

**UNITED STATES PATENT AND TRADEMARK OFFICE
Trademark Trial and Appeal Board
P.O. Box 1451
Alexandria, VA 22313-1451**

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Mailed: August 29, 2008

Opposition No. 91178825

Rising Pharmaceuticals, Inc.

v.

Pedinol Pharmaceutical, Inc.

**Before Walters, Drost, and Taylor,
Administrative Trademark Judges.**

By the Board:

Pedinol Pharmaceutical, Inc. ("applicant") filed an application to register the mark LACTINOL in standard character form for "medicated lotions for use in treatment of dry, scaly, itching skin; pharmaceutical skin lotions" in International Class 5.¹

On August 8, 2007, Rising Pharmaceuticals, Inc. ("opposer") filed a notice of opposition to registration of applicant's LACTINOL mark. As grounds for opposition, opposer alleges that (1) applicant's use of its LACTINOL mark in connection with the goods identified in its application constitutes unlawful use in commerce in

¹Application Serial No. 77060983, filed July 22, 2005, based on an allegation of use in commerce under Trademark Act Section 1(a), 15 U.S.C. Section 1051(a), alleging June 17, 1992 as both the date of first use anywhere and date of first use in commerce.

violation of the United States Food, Drug and Cosmetic Act ("FDA") and the regulations and guidance promulgated thereunder, inasmuch as applicant has failed to seek or obtain the approval of the FDA for use of its goods identified in the application or for the name LACTINOL used in connection therewith and (2) applicant has violated trademark laws by using the ® symbol in connection with the LACTINOL mark when no such registration has been issued by the USPTO or any other authority.

Concurrently with filing its answer, applicant filed a motion to dismiss under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted solely in regard to opposer's alleged claim of unlawful use in commerce. The motion is fully briefed.

As grounds for its motion, applicant asserts that opposer has failed to demonstrate that (1) it will be legally damaged by the registration of applicant's mark, (2) it has standing to raise or enforce the FDA's regulations before the Board, or (3) it has alleged any statutory grounds which would negate the applicant's right to registration of its mark. In further support of its motion, applicant argues the merits of opposer's pleaded claim of unlawful use by arguing that it is in compliance with FDA regulations and/or that it may be exempt from such regulations.

In response, opposer contends that (1) it has sufficiently pleaded its standing to bring this opposition proceeding, (2) unlawful use in commerce cannot give rise to the right of registration and that the Board has jurisdiction to entertain such a claim, and (3) it has sufficiently pleaded a claim of unlawful use in commerce. Moreover, opposer contends that applicant improperly argues the merits of opposer's unlawful use in commerce claim by asking the Board to consider applicant's arguments that it is in compliance with FDA regulations or may be exempt therefrom. Opposer argues that such argument is a substantive legal issue that needs to be addressed during the trial period, not on a motion to dismiss

In order to withstand a motion to dismiss under Rule 12(b)(6), a pleading need only allege such facts as would, if proved, establish that the plaintiff is entitled to the relief sought, that is, that (1) plaintiff has standing to maintain the proceeding, and (2) a valid ground exists for denying the registration sought. The pleading must be examined in its entirety, construing the allegations therein liberally, as required by Fed. R. Civ. P. 8(f), to determine whether it contains any allegations, which, if proved, would entitle plaintiff to the relief sought. *See Lipton Industries, Inc. v. Ralston Purina Co.*, 670 F.2d 1024, 213 USPQ 185 (CCPA 1982); *Kelly Services Inc. v. Greene's Temporaries Inc.*, 25 USPQ2d 1460 (TTAB 1992); and TBMP § 503.02 (2d ed. rev. 2004).

In the case of a notice of opposition, the standing requirement has its basis in Section 13 of the Trademark Act which provides in relevant part that "[a]ny person who believes that he would be damaged by the registration of a mark upon the principal register, ...may, upon payment of the prescribed fee, file an opposition in the Patent and Trademark Office, stating the grounds therefor..." An opposer must also satisfy two judicially-created requirements in order to have standing: the opposer (1) must have a "real interest" in the proceedings, and (2) must have a "reasonable" basis for his belief of damage. See *Ritchie v. Simpson*, 170 F.3d 1092, 50 USPQ2d 1023 (Fed. Cir. 1999).

With respect to its standing, the Board notes that opposer has made the following allegations in its notice of opposition:

Paragraph 1

Opposer is a pharmaceutical company which has been selling prescription lactic acid drug products since 2002. Opposer sells its prescription lactic acid 10% under the descriptive name "Lactic Acid 10%."

Paragraph 2

Applicant is a competing pharmaceutical company which is using the LACTINOL mark in connection with its lactic acid 10% prescription drug.

Paragraph 4

Applicant's use of the LACTINOL mark, alleged to have been since June 17, 1992, has been predicated upon unlawful use in commerce in violation of the United States Food and Drug and Cosmetic Act, 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.

Paragraph 5

Applicant has not sought or obtained approval for its Lactic Acid 10% product and its use of the LACTINOL name in connection therewith [and] is therefore predicated on unlawful commerce.

Paragraph 7

Opposer would be injured by the granting to Applicant of a Certificate of Registration for the mark LACTINOL because Applicant would thereby be granted exclusive rights in such mark based upon lawful use, in violation of the Trademark Act, Title 15 U.S.C., and the grant of such registration would provide Applicant with the unfair benefits of the imprimatur of approval of a "brand name" in order to represent and imply, and thereby confuse Opposer's customers, potential customers and the market in general, into mistakenly believing that Applicant's prescription lactic acid 10% drug products are FDA-approved.

Paragraph 8

Applicant's use is further predicated on unlawful commerce in violation of 21 C.F.R. § 201.10(g)(1) because Applicant has used the mark as a proprietary name for a prescription drug without providing the established name corresponding to such proprietary name each time it is featured on the label or in the labeling for the drug product.

Paragraph 9

Registration of the mark LACTINOL by Applicant will likely harm Opposer because Applicant's unlawful use of a proprietary name without providing the established name for prescription drug is likely to confuse Opposer's customers and the marketplace into believing that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug is a common substance, sold by Opposer and others under the established name, the limitations of which would be readily recognized if

Applicant properly disclosed the established drug or ingredient name.

Applying the principles established in *Ritchie, supra*, to this case, the Board finds that opposer has sufficiently pleaded a "real interest" in the proceedings inasmuch as opposer has alleged it is a direct competitor of applicant and has alleged facts which, if proven, would show opposer has a "reasonable" basis for its belief of damage.

We now turn to the issue of whether a valid ground exists for denying the registration sought. As noted, above, the grounds for opposition include allegations that applicant's use of its LACTINOL mark in connection with the goods identified in its application constitutes unlawful use in commerce in violation of FDA regulations.

The "lawful use" in commerce doctrine is based solely upon the U.S. Patent and Trademark Office's interpretation of the use in commerce requirement of the Act, as necessitating use in compliance with the other Acts of Congress. See e.g., *Santinine Societa v. P.A.B. Produits*, 209 USPQ 958 (TTAB 1981). This interpretation has been codified in Trademark Rule 2.69, which states that "[w]hen the sale or transportation of any product for which registration of a trademark is sought is regulated under an Act of Congress, the Patent and Trademark Office may make appropriate inquiry as to compliance with such Act for the

sole purpose of determining the lawfulness of the commerce recited in the application." While inquiries during *ex parte* examination are no longer made, this provision lends support to the interpretation that "unlawful use" implies only such commerce as is unlawful under the Acts of Congress. Whether use of a mark is lawful is an issue only when the question of compliance has previously been determined (with a finding of non-compliance) by a court or government agency having competent jurisdiction under the statute involved, or where there has been a *per se* violation of a statute regulating the sale of a party's goods. See *e.g.*, *General Mills Inc. v. Health Valley Foods*, 24 USPQ2d 1270 (TTAB 1992); *Kellogg Co. v. New Generation Foods, Inc.*, 6 USPQ2d 2045 (TTAB 1988).

Therefore, in view of the foregoing, the Board notes that a claim for unlawful use in commerce for violation of a federal agency regulation or statute is a valid ground for denying a registration being sought as long as a plaintiff pleads (and later proves) that (1) a court or the responsible federal agency has issued a finding of noncompliance under the relevant statute; or (2) there has been a clear *per se* violation of the relevant statute. See *General Mills, supra*; *Kellogg Co., supra*.

After a careful review of opposer's notice of opposition, the Board finds that opposer has sufficiently

pleaded, for notice pleading purposes, that applicant's use of its mark in commerce is a *per se* violation of the relevant FDA statute and/or regulation and, therefore, has sufficiently stated a claim of unlawful use in commerce. Further, the Board agrees with opposer that applicant's arguments as to whether it is in compliance with FDA regulations or whether it may be exempt therefrom goes to the merits of opposer's unlawful use in commerce claim, and not to the pleading requirements for such a claim

In view of the foregoing, applicant's motion to dismiss is **denied**.

Proceedings herein are resumed. Applicant's answer filed on September 24, 2007 is noted and accepted.

Discovery and trial dates are reset as follows:

DISCOVERY PERIOD TO CLOSE:	1/31/2009
Testimony period for party in position of plaintiff to close: (opening thirty days prior thereto)	5/1/2009
Testimony period for party in position of defendant to close:(opening thirty days prior thereto)	6/30/2009
Rebuttal testimony period to close: (opening fifteen days prior thereto)	8/14/2009

NEWS FROM THE TTAB:

The USPTO published a notice of final rulemaking in the Federal Register on August 1, 2007, at 72 F.R. 42242. By this notice, various rules governing Trademark Trial and

Appeal Board inter partes proceedings are amended. Certain amendments have an effective date of August 31, 2007, while most have an effective date of November 1, 2007. For further information, the parties are referred to a reprint of the final rule and a chart summarizing the affected rules, their changes, and effective dates, both viewable on the USPTO website via these web addresses:

<http://www.uspto.gov/web/offices/com/sol/notices/72fr42242.pdf>
http://www.uspto.gov/web/offices/com/sol/notices/72fr42242_FinalRuleChart.pdf

By one rule change effective August 31, 2007, the Board's standard protective order is made applicable to all TTAB inter partes cases, whether already pending or commenced on or after that date. However, as explained in the final rule and chart, this change will not affect any case in which any protective order has already been approved or imposed by the Board. Further, as explained in the final rule, parties are free to agree to a substitute protective order or to supplement or amend the standard order even after August 31, 2007, subject to Board approval. The standard protective order can be viewed using the following web address:

<http://www.uspto.gov/web/offices/dcom/ttab/tbmp/stndagmnt.htm>