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

Proceeding	91178825
Party	Defendant Pedinol Pharmaceutical, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

RISING PHARMACEUTICALS, INC.	§	
	§	Opposition No. 91178825
Opposer,	§	
	§	Serial No. 77/060,983
	§	
v.	§	
	§	
PEDINOL PHARMACEUTICAL, INC.	§	
	§	
Applicant.	§	

APPLICANT’S PARTIAL MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM
UPON WHICH RELIEF CAN BE GRANTED

Applicant, Pedinol Pharmaceutical, Inc. moves to dismiss paragraphs one (1) through ten (10) of the opposition for failure to state a claim upon which relief can be granted. In paragraphs one (1) through ten (10) Opposer, Rising Pharmaceuticals, Inc., has not shown that it will be legally damaged by the registration of applicant’s mark, has standing to raise or enforce the FDA’s laws before the TTAB nor has it alleged any valid statutory grounds which would negate the applicant’s right to registration, as required by §2.104(a) of the U.S. Trademark Law Rules of Practice and §§ 309.03 (a)(2), (b), & (c) of the Trademark Trial and Appeal Board Manual of Procedure. Therefore, to avoid wasting any further costs of litigation, Applicant requests that the claims based paragraphs one (1) through ten (10) of Opposer’s opposition be dismissed with prejudice. The only remaining claim is based on Applicant’s alleged misuse of the ® which did not exist at the time Applicant filed its application.

I. SUMMARY

This opposition proceeding concerns Applicant's federal trademark application for LACTINOL filed on July 10, 2007, assigned the serial no. 77/609,983 and used in public at least as early as June 16, 1992.

In its Notice of Opposition, Rising Pharmaceuticals Inc., having its principal place of business at 3 Pearl Court, Allendale, New Jersey 07401, alleges that Applicant's use of the LACTINOL mark is "predicated upon unlawful use in commerce in violation of the United States Food Drug and Cosmetic Act ("FDA"), 21 U.S.C. §355(a), *et seq.*, and the regulations and guidance promulgated thereunder, which require prescription drug products to be pre-approved by the FDA prior to marketing."

Opposer further alleges that it will be damaged by the registration of Applicant's mark and thereby opposes the issuance of the mark. Opposer does not assert that it is the prior user or that it has superior rights to any confusingly similar name or that Applicant is not entitled to a registration for any reason within the Trademark Trial and Appeal Board's jurisdiction.

II. Standards

FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

The Trademark Trial and Appeal Board Manual of Procedure (TBMP) at §503.02 states that, "a motion to dismiss for failure to state a claim upon which relief can be granted is a test solely of the legal sufficiency of a complaint. In order to withstand such a motion, a pleading need only allege such facts as would, if proved, establish that the plaintiff is entitled to the relief

sought, that is (1) the plaintiff has standing to maintain the proceeding, and (2) a valid ground exists for denying the registration sought, or for canceling the subject registration.”

Section 503.02 of the TBMP further states that “for the purposes of determining a motion to dismiss for failure to state a claim upon which relief can be granted, all of the plaintiff’s well-pleaded allegations must be accepted as true, and the complaint must be construed in the light most favorable to the plaintiff. Dismissal for insufficiency is appropriate only if it appears certain that the plaintiff is entitled to no relief under any set of facts that could be proved in support of its claim.”

III. DISCUSSION

FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

The Lanham Act broadly provides that “any person” who believes he has been damaged by an applicant’s use of a mark may oppose registration. However, the Trademark Trial and Appeal Board Manual of Procedure, under 15 U.S.C. §303.03, strictly states that “a party may establish its standing to oppose . . . by showing that it has a ‘real interest’ in the case, that is, a personal interest in the outcome of the proceeding and a reasonable basis for its belief of damage.” Moreover, under §2.104(a) of the U.S. Trademark Law Rules of Practice, a party initiating an opposition proceeding must present a short and plain statement showing *why* the Opposer believes that he, she or it would be damaged by the registration of the applicant’s mark and state the *grounds* for the opposition.¹ (emphasis added). In this case, the Opposer’s short and plain statement does not establish a reasonable basis for its belief in damage. Though the Opposer would have the court infer that registration of Applicant’s mark somehow establishes a reasonable belief of damage, the Opposer has not alleged any facts in its Notice of Opposition

¹ See also §309.03(a)(2) of the Trademark Trial and Appeal Board Manual of Procedure (TBMP).

which would connect registration of the LACTINOL mark with any potential damage.² Without providing a reasonable basis in fact to support its belief that its interests will be damaged by the granting of registration to Applicant, the Opposer has not shown that it has standing to initiate an opposition proceeding and raise violation of the FDA laws and regulations.

I. Rising's unlawful use claim fails because it is premised entirely on allegations of non-compliance with the FDCA, which has caused no harm to Rising.

A. *The FDA has primary jurisdiction to determine a drug's regulatory status and whether it is being unlawfully marketed, and has exercised its enforcement discretion to permit thousands of "unapproved" drugs – including Plaintiff's and Defendant's drugs – to remain on the market.*

Since 1962, the Federal Food, Drug, and Cosmetic Act (FDCA) has required that all "drugs" (defined to include any article intended to affect the structure of function of the human body³) have a FDA-"approved" New Drug Application ("NDA") with respect to their safety and effectiveness unless they meet one of the following exceptions:

1. The 1938 Grandfather Exception: the drug is the same in (a) formulation and (b) labeled indications to a drug that (c) was introduced into interstate commerce in the United States between 1906 and 1938;⁴

2. The 1962 Grandfather Exception: the drug is the same in (a) formulation and (b) labeled indications to a drug that (c) was commercially sold in the United States and (d) generally recognized by qualified experts as safe for its intended uses but that (e) was not covered by an effective NDA under the 1938 Act;⁵ *or*

3. The "GRAS/E" Exception: the drug is (a) generally recognized as safe and

² See *Ritchie v. Simpson*, *supra* at 1026-1027 (citing *Universal Oil Products v. Rexall Drug & Chemical Co.*, 463 F.2d 1122, 174 USPQ 458, 459-60 (CCPA 1972) and stating that the belief of damage alleged by plaintiff must be more than a subjective belief). See also *Lipton Industries, Inc. v. Ralston Purina Co.*, *supra*. See also *Boswell v. Mavety Media Group Ltd.*, 52 U.S.P.Q.2d 1600 (T.T.A.B. 1999)(finding that white male lacks standing to oppose registration of BLACK TAIL for adult entertainment magazines because he "failed to establish facts on which he could base a reasonable belief that he would be damaged" by the registration) and *The American Angus Ass'n v. Sysco Corp.*, 865 F. Supp. 1180 (W.D.N.C. 1993), where the court held that a competitor of a certification mark registrant did not have standing to challenge registration.

³ 21 U.S.C. § 321(g)(1).

⁴ See 21 U.S.C. § 355(a) (requiring approval for "new drugs"); 21 U.S.C. § 321(p)(1) (setting forth the 1938 grandfather exception).

⁵ See Drug Amendments of 1962, Pub. L. No. 87-781, § 107(c)(4) (reported in Note following 21 U.S.C.A. § 321) (setting forth the 1962 grandfather exception); see also *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 614 (1973) (discussing same).

effective (“GRAS/E”), among experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug; (b) “substantial evidence” supports this consensus; and (c) the drug has been used for a material extent or for a material time under such conditions.⁶

There are also other categories of “unapproved”⁷ drugs, such as “DESI” drugs that are, according to government sources, “permitted to remain on the market” and be reimbursed by Medicaid while evidence of their effectiveness is reviewed and until the FDA publishes a Notice of Opportunity for a Hearing (NOOH) in the Federal Register concerning its proposal to withdraw approval of the drug for marketing. A “DESI” drug is identical, related, or similar (IRS) to an FDA “approved drug” that the FDA had “approved” for safety between 1938 and 1962, but that the FDA has not “approved” for effectiveness. Industry and government officials have long referred to drugs that were never “approved” even for safety, but that allegedly fell into one of the non-DESI exceptions above, as “DESI-II” drugs, even though these drugs are not technically “DESI” drugs.⁸

There may be another exception to the pre-approval requirement. In *United States v. Generix Drug Corp.*,⁹ the Supreme Court acknowledged, in dicta, that an argument could be made that “two demonstrably bioequivalent products, containing the same active ingredients but different excipients, might under some circumstances be the same ‘drug.’” Subsequent courts have referred to this category as the “bioequivalency exception.”¹⁰ The Courts wisely defer to

⁶ See 21 U.S.C. § 321(p)(1) & (2) (setting forth GRAS/E exception); see also 47 FED. REG. 19208, 19219 (1982) (explaining separate GRAS/E, 1962 and 1938 grandfather exceptions); *United States v. Alcon Laboratories*, 636 F.2d 876, 878-79 (1st Cir. 1981) (summarizing ‘three reasons’ for marketing a drug without prior FDA approval).

⁷ The FDA considers any drug that does not have an approved New Drug Application (“NDA”) or Abbreviated New Drug Application (“ANDA” or “Generic”) to be “unapproved.” This does not remotely mean that it is unlawful to market one the thousands of “unapproved” prescription drugs and does not have an “approved” NDA or ANDA.

⁸ See, e.g., *Healthpoint Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp.2d 769, 798 n.182 (W.D. Tex. 2001) (“The term ‘DESI II’ is used to refer to prescription drugs marketed before 1962, or ‘me to copies’ that were not the subject of NDAs.”).

⁹ 460 U.S. 453, 460-61 (1983).

¹⁰ See *United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1410 (7th Cir. 1990).

the FDA’s expertise in evaluating whether an “unapproved” drug meets an exception to the pre-market approval requirements, and to the FDA’s discretion on whether to remove such a drug from the market.¹¹ The FDA, after all, may waive evidentiary requirements for establishing an exception or proof of effectiveness.¹² The TTAB has and should continue to defer to the expertise of the FDA.

The FDA has, for the most part, wielded its broad powers and enforcement discretion pragmatically and prudently.¹³ For a variety of historical, economic, and humanitarian reasons, the FDA has for decades permitted thousands of drugs, which have been registered with the FDA but never specifically reviewed and “approved” for safety and effectiveness in very costly double-blind peer-reviewed studies, to be sold every day in retail, brick-and-mortar U.S. pharmacies, such as Walgreens, Eckerds, and CVS.¹⁴ Rest assured, though, that the FDA believes that none of these “unapproved” drugs represents an imminent safety hazard.¹⁵ (And

¹¹ See 21 U.S.C. § 337(a) (“[A]ll such proceedings for the enforcement, or to restrain violations of [the Act] shall be in the name of the United States.”); *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 624 (1973) (“It is clear to us that FDA has power to determine whether particular drugs require an approved NDA in order to be sold to the public.... [I]t has authority to determine what drugs are “new drugs” under § 201(p) and whether they are exempt from the efficacy requirements of the 1962 amendments by the grandfather clause of § 107(c)(4).”); *PDK Labs., Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (rejecting unfair competition counterclaim based on failure to seek FDA approval: “Friedlanders dogged insistence that PDK’s products are sold without proper FDA approval suggests – as the district court observed in the Georgia action – that Friedlander’s true goal is to privately enforce alleged violations of the FDCA.”); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (upholding dismissal of claim that defendant had falsely represented that its drug was approved by the FDA by “the very act of placing the drug on the market” as an impermissible attempt to enforce the FDCA and FDA regulations); *Summit Tech., Inc. v. High-Line Med. Instru. Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996) (dismissing unfair competition claims that defendants failed to disclose the un-approved status of their medical devices, because it would force the court rather than the FDA to decide the legality of defendant’s product).

¹² See 21 C.F.R. § 314.200(e)(1) (FDA may waive evidentiary requirements, in whole or part, for establishing GRAS/E exception); 21 C.F.R. § 314.126(c) (permitting Director of the Center for Drug Evaluation and Research to “waive in whole or in part any of the criteria in paragraph (b) . . . in the evaluation of a completed study”).

¹³ *But see Abigail Alliance for Better Access to Dev. Drugs v. Von Eschenbach*, 469 F.3d 129, 136 (D.C. Cir. Nov. 21, 2006) (in denying petition for rehearing, holding that terminally ill patients had standing to challenge to restrictive FDA policy and had a fundamental due process interest in accessing potentially life-saving, but unapproved drugs), *pet. for rehearing en banc granted*, 2006 U.S. App. LEXIS 28974 (Nov. 21, 2006).

¹⁴ See *Florida Breckenridge, Inc. v. Solvay Pharms., Inc.*, 174 F.3d 1227, *6 (11th Cir. 1999) (opinion withdrawn) (“[T]hirty-six years after the 1962 amendments to the FDCA, there are still thousands of these unapproved drugs on the market”).

¹⁵ See FDA Talk Paper: “FDA Issues Letter Discussing its Enforcement Policy for Unapproved Drugs.”

the FDA considers lactic acid to be safe.¹⁶⁾

The FDA knows that the consequences of an unflinchingly rigid, Javertian¹⁷ approach to enforcement would be disruptive, deadly, and devastating.¹⁸ Examples of “unapproved” drugs whose sale the FDA has long allowed include phenobarbital, used to control epileptic seizures;¹⁹ papain-urea debriding ointments for treatment of potentially deadly necrotic tissue;²⁰ pancreatic enzyme supplements to treat cystic fibrosis patients afflicted with a disorder that prevents their bodies from producing enzymes needed to digest their food;²¹ and hyoscyamine sulfate tablets for irritable bowel syndrome.²²

Additional examples of “unapproved” drugs whose marketing the FDA allowed for decades, until another industry participant obtained approval of that drug, include digoxin for treatment of mild to moderate congestive heart failure;²³ levothyroxine for the treatment of hypothyroidism (which causes impaired intellectual development, weight gain, fatigue, lethargy, and cold intolerance);²⁴ and extended-release guaifenesin,²⁵ a long and extremely widely used

¹⁶ See *infra*, notes 30-32 and accompanying text.

¹⁷ Inspector Javert was the unflinching law-and-order anti-hero in Victor Hugo’s *Les Misérables*.

¹⁸ Many of these drugs could probably win FDA approval, if their proprietors had sufficient incentive to undertake the expense of performing the time-consuming and expensive trials needed for an NDA. But these drugs are not eligible for patent protection, and in most cases the limited periods of exclusivity (see 21 C.F.R. § 314.108) eligible to some NDA grantees are too short to recoup the expected cost. The Branded Pharmaceutical Association estimates that the total cost of preparing a new drug application (NDA) for an “older” drug product likely ranges from about \$3 million to \$20 million or more.

¹⁹ See FDA, “Questions and Answers for Consumers about Unapproved Drugs” (“Some unapproved drugs, such as Phenobarbital, used to control seizures, are very important therapies in the treatment of significant medical conditions and appear to have benefits for patients...”).

²⁰ See *Healthpoint Ltd. v. Stratus Pharms., Inc.*, 273 F.Supp.2d 769, 794-99 (W.D. Tex. 2001).

²¹ See *Solvay Pharms., Inc. v. Global Pharms.*, 298 F. Supp.2d 880, 881 (D. Minn. 2004).

²² *Schwarz v. Breckenridge*, 388 F. Supp.2d 967, 969, 972 (E.D. Wis. 2005).

²³ See 65 FED. REG. 70538 (Nov. 24, 2000) (proposing to revoke 1970s stay of requirement for submission of NDAs and reaffirming previous conclusion that digoxin products for oral use were new drugs); 67 FED. REG. 42992 (June 26, 2002) (announcing that digoxin tablets marketed after that date would be subject to regulatory action).

²⁴ See 62 FED. REG. 43535 (Aug. 14, 1997) (establishing 3-year deadline for submission of NDAs); 65 FED. REG. 24488 (Apr. 26, 2000) (extending deadline by a year); 66 FED. REG. 36794 (July 13, 2001) (establishing gradual phase-out of remaining unapproved levothyroxine products); see also FDA Talk Paper: “FDA Approves First NDA for Levothyroxine Sodium” (noting that “oral levothyroxine drug products have been marketed in the United States since the 1950’s”).

expectorant that did not obtain FDA approval until July 2002.²⁶

In its “Questions and Answers for Consumers about Unapproved Drugs,” the FDA cautions consumers to *not* stop taking “unapproved” drugs without first talking to their doctor:

Some unapproved drugs, such as Phenobarbital, used to control seizures, are very important therapies in the treatment of significant medical conditions and appear to have benefits for patients, so patients should not stop taking an unapproved drug without talking to their doctor first to determine their best treatment options.²⁷

On June 20, 2006, the FDA issued an updated compliance policy guide (CPG) describing how the FDA intends to exercise its enforcement discretion with regard to the several thousand currently “unapproved” drugs being marketed in the United States. The CPG states that after the FDA determines that a drug is being marketed illegally, it may “exercise enforcement discretion *to allow continued marketing*,” if justified by the circumstances.²⁸ Factors the CPG indicates might justify a “grace period” include “(1) the effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of legally marketed products to meet the needs of patients taking the drug); (2) the difficulty associated with conducting any required studies, preparing and submitting applications, and obtaining approval of an application; [and] (3) the burden on affected parties of immediately removing the products from the market.”²⁹

B. Lactic acid products have long been used safely and effectively for the treatment of various skin conditions.

It is up to the FDA to determine LACTINOL’s regulatory status, and, if it determines that LACTINOL is a “new drug” after inspecting the LACTINOL manufacturing plant and LACTINOL warehouse many times since 1992, whether and under what circumstances to allow

²⁵ Guafenesin is one of the primary active ingredients in cough syrup, which is typically sold over the counter unless it contains ingredients like codeine.

²⁶ See FDA Talk Paper: “FDA Issues Letter Discussing its Enforcement Policy for Unapproved Drugs.”

²⁷ See FDA, “Questions and Answers for Consumers about Unapproved Drugs.”

²⁸ See CPG 7132c.02 at III(B) (emphasis added).

²⁹ *Id.*

its continued marketing. In any event, there *is* pervasive evidence that LACTINOL's active ingredient has been used for a material time and for a material extent and is broadly recognized as safe and effective for the treatment of various skin conditions.

The use of 5-10% lactic acid in topical treatments is generally recognized as safe. On October 3, 1980, the FDA issued a Federal Register notice stating that its Advisory Review Panel on OTC Miscellaneous External Drug Products concluded that 5-10% concentrations of lactic acid in topical drugs was safe, but that there was insufficient data to determine whether it was effective for *wart removal*.³⁰ In a more recent safety review the FDA performed on topically applied alpha hydroxy acids, the FDA cited an expert panel's conclusion that lactic acid was safe for use in non-prescription cosmetic products at concentrations of $\leq 10\%$, and at final formulation pH ≥ 3.5 , and in non-prescription salon products at concentrations of $\leq 30\%$, and at final formulation pH ≥ 3.0 .³¹ Lactic acid is also generally recognized as safe for human consumption.³²

People have used lactic acid products for millennia to treat skin conditions. Cleopatra, the queen of Egypt (51 BC), bathed in sour goat's milk – which contained lactic acid – to rejuvenate her skin.³³ Today, one can find a variety of lactic acid products in the cosmetic section of one's local pharmacy. For example, Upsher-Smith's AmLactin® 12% Moisturizing Lotion, comprising 12% lactic acid neutralized with ammonium hydroxide, is available at Walgreens.

It has been reported that lactic acid and other alpha-hydroxy acids induce shedding of dry

³⁰ 45 FED. REG. 65609, 65615-16 (Oct. 3, 1980).

³¹ See FDA "Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients."

³² 21 U.S.C. § 184.1061.

³³ Marcia Ramos-E-Silva, M.D., Ph.D., et al., *Hydroxy Acids and Retinoids in Cosmetics*, 19 CLINICS IN DERMATOLOGY 460, 460-61 (2001).

skin scales; moisturize and stimulate the growth of new skin; increase dermal perfusion;³⁴ and are effective in treating and preventing the recurrence of xerosis.³⁵ According to one peer-reviewed medical publication, formulations containing up to 12% lactic acid are effective for the treatment of ichthyosis and xerosis.³⁶ This same publication also states that products with higher concentrations of alpha-hydroxy acids are more effective than lower concentrations; that pH is a more important factor than concentration; and that a lower pH causes more action (albeit with a greater potential for skin irritation).³⁷

Furthermore, the FDA has already concluded that one brand of ammonium lactate cream – Lac-Hydrin Cream, 12% – is a safe and effective prescription drug for the treatment of ichthyosis vulgaris and xerosis. In *United States v. Generix Drug Corp.*,³⁸ the Supreme Court suggested that an argument could be made that “two demonstrably bioequivalent products, containing the same active ingredients but different excipients, might under some circumstances be the same ‘drug.’”³⁹ Neither the FDA, nor any court, has made a determination that LACTINOL does not meet the “bioequivalency exception.”

C. Pedinol openly reports its activities with respect to LACTINOL to the FDA, and the FDA has inspected LACTINOL’s manufacturing facilities; but the FDA has not declared that LACTINOL is unlawfully marketed, nor has it demanded that that Pedinol remove LACTINOL from the market.

Long ago, the Supreme Court observed that where “[s]ome manufacturers ... have no NDA's in effect and are not seeking approval of any drugs,” the “FDA may make a declaratory order that a drug is a ‘new drug.’”⁴⁰ Furthermore, the FDA had primary jurisdiction to make that

³⁴ *Id.* at 461.

³⁵ A. V. Rawlings et al., *Effect of lactic acid isomers on keratinocyte ceramide synthesis, stratum corneum lipid levels and stratum corneum barrier function*, 288 ARCH DERMATOL RES 383, 388 (1996).

³⁶ Marcia Ramos-E-Silva, *supra* note 33, at 463.

³⁷ *Id.* at 462.

³⁸ 460 U.S. 453, 460-61 (1983).

³⁹ *Id.*

⁴⁰ *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 627 (1973).

determination.⁴¹

Pedinol admits that it has not sought or obtained the approval of an NDA from the Federal Drug Administration (FDA) to market LACTINOL. But Pedinol openly reports its activities with respect to the LACTINOL to the FDA. Furthermore, the FDA sends Pedinol annual requests to update the FDA records regarding LACTINOL. In 2005, the FDA visited the manufacturing facilities for LACTINOL, and witnessed Corwood's manufacture of LACTINOL. The FDA has never issued a declaratory order that LACTINOL is a new drug, nor has it ever taken action against Pedinol for the marketing of LACTINOL.

If the FDA in its broad discretion decides that LACTINOL is a "new drug," past experience suggests (albeit does not guarantee) that the FDA would likely allow Pedinol sufficient time to prepare, file and process an NDA, and would not require Pedinol to withdraw LACTINOL from the market pending approval of the NDA.

D. Rising has neither standing nor credibility to assail LACTINOL's regulatory status.

In the paragraphs that Rising pontificates about the allegedly unlawful status of LACTINOL, Rising never mentions the status of its own lactic acid products. Rising itself has never submitted an NDA or ANDA, or commissioned scientific studies to establish the safety or efficacy of its own lactic acid products and the FDA has never "approved" Rising's untested lactic acid products.

E. Recently, several courts in drug substitution cases have categorically rejected unlawful use defenses to false advertising claims.

The thrust of Rising's claims is that Pedinol is barred from registering or marketing LACTINOL because it has not obtained an FDA "approved" NDA. Rising's logic leads

⁴¹ *Id.* ("The heart of the new procedures designed by Congress is the grant of primary jurisdiction to FDA, the expert agency it created.").

inescapably to an absurd conclusion – that where a drug maker has for decades sold an “unapproved” prescription drug that the FDA has, in its discretion, allowed to continue marketing, anyone else can come along and, with civil impunity, palm off their own concoction as a “generic” equivalent to the prescribed product and completely appropriate the prescribed product maker’s good will and reputation as their own—Rising would have it that trademark protection cannot even be afforded to the prescribed product’s maker. According to Rising, it is perfectly acceptable for a physician to prescribe LACTINOL brand lotion, and the pharmacy chain to substitute a more profitable, cheap, and untested knock-off while falsely representing the knock-off is phony “generic” or a therapeutic equivalent.

The Supreme Court rejected a similar unlawful-use argument almost a century ago in the trademark infringement *Coca-Cola Co. v. Koke Co.*,⁴² holding that “the defects of a plaintiff do not offer a very broad ground for allowing another to swindle him. The defence [sic] relied on here should be scrutinized with a critical eye. . . .”⁴³ Recently, numerous other courts in “unapproved” drug substitution cases have critically scrutinized, and categorically rejected, Rising’s unclean hands/unlawful use argument.

In *Healthpoint Ltd. v. Stratus Pharms., Inc.*,⁴⁴ and *Healthpoint Ltd. v. Ethex*,⁴⁵ the court recognized that (1) the regulatory status of the drugs is committed to the FDA’s primary jurisdiction and discretion, (2) even if the marketing of such drugs was illegal, it was not, given the FDA’s longstanding enforcement practices, the type of conduct that would equitably bar parties from obtaining relief.⁴⁶

⁴² 254 U.S. 143, 145 (1920).

⁴³ *Id.* at 146.

⁴⁴ 273 F. Supp.2d 769 (W.D. Tex. 2001).

⁴⁵ 273 F. Supp.2d 817 (W.D. Tex. 2001).

⁴⁶ *See infra*, notes 49-Error! Bookmark not defined..

In *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*,⁴⁷ the court likewise rejected Breckenridge's argument that Pediamed should be denied any relief because it marketed Viravan without FDA approval. Citing the *Stratus* case, the court held that Breckenridge's argument was precluded because it "requires direct application of the FDCA, which only the FDA is entitled to enforce."⁴⁸

Here, as in *Stratus*, *Ethex*, and *Pediamed*, "[t]he courts will not apply the doctrine when the defensive allegations are based on claims reserved for resolution by an administrative agency...."⁴⁹ Rising's unlawful use defense – like those of *Stratus*, *Ethex*, and *Breckenridge* – require direct application or interpretation of the FDCA or FDA regulations.⁵⁰ The FDA alone has primary jurisdiction to determine the products' regulatory status and to set forth the conditions of their continued marketing:

It is for the FDA to exercise its discretion to determine whether these four ointments are on the market lawfully, whether it be because they are grandfathered or otherwise qualify for any exception to the FDA pre-clearance process. Resolution of these questions in court would require the "direct interpretation and application of the FDCA . . . [which] . . . are more appropriately addressed by the FDA, especially in light of Congress's intention to repose in that body the task of enforcing the FDCA."⁵¹

The FDA's forbearance of such activity also means that such "illegality" "would not amount to 'unclean hands' to bar either party from obtaining judicial relief."⁵² Like Healthpoint, *Pedinol* openly reports its marketing of its "unapproved" drugs to the FDA, and the FDA had taken no action.⁵³

⁴⁷ 419 F. Supp.2d 715, 726-27 (D. Md. 2006),

⁴⁸ *Id.* at 727.

⁴⁹ *Ethex*, 273 F.Supp.2d at 851.

⁵⁰ *Stratus*, 273 F. Supp.2d at 787-88; *Ethex*, 273 F. Supp.2d at 841-42.

⁵¹ *Stratus*, 273 F. Supp.2d at 799 (quoting *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 U.S. Dist. LEXIS 2372, 1997 WL 94237 at * 6 (D. Kan. Feb. 26, 1997)).

⁵² *Stratus*, 273 F. Supp.2d at 799.

⁵³ *Stratus*, 273 F. Supp.2d at 796; *Ethex*, 273 F. Supp.2d at 852.

In order for Opposer to withstand this motion to dismiss, its pleading need only allege such facts as would, if proved, establish that it is entitled to the relief sought, where a valid ground exists for denying the registration sought, or for canceling the subject registration. In the instant case, Opposer raises only a question that is not within the jurisdiction of the TTAB or a Federal District court, whether the FDA allows the *use* of a mark for one the several thousand prescription drugs that have not yet been the subject of an FDA New Drug Application (“NDA”). As the TTAB, like the courts, is one of limited jurisdiction, it “is not authorized to determine the right to use.”⁵⁴ Accordingly, Opposer has not alleged a valid basis in order to ask this court to deny registration and the opposition should be dismissed.

IV. CONCLUSION

With the exception of paragraph eleven (11) of the complaint, Rising Pharmaceuticals, Inc., has failed to provide any reason for *why* the registration of Applicant’s mark will interfere with its rights or cause it damage and why it has standing to raise this claim. The Opposer has merely stated in its Notice of Opposition that it “believes” that it will be damaged by the registration of Applicant’s mark without giving any basis such as being the owner of a confusingly similar and prior used mark. Furthermore, in paragraphs one (1) through ten (10) Opposer has not shown *facts* which support its allegation that it will be damaged by the registration of applicant’s mark, nor has it alleged any grounds that are within the jurisdiction of this court and would negate the applicant’s right to registration. The TTAB should not deviate from its policy of not considering alleged, unestablished FDA violations in oppositions.

Thus, in light of its Notice to Opposition, the Opposer has failed to establish a claim upon which relief can be granted. For the foregoing reasons, we pray that the Trademark Trial and Appeals Board dismiss the claims based on paragraphs one (1) through ten (10) of this

⁵⁴ TBMP §102.01.

opposition proceeding with prejudice.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been forwarded on September 24, 2007 via first class mail to:

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