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

Pursuant to 37 C.F.R. § 2.127(a), applicant Pedinol Pharmaceutical, Inc. (“Pedinol”) files this, *Applicant’s Reply to Opposer’s Response to Applicant’s Partial Motion to Dismiss for Failure to State a Claim Upon Which Relief Can Be Granted* and in support thereof would show unto the court as follows:

I. SUMMARY

Opposer, Rising Pharmaceuticals, Inc., (“Rising”) has not alleged any valid statutory grounds which would negate the applicant’s right to registration LACTINOL, 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. As asserted in Pedinol’s original motion to dismiss, all grounds alleged by Rising are outside the jurisdiction of the TTAB.

In response to Pedinol’s motion to dismiss, Rising 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.* However, Rising does not identify any *per se* violation of law nor does it allege any agency determination that Pedinol is violating any law. Pedinol denies any allegation that it has failed to comply with any FDA laws or regulations. Further, if Rising truly believes that Pedinol is violating FDA laws or regulations it should file a complaint with the FDA instead of taking the round-about route of opposing registration of the LACTINOL mark.

II. ARGUMENT

A. The Trademark Trial and Appeal Board (TTAB) Does Not Have Jurisdiction to Determine Compliance or Lack of Compliance with FDA Rules and Regulations

As explained in Pedinol’s original Motion to Dismiss, the TTAB simply does not have jurisdiction to determine whether there is a violation of FDA laws or regulations. In responding to Pedinol’s motion to dismiss, Rising essentially argues that the TTAB should find a violation of the FDA and deny Pedinol’s trademark registration accordingly. While as explained below, Pedinol specifically denies Rising’s allegations of non-compliance with FDA rules and regulations, this is not a matter that should be decided before the TTAB.

Rising asserts that Pedinol’s alleged violations of FDA rules and regulations constitute “unlawful use.” However, it is undisputable that unlawful use can only be shown in the very limited circumstance where the person asserting the unlawful use claim proves by *clear and convincing* evidence that “the issue 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 is a *per se* violation of a statute regulating the sale of a party's goods."¹ As there is no FDA finding of non-compliance, Rising attempts solely to demonstrate a "*per se* violation" of FDA rules and regulations. This it fails to do.

In order to show a *per se* violation, it would be necessary for Rising to show that Pedinol, without a doubt, is in violation of FDA rules and regulations. To do this, Rising must show noncompliance in such a way that there is "no room for doubt, speculation, surmise, or interpretation."² Often this burden is met by an admission that there is an unlawful use.³ However, Pedinol believes that it is in compliance with FDA rules and regulations. Further, the FDA is aware that Pedinol is marketing the LACTINOL product and has not taken any action. As demonstrated in the sections below, Rising does not and cannot show by clear and convincing evidence that there is any unlawful use in commerce of the LACTINOL mark.

B. Pedinol is in Compliance with all FDA Labeling Laws

Rising alleges that Pedinol is in violation of FDA labeling laws because Pedinol "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 feature [sic] on the label or in the labeling for the drug product."⁴ In support of this contention Rising apparently relies on 21 C.F.R. §201.10(g)(1) and a partial label for a LACTINOL product. This reliance is misguided.

21 C.F.R. §201.10(g)(1) provides that "[i]f the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name if

¹ *Lane Capital Mgmt., Inc. v. Lane Capital Mgmt., Inc.*, 15 F. Supp. 2d 389, 397 (S.D.N.Y. 1998) (quoting *Erva Pharm., Inc. v. Am. Cyanamid Co.*, 755 F. Supp. 36, 40 (D.P.R. 1991).

² *Satinine Societa in Nome Collettivo di S.A. e M. Usellini v. P.A.B. Produits et Appareils de Beaute*, 209 U.S.P.Q. (BNA) 958, 965 (TTAB 1981) (stating that "nowhere is this more true than in a case where a plaintiff urges us to cancel, or to refuse to issue, a registration based upon the defendant's alleged failure to comply with the requirements of a statute which is outside of [the TTAB's] area of expertise").

³ *See, e.g. CreAgri v. USANA Health Sciences, Inc.*, 474 F.3d 626, 630 (9th Cir. 2007) ("it is undisputed that . . . Olivenol's labels were not in compliance with the labeling requirements") (emphasis added).

⁴ Rising Resp. to Pedinol's Mot. to Dismiss p. 3.

such there be, corresponding to such proprietary name or designation shall *accompany* such proprietary name or designation each time it is featured on the label or labeling for the drug.”⁵ Pedinol is clearly in compliance with this requirement—each and every LACTINOL product contains a “Drug Facts” section prominently listing the active ingredient as “Lactic Acid 10%.”⁶ In light of this clear compliance, Rising cannot show without room for doubt, speculation, surmise, or interpretation that Pedinol is in violation of any labeling law.

Further, even if Pedinol were in violation of some technical labeling requirement, this would not be enough to show unlawful use. In support of its labeling argument, Rising relies heavily on *CreAgri*.⁷ This case is easily distinguishable from this instant case for two primary reasons. First, the labeling violation in *CreAgri* involved mislabeling the quantity of an active ingredient of the product in such a way that the label misstated the quantity by up to 500%⁸. Secondly and more importantly, *CreAgri* *admitted* this violation thus removing the necessity of interpreting the law in question and establishing an *undisputed per se* violation.⁹ This case is clearly inapplicable.

Further, Rising fails to cite several trademark cases where minor labeling violations were found to not constitute unlawful use because the violation was “purely technical in nature.”¹⁰ For example, in *General Mills*, the court considered a situation where labeling requirements were

⁵ 21 C.F.R. §201.10(g)(1) (emphasis added).

⁶ Attached hereto as exhibit A is a LACTINOL label that was submitted with Pedinol’s initial trademark registration.

⁷ *CreAgri*, 474 F.3d 626 (9th Cir. 2007).

⁸ *See id.* at 628.

⁹ *Id.* at 630.

¹⁰ *Dessert Beauty, Inc. v. Fox*, No. 05-Civ.-3872(DC), 2007 U.S. Dist. LEXIS 58341 at *19 (S.D.N.Y. Aug. 7, 2007)(interestingly, this case happens to cite and distinguish the *CreAgri* case so heavily relied on by Rising); *General Mills, Inc. v. Health Valley Foods*, 1992 TTAB LEXIS 37 at *8-14 U.S.P.Q.2d (BNA) 1270 (Aug. 24, 1992) (determining that mere technical violations are not enough to show a *per se* violation of the labeling requirements were some boxes of cereal were sent without nutrition information); *Kellogg Co. v. New Generation Foods, Inc.*, Opp. No. 72,638, 1988 TTAB LEXIS 12, at *8-14, 6 U.S.P.Q.2d (BNA) 2045 (TTAB Mar. 3, 1988) (holding alleged labeling discrepancy not a *per se* violation); *Satinine*, 209 U.S.P.Q. at 964-965.

not met.¹¹ Determining that this was not an unlawful use, the court stated that the charging party had not met their burden of proof because the

only evidence [cited] in support of its claim consists of copies of the relevant portions of the statute and regulations. Where, as here, a party seeks to show that the use by the adverse party was unlawful by virtue of noncompliance with a labeling statutory provision, it is incumbent upon the party charging that the use was unlawful to demonstrate by clear and convincing evidence more than that the use in question was not in compliance with applicable law. Such party must prove also that the noncompliance was material, that is, was of such gravity and significance that the usage must be considered unlawful – so tainted that, as a matter of law, it could create no trademark rights – warranting cancellation of the registration of the mark.¹²

Clearly this is a hefty burden that cannot be met where, as in the instant case, the Opposer merely cites the statute without a showing of anything more than what they allege to be mere technical violations. Accordingly, even if Pedinol were in violation of labeling laws—which it is not—such violations are purely technical in nature and thus not a valid basis for an unlawful use claim.

C. Rising Cannot, With No Room for Doubt, Speculation, Surmise, or Interpretation, Establish That Pedinol's LACTINOL Product is Unlawfully Marketed

As discussed both above and in the original Motion to Dismiss, Pedinol does not believe itself to be in violation of any FDA laws or regulations. The LACTINOL product has been established since 1992 and the FDA is on notice that the product is marketed. Pedinol submits annual updates to the FDA with regard to the LACTINOL product and FDA inspectors visited LACTINOL manufacturing facilities in 2005. While Pedinol has not filed a New Drug Application for LACTINOL, there are several exceptions (i.e. GRAS/E and DESI) that may encompass the LACTINOL product. Whether LACTINOL fits into one of these exceptions is a matter to be determined by the FDA if and when they publish a Notice of Opportunity for a Hearing (“NOOH”).

¹¹ *General Mills, Inc.*, 1992 TTAB LEXIS 37 at *8-9; 24 U.S.P.Q.2d (BNA) 1270.

¹² *Id.* at *10-11.

The case at bar is similar to *Lane Capital Mgmt. Inc.* where unlawful use was not shown when the company had not registered with the Securities and Exchange Commission but there was an exception that might apply.¹³ It was determined that there was no fact issue and there could be no *per se* violation in the situation because the exception might apply.¹⁴ This is clearly at odds with the *CreAgri* case cited by Rising.

The primary difference between *Lane Capital Mgmt. Inc.* and *CreAgri* is that in the *CreAgri* case the exception itself made clear that an application must be made before it is applicable.¹⁵ Despite Rising's attempts to show otherwise, such is simply not the case with exceptions to the FDA's NDA requirement. 21 C.F.R. §314.200(e), cited by Rising for their contention that Pedinol must make application and obtain a ruling in order to be exempt from the NDA requirement, is clearly misconstrued. Contrary to Rising's argument, 21 C.F.R. §314.200(e) merely provides that a "[c]ontention[] that a drug product is not subject to the new drug requirements" must be made at the time the FDA publishes a NOOH. It provides no means for raising an exemption sooner.¹⁶

Finally, Pedinol would like to clarify regarding the allegation raised by Rising in its brief that Pedinol has "rushed to exploit" the "backlog in removal of unapproved products from the marketplace."¹⁷ This accusation is petty and ridiculous for a myriad of reasons. Namely, LACTINOL has been on the market for over 15 years. How Rising could allege that 15 years of regular marketing coupled with consistent communication with and inspection by the FDA could possibly constitute "rush[ing] to the market before the government can take adequate action on

¹³ *Lane Capital Mgmt., Inc.*, 15 F. Supp. 2d at 397.

¹⁴ *Id.*

¹⁵ See *CreAgri*, 474 F.3d at 628 and 628 n.2.

¹⁶ 21 C.F.R. §314.200(e).

¹⁷ Rising Resp. to Pedinol's Mot. to Dismiss p. 9.

the merits of its product”¹⁸ is unfathomable. If anything, Rising itself is guilty of rushing to exploit the backlog as Rising itself sells an unapproved 10% Lactic Acid product.

D. Rising’s Claims Regarding Pedinol’s Use of the ® Symbol are Irrelevant to the Instant Motion to Dismiss

Rising appears to address paragraphs ten (10) and eleven (11) of their opposition in the instant motion. While Pedinol does not concede or admit anything regarding these paragraphs, they were not addressed in the instant motion to dismiss. Furthermore, Pedinol was not misusing an ® when it filed its application for registration of LACTINOL. Additionally, Pedinol is the owner of incontestable US trademark registration number 1,688,680 for LACTINOL-E which was registered May 26, 1992 with an alleged date of first use of January 20, 1991 which is well before the date of first use of the instant application for registration of LACTINOL alone for the very same class of goods. The two marks are virtually the same since the addition of vitamin E is not a distinguishing trademark feature. While Rising’s claim regarding Pedinol’s use of the ® symbol is frivolous, the naked, albeit meritless, allegation of discontinued misuse is sufficient to avoid a Rule 12(b)(6) motion.

III. Conclusion

With the exception of paragraphs ten (10) and 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. Rising’s allegations of unlawful use are without merit. Rising has not and cannot prove beyond doubt, speculation, surmise, or interpretation that Pedinol’s use of the LACTINOL mark is unlawful.

Thus, in light of its Notice to Opposition, the Opposer has failed to establish a claim upon

¹⁸ *Id.*

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 nine (9) of this opposition proceeding with prejudice.

Dated November 13, 2007.

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 November 13, 2007 via the TTAB electronic filing system which will send notice to the following:

Michael F. Sarney
KATTEN MUCHIN ROSENMAN LLP
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New York, NY 10022



Charles W. Hanor

EXHIBIT A

NDC 0884-5292-12



LACTINOLTM LOTION

RELIEF OF DRY, SCALY,
ITCHING SKIN

Rx Only



NET WT. 12 OZ. (354.84mL)

DRUG FACTS

ACTIVE INGREDIENT	Purpose
Lactic Acid 10%	Moisturizer for dry skin (xerosis)

- USES**
- treats dry, scaly skin (xerosis)
 - moisturizes and softens dry, scaly skin
 - temporary relief of itching associated with these conditions

- WARNINGS**
- for external use only
 - avoid sun exposure to area treated

- PRECAUTIONS**
- do not use in or near eyes, lips and mucous membranes
 - stop use and ask PODIATRIST, DERMATOLOGIST or PHYSICIAN if irritation or sensitivity occurs
 - do not use on face due to potential irritation

Keep out of reach of children

- DIRECTIONS**
- apply thoroughly twice a day over affected areas

- OTHER INFORMATION**
- store at controlled room temperature 15°-30°C (59°-86°F)
 - see package insert for additional information

INACTIVE INGREDIENTS
 Water, Isopropyl Palmitate, Cetyl Alcohol, Glyceryl Stearate (and) PEG-100 Stearate, Glycerine, PEG-40 Stearate, Caprylic/Capric Triglyceride, Lecithin, Dimethicone, EDTA, Methyl Paraben, Propyl Paraben, Diazolidinyl Urea, Sodium Benzoate

Manufactured For: Pedinot Pharmaceutical Inc., Farmingdale, NY 11735



REV 9/98