:
- **Automatic behavior** - the performance of a routine task, without conscious awareness of doing it, and often without later memory of it
- **Other** - Side effects of the medications or problems resulting from a continual effort to cope with the symptoms may produce additional problems. Feelings of intense fatigue and continual lack of energy are often reported, and depression is not uncommon. The ability to concentrate and memorize may be compromised. Vision or focusing problems, or sleep eating or eating binges, may also occur. Alcohol may amplify or neutralize the effects of medications taken for the primary symptoms.

Question: How are these symptoms all related to narcolepsy?
Answer: For the average person, a sleep period begins with about 90 minutes of non-REM sleep before the REM cycles begin. When a person with narcolepsy falls asleep, REM episodes often begin within 5 minutes. Since the brain may not be fully asleep when REM/dreaming begins, the dream may be experienced far more vividly and realistically. This is defined as a hallucination. After waking, REM periods, or fragments of REM, may occur inappropriately throughout the day. When automatic behavior occurs for a person with narcolepsy, sleep has partially overtaken the brain, but the body continues to perform familiar tasks.

Question: Is narcolepsy a psychological or mental disorder?
Answer: Narcolepsy is a neurologically-based sleep disorder involving the dissociation of sleep states. Psychological problems can result from the individual's inability to cope with the symptoms and their family's misunderstanding of the disorder. It is very difficult for a person with narcolepsy and those around him/her to understand that sleepiness and sleep attacks are uncontrollable. Failure to accept this fact may seriously impact self-esteem and/or personal relationships. Health care counseling for persons with narcolepsy and their families can help alleviate these secondary problems. Educating the public, especially school health and human resource personnel, can help lessen or even prevent many of these problems.

Question: Does narcolepsy affect learning?
Answer: Although narcolepsy does not affect intelligence, learning cannot help but be affected by the symptoms. Study, concentration, memory, and attention span may be periodically impaired by sleep. Children with narcolepsy should be identified at the earliest possible age to prevent a pattern of failure from developing, thus fostering low self-esteem. Adjustments in study habits may be continually necessary. This can best be accomplished with the cooperation of school personnel.

Question: Is cataplexy dangerous?
Answer: Mild cataplexy, while perhaps embarrassing, is not dangerous. One can often find support for weakened head, neck, or arm muscles, so that others may not even be aware of the momentary loss of control. However, severe cataplexy, resulting in immediate and sudden body collapse, may cause injury. Companions should be told in advance what to expect and how to help. They should always check for the person's safety and comfort, immediately relieving any unnatural

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54 Records(s) found (This page: 1 ~ 54)

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Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78192109**
Filing Date	December 6, 2002
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	August 19, 2003
Owner	(APPLICANT) Abbott Laboratories CORPORATION ILLINOIS 100 Abbott Park Road, D-377, AP6A-1 Abbott Park ILLINOIS 600646008
Attorney of Record	Frances M. Jagla
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Serial Number	74034510
Filing Date	March 5, 1990
Current Filing Basis	1A
Original Filing Basis	1B
Published for Opposition	September 4, 1990
Registration Number	**1702392**
Registration Date	July 21, 1992
Owner	(REGISTRANT) PFIZER INC. CORPORATION DELAWARE 235 East 42nd Street New York NEW YORK 10017
Attorney of Record	STACY HALLERMAN
Type of Mark	TRADEMARK
Register	PRINCIPAL
Affidavit Text	SECT 15. SECT 8 (6-YR). SECTION 8(10-YR) 20020703.
Renewal	1ST RENEWAL 20020703
Live/Dead Indicator	LIVE

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Mark Drawing Code	(1) TYPED DRAWING
Serial Number	78303381
Filing Date	September 22, 2003
Current Filing Basis	44E
Original Filing Basis	44E
Published for Opposition	March 16, 2004
Registration Number	**2851060**
Registration Date	June 8, 2004
Owner	(REGISTRANT) Bayer Aktiengesellschaft JOINT STOCK COMPANY FED REP GERMANY D-51368 Leverkusen-Bayerwerk FED REP GERMANY
Attorney of Record	Stanley C. Macel, III, Esq.
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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TARR Status | ASSIGN Status | TDR Status | TTAB Status *(Use the "Back" button of the Internet Browser to return to TESS)*

Typed Drawing

Word Mark	XILIARX
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of disorders of the central nervous system, the immune system, the cardiovascular system, the respiratory system, the musculoskeletal system, the genitourinary system, for the treatment of inflammatory disorders, for the treatment of skin disorders, for the treatment of gastroenterological disorders, for the treatment of cancer, and for the treatment of eye disorders
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	78199675
Filing Date	January 3, 2003
Current Filing Basis	44E
Original Filing Basis	1B;44D
Published for Opposition	December 16, 2003
Registration Number	**2895228**
Registration Date	October 19, 2004
Owner	(REGISTRANT) Novartis AG CORPORATION SWITZERLAND CH-4056 BASEL SWITZERLAND
Attorney of Record	STEVEN H. HARTMAN
Priority Date	October 8, 2002
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Record 1 out of 1

Typed Drawing

Word Mark	ZYZCALM
Goods and Services	IC 003. US 001 004 006 050 051 052. G & S: Body soaps; perfume; essential oils for personal use; cosmetics; hair lotions; dentifrices IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for preventing or curing diseases in humans, namely, for treating the muscular-skeletal system and the nervous system; dietetic substances, namely, diet capsules, diet pills, dietary food supplements; food for babies; medical plasters; materials for dressings, namely, medical dressings, surgical dressings, wound dressings; material for stopping teeth; dental wax IC 010. US 026 039 044. G & S: Artificial limbs, eyes and teeth
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	76334213
Filing Date	November 5, 2001
Current Filing Basis	44E
Original Filing Basis	1B;44D
Published for Opposition	July 22, 2003
Registration Number	**2773066**
Registration Date	October 14, 2003
Owner	(REGISTRANT) Berolina Drug Development AB CORPORATION SWEDEN Sjodala Gard Sjodalavagen 85 S-23335 Svedala SWEDEN
Attorney of Record	EDWARD M KRIEGSMAN
Priority Date	May 7, 2001
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Record 1 out of 1

Typed Drawing

Word Mark	ZICAM
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: PHARMACEUTICAL AND HOMEOPATHIC PREPARATIONS FOR THE RELIEF OF COLDS AND ALLERGY SYMPTOMS, SPECIFICALLY EXCLUDING PREPARATIONS TO ASSIST IN SMOKING CESSATION OR TO TREAT SMOKING-RELATED CONDITIONS OTHER THAN COLDS AND ALLERGY SYMPTOMS. FIRST USE: 19981200. FIRST USE IN COMMERCE: 19981200
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	76261513
Filing Date	May 22, 2001
Current Filing Basis	1A
Original Filing Basis	1A
Published for Opposition	September 18, 2001
Registration Number	**2517404** .
Registration Date	December 11, 2001
Owner	(REGISTRANT) GEL TECH, L.L.C. LIMITED LIABILITY COMPANY ARIZONA 246 East Watkins Phoenix ARIZONA 85004 (LAST LISTED OWNER) ZICAM, LLC LIMITED LIABILITY COMPANY ARIZONA 2375 EAST CAMELBACK ROAD PHOENIX ARIZONA 85016
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	TOD R. NISSLE
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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TARR Status | ASSIGN Status | TDR Status | TTAB Status *(Use the "Back" button of the Internet Browser to return to TESS)*

Typed Drawing

Word Mark	ZYTRON
Goods and Services	IC 005. US 018. G & S: PHARMACEUTICAL PRODUCTS, NAMELY, FORMULATIONS THAT AID IN REDUCING PAIN AND/OR INFLAMMATION. FIRST USE: 19860200. FIRST USE IN COMMERCE: 19860200
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	73685370
Filing Date	September 21, 1987
Current Filing Basis	1A
Original Filing Basis	1A
Published for Opposition	February 2, 1988
Registration Number	**1485937**
Registration Date	April 26, 1988
Owner	(REGISTRANT) ZYTRON SPORTS INJURY PRODUCTS, INC. CORPORATION NEW YORK 999 OLD TOWN ROAD CORAM NEW YORK 11727
Attorney of Record	EDWIN D. SCHINDLER
Type of Mark	TRADEMARK
Register	PRINCIPAL
Affidavit Text	SECT 15. SECT 8 (6-YR).
Live/Dead Indicator	LIVE

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Record 1 out of 1

Typed Drawing

Word Mark	ZILBRIX
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: vaccines for human use
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78036790**
Filing Date	November 28, 2000
Current Filing Basis	1B;44E
Original Filing Basis	1B;44D
Published for Opposition	August 31, 2004
Owner	(APPLICANT) GLAXOSMITHKLINE BIOLOGICALS S.A. CORPORATION BELGIUM RUE DE L'INSTITUT 89 RIXENSART BELGIUM B-1330
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	PAMELA A. MAY
Priority Date	October 14, 2000
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

EXHIBIT 5 ,PAGE 8 OF 53

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Record 1 out of 1

Typed Drawing

Word Mark	ZYZMYON
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparations for preventing or curing diseases in humans, namely, for treating the muscular-skeletal system and the nervous system; dietetic substances, namely, diet capsules, diet pills, dietary food supplements; food for babies; medical plasters; materials for dressings, namely, medical dressings, surgical dressings, wound dressings; material for stopping teeth; dental wax IC 003. US 001 004 006 050 051 052. G & S: Body soaps; perfume; essential oils for personal use; cosmetics; hair lotions; dentifrices IC 010. US 026 039 044. G & S: artificial limbs, eyes and teeth
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	76334208
Filing Date	November 5, 2001
Current Filing Basis	44E
Original Filing Basis	1B;44D
Published for Opposition	July 22, 2003
Registration Number	**2773065**
Registration Date	October 14, 2003
Owner	(REGISTRANT) Berolina Drug Development AB CORPORATION SWEDEN Sjodala Gard Sjodalavagen 85 S-23335 Svedala SWEDEN
Attorney of Record	EDWARD M KRIEGSMAN
Priority Date	May 7, 2001
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	**ZYLOPRIM**
Goods and Services	IC 005. US 018. G & S: Drug for the Treatment of Gout, Lukemia and Related Conditions. FIRST USE: 19631029. FIRST USE IN COMMERCE: 19631029
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	72180834
Filing Date	November 12, 1963
Current Filing Basis	1A
Original Filing Basis	1A
Registration Number	0773095
Registration Date	July 14, 1964
Owner	(REGISTRANT) Burroughs Wellcome & Co. (U.S.A.) Inc. CORPORATION NEW YORK 1 SCARSDALE ROAD Tuckahoe NEW YORK (LAST LISTED OWNER) PROMETHEUS LABORATORIES INC. CORPORATION CALIFORNIA 5739 PACIFIC CENTER BOULEVARD SAN DIEGO CALIFORNIA 92121
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	RICHARD Y. KIM
Type of Mark	TRADEMARK
Register	PRINCIPAL
Affidavit Text	SECT 15. SECTION 8(10-YR) 20040529.
Renewal	2ND RENEWAL 20040529
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYZMYON
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparations for preventing or curing diseases in humans, namely, for treating the muscular-skeletal system and the nervous system; dietetic substances, namely, diet capsules, diet pills, dietary food supplements; food for babies; medical plasters; materials for dressings, namely, medical dressings, surgical dressings, wound dressings; material for stopping teeth; dental wax IC 003. US 001 004 006 050 051 052. G & S: Body soaps; perfume; essential oils for personal use; cosmetics; hair lotions; dentifrices IC 010. US 026 039 044. G & S: artificial limbs, eyes and teeth
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	76334208
Filing Date	November 5, 2001
Current Filing Basis	44E
Original Filing Basis	1B;44D
Published for Opposition	July 22, 2003
Registration Number	**2773065**
Registration Date	October 14, 2003
Owner	(REGISTRANT) Berolina Drug Development AB CORPORATION SWEDEN Sjodala Gard Sjodalavagen 85 S-23335 Svedala SWEDEN
Attorney of Record	EDWARD M KRIEGSMAN
Priority Date	May 7, 2001
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	XIGRIS
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparation, namely, an antithrombotic agent, an anti-inflammatory agent, an anticoagulant agent and a pro-fibrinolytic agent. FIRST USE: 20011123. FIRST USE IN COMMERCE: 20011123
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	75531376
Filing Date	August 5, 1998
Current Filing Basis	1A
Original Filing Basis	1B
Published for Opposition	June 22, 1999
Registration Number	**2574061**
Registration Date	May 28, 2002
Owner	(REGISTRANT) Eli Lilly and Company CORPORATION INDIANA Lilly Corporate Center Indianapolis INDIANA 46285
Attorney of Record	David E. Kirtley
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	XIMBALTA
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical and medicinal preparations for the treatment of diseases and disorders of the central nervous system
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**76334977**
Filing Date	November 2, 2001
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	May 14, 2002
Owner	(APPLICANT) Eli Lilly and Company CORPORATION INDIANA Lilly Corporate Center Indianapolis INDIANA 46285
Attorney of Record	Mr. Bruce W. Longbottom, Counsel
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	XIRELYS
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparations for the treatment of hormonal related conditions
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	78176427
Filing Date	October 21, 2002
Current Filing Basis	44E
Original Filing Basis	1B;44E
Published for Opposition	September 2, 2003
Registration Number	**2786452**
Registration Date	November 25, 2003
Owner	(REGISTRANT) AVENTIS PHARMA S.A. CORPORATION FRANCE 20 Avenue Raymond Aron Antony Cedex FRANCE F-92165
Attorney of Record	Margaret H. Bitler
Prior Registrations	2062979
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	XYZAL
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of respiratory diseases, namely, antiallergic decongestant and antiasthmatic
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	75874693
Filing Date	December 17, 1999
Current Filing Basis	44E
Original Filing Basis	1B;44D
Published for Opposition	May 29, 2001
Registration Number	**2479307**
Registration Date	August 21, 2001
Owner	(REGISTRANT) UCB Farchim SA CORPORATION SWITZERLAND Z.I. Planchy Chemin de Croix-Blanche, 10, C.P. 41 CH-1630 Bulle SWITZERLAND
Attorney of Record	KAUSHAL R. ODEDRA
Priority Date	October 5, 1999
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYDRIVE
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment and prevention of diabetes, incontinence, cardiovascular diseases, central nervous system diseases and disorders, stroke, cancer, inflammation and inflammatory diseases, respiratory and infectious diseases, auto-immune diseases, solid organ transplant rejection; pharmaceutical preparations, namely, antibiotics, anti-fungals, anti-virals and immunosuppressants
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78313109**
Filing Date	October 14, 2003
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	July 20, 2004
Owner	(APPLICANT) Bristol-Myers Squibb Company CORPORATION DELAWARE 345 Park Avenue New York NEW YORK 10154
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Record 1 out of 1

Typed Drawing

Word Mark	ZYPHAGE
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: PHARMACEUTICALS PRODUCTS FOR PREVENTION AND TREATMENT OF DIABETES AND COMPLICATIONS THEREOF
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	75810879
Filing Date	September 29, 1999
Current Filing Basis	44E
Original Filing Basis	1B;44D
Published for Opposition	October 17, 2000
Registration Number	**2418989**
Registration Date	January 9, 2001
Owner	(REGISTRANT) LIPHA CORPORATION FRANCE 37, rue Saint-Romain 69008 LYON FRANCE
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	BROOKS R. BRUNEAU
Priority Date	March 31, 1999
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYFLO
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparations, namely, an anti-inflammatory. FIRST USE: 19970106. FIRST USE IN COMMERCE: 19970106
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	75179009
Filing Date	October 9, 1996
Current Filing Basis	1A
Original Filing Basis	1B
Published for Opposition	June 17, 1997
Registration Number	**2157636**
Registration Date	May 12, 1998
Owner	(REGISTRANT) Abbott Laboratories CORPORATION ILLINOIS 100 Abbott Park Road Abbott Park ILLINOIS 600643500 (LAST LISTED OWNER) CRITICAL THERAPEUTICS, INC. CORPORATION DELAWARE 60 WEST VIEW STREET LEXINGTON MASSACHUSETTS 02421
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	JOHN L. DUPRÉ
Type of Mark	TRADEMARK
Register	PRINCIPAL
Affidavit Text	SECT 8 (6-YR).
Live/Dead Indicator	LIVE

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ZYMERYS

Word Mark	ZYMERYS
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparations for the treatment of diseases and disorders of the central nervous system
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	**78342718**
Filing Date	December 18, 2003
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	October 5, 2004
Owner	(APPLICANT) Eli Lilly and Company CORPORATION INDIANA Lilly Corporate Center Indianapolis INDIANA 46285
Attorney of Record	Bruce W. Longbottom
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

United States Patent and Trademark Office

Trademark Electronic Search System(Tess)

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Record 1 out of 1

Typed Drawing

Word Mark	XINOD
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: [Pharmaceutical preparations and substances for the prevention and treatment of diseases and disorders of the respiratory system, central nervous system, peripheral nervous system, cardiovascular system, gastrointestinal system; pharmaceutical preparations and substances for use in pain control, arthritis, anaesthesia, oncology, infection, inflammation, urology, gynecology; Pharmaceutical preparations and substances for the treatment and prevention of diabetes;;] Pharmaceutical preparations and substances for the prevention and treatment of diseases and disorders of the respiratory system, central nervous system, peripheral nervous system, cardiovascular system, gastrointestinal system; pharmaceutical preparations and substances for use in pain control, arthritis, anaesthesia, oncology, infection, inflammation, urology, gynecology; Pharmaceutical preparations and substances for the treatment and prevention of diabetes
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	78170628
Filing Date	October 3, 2002
Current Filing Basis	44E
Original Filing Basis	1B;44D
Published for Opposition	August 26, 2003
Change In Registration	CHANGE IN REGISTRATION HAS OCCURRED
Registration Number	**2784308**
Registration Date	November 18, 2003
Owner	(REGISTRANT) AstraZeneca UK Limited a limited liability company UNITED KINGDOM 15 Stanhope Gate London UNITED KINGDOM W1Y 6LN
Attorney of Record	KEITH E DANISH
Priority Date	September 25, 2002
Type of Mark	TRADEMARK

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TARR Status | ASSIGN Status | TDR Status | TTAB Status *(Use the "Back" button of the Internet Browser to return to TESS)*

Typed Drawing

Word Mark	ZYLID
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: PHARMACEUTICAL PREPARATIONS, NAMELY PREPARATIONS FOR THE TREATMENT OF INFECTIOUS DISEASES; CANCER; OPHTHALMOLOGIC CONDITIONS AND DISEASES; CENTRAL NERVOUS SYSTEMS DISEASES AND DISORDERS; PARKINSON'S DISEASE; CARDIOVASCULAR DISEASES AND CONDITIONS; MIGRAINES; PREPARATIONS FOR THE TREATMENT AND SYMPTOMS OF DIABETES; PREPARATIONS FOR THE TREATMENT OF GYNECOLOGIC DISORDERS AND DISEASES; HORMONAL PREPARATIONS; ANALGESICS, ANTI-INFLAMMATORY PHARMACEUTICAL PREPARATIONS
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78017358**
Filing Date	July 19, 2000
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	September 24, 2002
Owner	(APPLICANT) PHARMACIA & UPJOHN COMPANY LLC LIMITED LIABILITY COMPANY DELAWARE 100 ROUTE 206 NORTH PEAPACK NEW JERSEY 07977
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	CYNTHIA B. SUMMERFIELD
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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TARR Status | ASSIGN Status | TDR Status | TTAB Status *(Use the "Back" button of the Internet Browser to return to TESS)*

Typed Drawing

Word Mark	ZYMASE
Goods and Services	IC 005. US 018. G & S: PHARMACEUTICAL COMPOSITION FOR TREATMENT OF CHRONIC PANCREATITIS, PANCREATECTOMY, CYSTIC FIBROSIS, AND STEATORRHEA FROM DIVERSE ETIOLOGIES. FIRST USE: 19880405. FIRST USE IN COMMERCE: 19880405
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	73761578
Filing Date	November 3, 1988
Current Filing Basis	1A
Original Filing Basis	1A
Published for Opposition	January 23, 1990
Registration Number	**1591635**
Registration Date	April 17, 1990
Owner	(REGISTRANT) ORGANON INC. CORPORATION NEW JERSEY 375 MT. PLEASANT AVENUE WEST ORANGE NEW JERSEY 07052 (LAST LISTED OWNER) ORGANON USA INC. CORPORATION NEW JERSEY 375 MOUNT PLEASANT AVENUE WEST ORANGE NEW JERSEY 07052
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	JOAN M. MCGILLYCUDDY
Type of Mark	TRADEMARK
Register	PRINCIPAL
Affidavit Text	SECT 15. SECT 8 (6-YR). SECTION 8(10-YR) 20000720.
Renewal	1ST RENEWAL 20000720
Live/Dead Indicator	LIVE

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TARR Status | ASSIGN Status | TDR Status | TTAB Status *(Use the "Back" button of the Internet Browser to return to TESS)*

Typed Drawing

Word Mark	ZYVOX
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparation, namely an antibiotic. FIRST USE: 20000417. FIRST USE IN COMMERCE: 20000417
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	75603337
Filing Date	December 10, 1998
Current Filing Basis	1A
Original Filing Basis	1B;44D
Published for Opposition	March 28, 2000
Registration Number	**2959967**
Registration Date	June 7, 2005
Owner	(REGISTRANT) PFIZER CARIBE LIMITED COMPANY ORGANIZED IN JERSEY UNITED KINGDOM COUTTS HOUSE, LE TRUCHOT, ST. PETER PORT GUERNSEY UNITED KINGDOM GY1 1WD
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	William G. Jameson
Priority Date	September 18, 1998
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYMAR
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of bacterial conjunctivitis. FIRST USE: 20020711. FIRST USE IN COMMERCE: 20030331
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	78144816
Filing Date	July 17, 2002
Current Filing Basis	1A
Original Filing Basis	1B
Published for Opposition	January 14, 2003
Registration Number	**2843896**
Registration Date	May 18, 2004
Owner	(REGISTRANT) Allergan, Inc. CORPORATION DELAWARE 2525 Dupont Drive Irvine CALIFORNIA 926121599
Attorney of Record	Mark I. Peroff
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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XIFAXAN

Word Mark	XIFAXAN
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment, prevention and/or alleviation of disorders of the gastrointestinal tract. FIRST USE: 20040719. FIRST USE IN COMMERCE: 20040719
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	78428755
Filing Date	June 2, 2004
Current Filing Basis	1A
Original Filing Basis	1B
Published for Opposition	April 12, 2005
Registration Number	**2965332**
Registration Date	July 5, 2005
Owner	(REGISTRANT) Salix Pharmaceuticals, Inc. CORPORATION CALIFORNIA 1700 Perimeter Park Drive Morrisville NORTH CAROLINA 27560
Attorney of Record	Maury M. Tepper, III
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYPREXA
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical products, namely antipsychotics. FIRST USE: 19961001. FIRST USE IN COMMERCE: 19961001
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	75078626
Filing Date	March 26, 1996
Current Filing Basis	1A
Original Filing Basis	1B
Published for Opposition	November 19, 1996
Registration Number	**2072867**
Registration Date	June 17, 1997
Owner	(REGISTRANT) Eli Lilly and Company CORPORATION INDIANA Lilly Corporate Center Indianapolis INDIANA 46285
Attorney of Record	ROBERT E. LEE, JR.
Type of Mark	TRADEMARK
Register	PRINCIPAL
Affidavit Text	SECT 15. SECT 8 (6-YR).
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	XILENTO
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations, namely, preparations for the treatment of immunological, oncological, neurological and cardiovascular diseases IC 041. US 100 101 107. G & S: Medical instruction services; teaching in the field of medicine
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	78216534
Filing Date	February 19, 2003
Current Filing Basis	44E
Original Filing Basis	44D
Published for Opposition	January 25, 2005
Registration Number	**2941576**
Registration Date	April 19, 2005
Owner	(REGISTRANT) Ares Trading S.A. CORPORATION SWITZERLAND Zone Industrielle de L'Ounettaz CH-1170 Aubonne SWITZERLAND 2028
Attorney of Record	Peter S. Sloane
Priority Date	September 16, 2002
Type of Mark	TRADEMARK. SERVICE MARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYLEMPO
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations and substances for the treatment of cancer, stroke, traumatic brain injury, cardiovascular diseases and disorders, metabolic diseases and disorders; antibacterial pharmaceuticals, antiviral preparations, anticoagulants and platelet aggregation inhibitors, antithrombotic agents; diagnostic preparations and reagents for medical use
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	78152614
Filing Date	August 9, 2002
Current Filing Basis	44E
Original Filing Basis	44D;44E
Published for Opposition	November 11, 2003
Registration Number	**2810468**
Registration Date	February 3, 2004
Owner	(REGISTRANT) Bayer Aktiengesellschaft joint stock company FED REP GERMANY D-51368 Leverkusen-Bayerwerk FED REP GERMANY
Attorney of Record	Stanley C. Macel, III
Priority Date	February 11, 2002
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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XIRATUSS

Word Mark	XIRATUSS
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparation for the symptomatic relief of the cough and nasal congestion associated with the common cold. FIRST USE: 20011100. FIRST USE IN COMMERCE: 20011100
Mark Drawing Code	(5) WORDS, LETTERS, AND/OR NUMBERS IN STYLIZED FORM
Serial Number	76525102
Filing Date	June 16, 2003
Current Filing Basis	1A
Original Filing Basis	1A
Published for Opposition	February 24, 2004
Registration Number	**2842771**
Registration Date	May 18, 2004
Owner	(REGISTRANT) Hawthorn Pharmaceuticals, Inc. CORPORATION MISSISSIPPI 6531 Dogwood View Parkway Suite A Jackson MISSISSIPPI 39213
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	L. Jager Smith, Jr.
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYFETOR
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations and substances for the treatment of diseases and disorders of the metabolic, genito-urinary and central nervous systems.
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78233842**
Filing Date	April 4, 2003
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	November 25, 2003
Owner	(APPLICANT) Glaxo Group Limited CORPORATION UNITED KINGDOM Glaxo Wellcome House Berkeley Avenue Greenford, Middlesex UNITED KINGDOM UB6 ONN
Attorney of Record	Sheldon R. Pontaoe
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYMTHER
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of respiratory and gastro-intestinal diseases and conditions
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78075872**
Filing Date	July 26, 2001
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	June 25, 2002
Owner	(APPLICANT) ALTANA PHARMA AG CORPORATION FED REP GERMANY Byk-Gulden-Strasse 2 78467 Konstanz FED REP GERMANY
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	Mark I. Peroff
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYLEST
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations, namely preparations for the treatment of infectious diseases, cancer, ophthalmologic conditions and diseases, central nervous systems diseases and disorders, Parkinson's disease, cardiovascular diseases and conditions, migraines; pharmaceutical preparations for the treatment of diabetes; pharmaceutical preparations for the treatment of urological disorders; pharmaceutical preparations for gynecological uses, namely, for the treatment of menopausal diseases and disorders; pharmaceutical preparations for the treatment of urinary tract and bladder infections, analgesics, anti-inflammatory pharmaceutical preparations
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78145051**
Filing Date	July 18, 2002
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	February 11, 2003
Owner	(APPLICANT) PHARMACIA & UPJOHN COMPANY LLC CORPORATION DELAWARE 100 ROUTE 206 NORTH PEAPACK NEW JERSEY 07977
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	Cynthia B. Summerfield
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	XINLAY
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF CANCER, AUTO IMMUNE DISEASE, CARDIOVASCULAR DISORDERS, OBESITY
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	**78192080**
Filing Date	December 6, 2002
Current Filing Basis	1B
Original Filing Basis	1B
Published for Opposition	August 19, 2003
Owner	(APPLICANT) Abbott Laboratories CORPORATION ILLINOIS 100 Abbott Park Road, D-377, AP6A-1 Abbott Park ILLINOIS 600646008
Attorney of Record	Frances M. Jagla
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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Typed Drawing

Word Mark	ZYRKAMINE
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of cancer
Mark Drawing Code	(1) TYPED DRAWING
Serial Number	76101350
Filing Date	August 1, 2000
Current Filing Basis	44E
Original Filing Basis	1B
Published for Opposition	September 21, 2004
Registration Number	**2909394**
Registration Date	December 14, 2004
Owner	(REGISTRANT) Sanofi-Synthelabo CORPORATION FRANCE 174, Avenue de France Paris FRANCE 75013 (LAST LISTED OWNER) SANOFI-AVENTIS CORPORATION FRANCE 174 AVENUE DE FRANCE 75013 PARIS FRANCE
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	William S. Frommer
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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