

FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CREAGRI, INC., a California
corporation,

Plaintiff-counter-claim-defendant-
Appellant,

v.

USANA HEALTH SCIENCES, INC., a
Utah corporation,

Defendant-counter-claimant-
Appellee.

No. 05-15305
D.C. No.
CV-03-3216-MMC
OPINION

Appeal from the United States District Court
for the Northern District of California
Maxine M. Chesney, District Judge, Presiding

Argued and Submitted
December 6, 2006—San Francisco, California

Filed January 16, 2007

Before: John T. Noonan, Michael Daly Hawkins, and
Sidney R. Thomas, Circuit Judges.

Opinion by Judge Hawkins

COUNSEL

Robin M. Pearson (argued) and Antonio Valla, Gilliss, Valla & Dalsin, Lafayette, California, together with Katheryn C. Ashton, Hancock, Rothert & Bunshoft, San Francisco, California, for the plaintiff-counter-claim-defendant-appellant.

James W. Kinnear (argued), Holme, Roberts & Owen, San Francisco, California, for the defendant-counter-claimant-appellee.

OPINION

HAWKINS, Circuit Judge:

In a contest involving competing products claiming trademark priority, the district court determined, in order to acquire priority, a “use in commerce” means a lawful use—here, a use compliant with federal labeling requirements. We agree.

BACKGROUND

In the spring of 2001, Appellant CreAgri, Inc. (“CreAgri”) began selling Olivenol, a dietary supplement containing an apparently beneficial antioxidant found in olives called hydroxytyrosol. At the time, Olivenol’s label indicated that each tablet contained 25mg of hydroxytyrosol, the product’s primary active ingredient.¹ Although the scientist who devel-

¹Olivenol is now sold not only in tablet form, but also in capsule and liquid forms. As there is no relevant difference between the three dosage methods for purposes of this appeal, we will use “tablet” to refer to all three forms.

oped Olivenol claimed no standardized method to accurately measure a substance's hydroxytyrosol content was yet available, neither he nor CreAgri applied for an exemption from the Food, Drug, and Cosmetic Act's ("FDCA") labeling requirements due to this technological limitation,² apparently content with the results of CreAgri's own testing and the testing done by two outside companies selected and paid for by CreAgri.

One year later, however, Olivenol's label had changed. It had been brought to CreAgri's attention that its 25mg hydroxytyrosol measurement might be in error; thus, CreAgri ordered further testing, which suggested that each Olivenol tablet contained only 5mg of hydroxytyrosol. CreAgri changed the Olivenol label accordingly but—despite its contention that a standardized measurement method was *still* unavailable—again failed to apply for an exemption from the FDCA's labeling requirements and, in fact, claimed on Olivenol's label that the 5mg measurement was "HPLC Certified."³

CreAgri now admits that each tablet contains at most 3mg of hydroxytyrosol and that Olivenol was, therefore, inaccurately labeled in both instances. Indeed, as a result of this lawsuit—which prompted CreAgri to test Olivenol again, using what Olivenol's developer admits to be a more accurate testing method than the methods previously used—Olivenol's label was again changed in February 2004 to accurately reflect the product's contents.⁴ By this time, CreAgri's appli-

²Dietary supplements like Olivenol are required to be sold in compliance with the labeling regulations detailed in 21 C.F.R. §§ 101.9 and 101.36; however, one may apply for an exemption from these regulations—which the Food and Drug Administration ("FDA"), in its discretion, may grant or deny—when it believes compliance would be impracticable under the circumstances. 21 C.F.R. § 101.36(f)(2).

³HPLC or High Performance Liquid Chromatography is a standard method of testing the characteristics of food supplements and additives.

⁴This new label makes no claim about the product's hydroxytyrosol content, but instead claims that each Olivenol tablet contains 5mg of polyphenols, of which hydroxytyrosol is just one variety. USANA does not dispute the accuracy of this label.

cation to register “Olivenol” on the principal register had been denied,⁵ but—upon CreAgri’s October 9, 2002 amended application—“Olivenol” had been listed on the supplemental register.⁶

On June 18, 2002—more than a year after CreAgri began selling Olivenol—Appellee USANA Health Sciences, Inc. (“USANA”) filed an intent to use application with the Patent and Trademark Office (“PTO”) asserting that it intended to begin selling a series of vitamins, minerals, and nutritional supplements containing an ingredient called Olivol, which—like Olivenol—is an olive extract containing apparently beneficial polyphenols. USANA began selling these products in August 2002, the PTO granted USANA’s application, and “Olivol” is now listed on the principal register with a priority date of June 18, 2002.⁷ The present suit arises because,

⁵The principal register is the primary register of trademarks in the United States. Marks on the principal register receive a variety of evidentiary benefits, including presumptions of validity and ownership, as well as a presumption that the registrant has the “exclusive right to use the registered mark in commerce.” 15 U.S.C. § 1057(b). CreAgri’s principal register application was denied based on its representation to the Patent and Trademark Office that the word “Olivenol” translated to the German for “olive oil,” making Olivenol—which contained no olive oil—deceptively misdescriptive. *See id.* § 1052(e) (prohibiting registration of deceptively misdescriptive marks). Although CreAgri now rescinds its prior representation, the fact remains that Olivenol does not appear on the principal register and is therefore ineligible for its evidentiary benefits. *Id.* § 1057(b).

⁶“All marks capable of distinguishing applicant’s goods or services and not registrable on the principal register” can be registered on the supplemental register. 15 U.S.C. § 1091(a). However, “registrations on the supplemental register shall not . . . receive [some of] the advantages” extended to marks registered on the principal register. *Id.* § 1094. In particular, unlike principal registration, supplemental registration is not “prima facie evidence of the validity of the registered mark . . . , of the registrant’s ownership of the mark, [or] of the registrant’s exclusive right to use the registered mark in commerce.” *Id.* § 1057(b).

⁷Under 15 U.S.C. §§ 1051(b), 1051(d), and 1057(c), as long as an applicant’s mark is eventually granted registration on the principal register, and as long as the applicant does, in fact, use the mark in commerce within a set period of time thereafter, the filing of an intent to use application constitutes “constructive use of the mark, conferring a right of priority, nationwide in effect.”

according to CreAgri, the name of USANA's Olivol ingredient is confusingly similar to the name of its own Olivenol product and, therefore—despite the June 18, 2002 priority date attached to Olivol's principal registration—USANA is infringing upon the trademark rights CreAgri acquired when it began selling Olivenol more than a year earlier.

PROCEDURAL HISTORY

Shortly after USANA began distribution of its product, CreAgri brought an action for trademark infringement, unfair competition, unjust enrichment, and a number of related claims. USANA counterclaimed requesting declaratory relief as to all of CreAgri's claims, as well as cancellation of the Olivenol mark from the supplemental register.

Following briefing, the district court granted USANA's motion for summary judgment. The court concluded that, even viewing the evidence in the light most favorable to CreAgri, the Olivenol mark had not been lawfully used in commerce prior to USANA's priority date—a prerequisite to all of CreAgri's claims against USANA. Accordingly, the district court dismissed CreAgri's claims, entered declaratory judgment in favor of USANA on its counterclaims, and ordered "Olivenol" cancelled from the supplemental register. CreAgri appeals this final judgment.

DISCUSSION

"We review the district court's grant of summary judgment de novo." *Klamath Siskiyou Wildlands Ctr. v. Boody*, 468 F.3d 549, 554 (9th Cir. 2006). For CreAgri to ultimately prevail on its trademark infringement claims, it must have acquired trademark rights to "Olivenol" before USANA had acquired trademark rights to "Olivol." See *Sengoku Works Ltd. v. RMC Int'l, Ltd.*, 96 F.3d 1217, 1219 (9th Cir. 1996) ("It is axiomatic in trademark law that the standard test of

ownership is priority of use.”).⁸ Because “Olivol” was registered on the principal register with a priority date of June 18, 2002—and CreAgri does not challenge the lawfulness of that registration—the question becomes whether CreAgri had acquired trademark rights to “Olivenol” prior to that date. *See* 15 U.S.C. § 1057(b) (“[R]egistration of a mark upon the principal register . . . shall be prima facie evidence of . . . the registrant’s ownership of the mark, and of the registrant’s exclusive right to use the registered mark in commerce.”).

If “use in commerce” were the only requirement for acquiring trademark rights,⁹ then CreAgri would have an easier path to establishing priority of its mark because it began selling Olivenol more than one year before USANA’s intent to use application was filed. *See* 15 U.S.C. §§ 1051(a)(1), 1127 (requiring “use in commerce” to establish trademark rights); Cal. Bus. & Prof. Code §§ 14207, 14209 (mirroring federal law).

[1] But the inquiry does not stop with use in commerce. It has long been the policy of the PTO’s Trademark Trial and Appeal Board that use in commerce only creates trademark rights when the use is *lawful*. *See, e.g., In re Midwest Tennis & Track Co.*, 29 U.S.P.Q.2d 1386, 1386 n.2 (T.T.A.B. 1993); *Clorox Co. v. Armour-Dial, Inc.*, 214 U.S.P.Q. 850, 851 (T.T.A.B. 1982); *In re Pepcom Indus., Inc.*, 192 U.S.P.Q. 400, 401 (T.T.A.B. 1976); *In re Stellar Int’l, Inc.*, 159 U.S.P.Q. 48, 51 (T.T.A.B. 1968). At least one circuit has adopted and applied this rule. *See United Phosphorus, Ltd. v. Midland Fumigant, Inc.*, 205 F.3d 1219, 1225 (10th Cir. 2000). A question of first impression in this circuit, we also agree with

⁸As the district court correctly noted, the success of CreAgri’s other claims rises or falls with its success on its trademark infringement claims.

⁹We assume, for discussion purposes, that CreAgri’s mark is eligible for trademark protection—i.e., that it is inherently distinctive or has acquired distinctiveness through secondary meaning. *See KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 408 F.3d 596, 602 (9th Cir. 2005).

the PTO's policy and hold that only *lawful* use in commerce can give rise to trademark priority.

[2] The rationale for this rule is twofold. First, as a logical matter, to hold otherwise would be to put the government in the "anomalous position" of extending the benefits of trademark protection to a seller based upon actions the seller took in violation of that government's own laws. *See In re Stellar*, 159 U.S.P.Q. at 51. It is doubtful that the trademark statute—passed pursuant to Congress's power under the Commerce Clause—"was . . . intended to recognize . . . shipments in commerce in contravention of other regulatory acts promulgated [by Congress] under [that same constitutional provision]." *Id.* Second, as a policy matter, to give trademark priority to a seller who rushes to market without taking care to carefully comply with the relevant regulations would be to reward the hasty at the expense of the diligent.

[3] Here, it is undisputed that, at all times prior to USANA's priority date, Olivenol's labels were not in compliance with the labeling requirements of 21 C.F.R. § 101.9(g)(4)(i) and, thus, Olivenol was being sold in violation of 21 U.S.C. §§ 331(a), 343(a) (prohibiting sale of misbranded food as determined by reference to the relevant regulations). By CreAgri's own admission, each tablet sold under the Olivenol name before June 18, 2002 contained, at most, 3mg of hydroxytyrosol, while Olivenol's label claimed that each tablet contained either 25mg or 5mg of this nutrient. 21 C.F.R. § 101.9(g)(4)(i), however, requires that the actual amount of a nutrient added to a product be "at least equal to the value for that nutrient declared on the label."¹⁰ Because

¹⁰This is the standard for a Class I vitamin, which we agree with the district court is the correct categorization for hydroxytyrosol. Although hydroxytyrosol may naturally be found in *olives*, it is not naturally found in *Olivenol*, but rather is added to Olivenol, which is manufactured pursuant to a patented method. Compare 21 C.F.R. § 101.9(g)(3)(i) (Class I vitamins are "[a]dded nutrients in fortified or fabricated foods"), with *id.* § 101.9(g)(3)(ii) (Class II vitamins are "[n]aturally occurring (indigenous) nutrients").

the actual amount of hydroxytyrosol (at most 3mg) was less than the values for hydroxytyrosol declared on Olivenol's labels (25mg and 5mg), CreAgri's product was, at all relevant times, in violation of 21 C.F.R. § 101.9(g)(4)(i).¹¹

CreAgri seeks to avoid the consequences of its non-compliance in three ways: first, by arguing that the nexus between its labeling violation and its use of the Olivenol mark is too attenuated to justify depriving "Olivenol" of trademark protection; second, by contending that it was technologically infeasible to accurately measure the content of hydroxytyrosol when Olivenol was mislabeled and that, because the regulations provide for an exemption in such circumstances, sale of Olivenol was not actually unlawful; and third, by asserting that its violation was not material, citing *General Mills, Inc. v. Health Valley Foods*, 24 U.S.P.Q.2d 1270, 1274 (T.T.A.B. 1992). We are not persuaded by these arguments.

Nexus

The nexus requirement springs from decisions of the Trademark Trial and Appeal Board: "There must be some nexus between . . . use of [a] mark and [an] alleged violation before it can be said that the unlawfulness of [a] sale or shipment has resulted in [a trademark's] invalidity" *Satinine Societa in Nome Collettivo v. P.A.B. Produits*, 209 U.S.P.Q. 958, 967 (T.T.A.B. 1981) (Kera, concurring); *General Mills*, 24 U.S.P.Q.2d at 1274 (adopting this rule). CreAgri argues that its labeling violation was collateral to its use of the Olivenol

¹¹Even if Olivenol were more leniently categorized as a Class II vitamin, "the [hydroxytyrosol] content of [Olivenol] would have to be] at least equal to 80 percent of the value for [hydroxytyrosol] declared on the label" to comply with the FDCA regulations. See 21 C.F.R. § 101.9(g)(4)(ii). Olivenol's actual hydroxytyrosol content (at most 3mg) is only 60 percent of the hydroxytyrosol content (5mg) declared on Olivenol's more recent label. Thus, at all relevant times, Olivenol's labels would have been in violation of section 101.9(g)(4)(ii), as well.

mark and, thus—under the *Satinine* rule—the former should not render the latter “unlawful.”

[4] We neither adopt nor reject the *Satinine* rule because, even if the rule were adopted, CreAgri could not benefit from it. While it may be possible to conceive of a situation in which violation of a law in connection with a trademarked product would have no effect on the rights inuring in that trademark, the nexus between a misbranded product and that product’s name, particularly one designed for human consumption, is sufficiently close to justify withholding trademark protection for that name until and unless the misbranding is cured.

Indeed, the concurrence in *Satinine* cuts against CreAgri’s position:

[W]e should not refuse registration or order the cancellation of a registration because of some purely collateral defect such as the use of a container which did not comply with an ICC regulation or the failure of a party to pay an excise tax. . . . [But, as] a general proposition, subject to qualification as the facts of particular cases require, I may venture to say that a registration *should* be refused or cancelled when it is unlawful to ship the goods in commerce (either because any shipment is forbidden or because required prior approval was not obtained) *or when the contents of the labelling [sic], of which the mark is a part, are unlawful.*”

209 U.S.P.Q. at 967 (Kera, concurring) (emphasis added).

[5] Without expressing an opinion as to whether the examples given in *Satinine* establish the appropriate dividing line between collateral and non-collateral defects, the labeling defect in this case was sufficiently related to the Olivenol mark so as to satisfy the nexus requirement. Cf. *Clorox*, 214

U.S.P.Q. at 851 (finding unlawful use in commerce when product label did not comply with the FDCA); *In re Pepcom*, 192 U.S.P.Q. at 401 (same); *In re Stellar*, 159 U.S.P.Q. at 51 (same).

Potential Exemption

We also reject CreAgri's argument that, because there was no accepted method for determining the hydroxytyrosol content of a given substance at the time Olivenol's labels were in error, Olivenol was exempt from the FDCA's labeling requirements. *See* 21 U.S.C. §§ 331(a), 343(a) (requiring that dietary supplements be sold in accordance with the FDCA's labeling regulations, including 21 C.F.R. §§ 101.9 and 101.36); 21 C.F.R. § 101.36(f)(2) (allowing a seller to apply for an exemption from these regulations if it is technologically infeasible or otherwise impracticable to comply with them).

[6] While it is unclear, as a factual matter, whether appropriate testing was technologically feasible at the time, section 101.36(f)(2) does not provide for an *automatic* exemption but, rather, expressly requires sellers to *apply for and receive* an exemption from the FDA. CreAgri did neither. Cf. *Lane Capital Mgmt., Inc. v. Lane Capital Mgmt., Inc.*, 15 F. Supp. 2d 389, 397 (S.D.N.Y. 1998) (noting that “[a]n investment adviser is exempt from registering with the SEC” under 15 U.S.C. § 80b-3(b)(3) if the adviser has certain characteristics; the adviser need not apply in order to qualify). As per the clear language of 21 C.F.R. § 101.36(f)(2) (emphasis added):

When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA *may* permit alternative means of compliance or additional exemptions to deal with the situation in accordance with § 101.9(g)(9). Firms in need of such special allowances *shall* make their request in writ-

ing to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[7] Thus, *if* CreAgri had applied for, and *if* the FDA had exercised its discretion by granting, an exemption on the basis of technological infeasibility, *then* CreAgri's violation of section 101.9(g)(4) would be properly excused. CreAgri, however, offered no evidence to show that it so much as applied to the Office of Nutritional Products for an exemption pursuant to the procedures set forth in 21 C.F.R. § 101.36(f)(2), much less that the FDA granted CreAgri "special allowances" from the FDCA's labeling requirements. As such, sale of Olivenol until at least June 18, 2002 was unlawful and was not excused by CreAgri's hypothetical eligibility for an "upon-application-only" exemption for which CreAgri never applied. Cf. 21 C.F.R. § 101.36(h) (providing automatic exemptions from § 101.9's labeling requirements in other circumstances); *Lane*, 15 F. Supp. 2d at 397.

Materiality

CreAgri's final argument with respect to the apparent unlawfulness of its use of "Olivenol" in commerce prior to USANA's priority date is that the labeling defect was so harmless or de minimis that it should be excused as "immaterial" under *General Mills*, 24 U.S.P.Q.2d at 1274 (holding that a labeling defect is "material" only when it is "of such gravity and significance that the usage must be considered unlawful—so tainted that, as a matter of law, it [can] create no trademark rights").

General Mills involved a dispute between Health Valley Foods (seller of Fiber 7 Flakes cereal) and General Mills, Inc. (seller of Fiber One cereal), in which the former accused the latter of not having lawfully used "Fiber One" in commerce

when the latter applied for trademark registration.¹² *Id.* at 1271-72. Although the first eighteen boxes of Fiber One—indeed, all boxes sold before General Mills applied for trademark registration of the Fiber One mark—were mislabeled under the FDCA, General Mills noticed the error, promptly corrected it, and then sold over 600,000 correctly labeled boxes to consumers *before* Health Valley Foods even applied to register “Fiber 7 Flakes.” *Id.* at 1271-73 & n.1. Under these facts, the Trademark Trial and Appeal Board concluded that cancelling Fiber One’s registration based on the original eighteen mislabeled boxes would be “Draconian.” *Id.* at 1273.

This case is categorically different. Whereas General Mills corrected its labeling error before its competitor’s priority date—thus eventually establishing the “lawful use in commerce” necessary for trademark protection—CreAgri *did not* correct its labeling error before USANA’s priority date, and thus, there is not a single instance of “lawful use in commerce” prior to June 18, 2002 upon which CreAgri can base its claim of priority. Accordingly, we need not decide whether to adopt the *General Mills* test for materiality; by any definition, Olivenol’s defect—which existed as to *every* bottle of Olivenol sold prior to the competing registrant’s priority date—was material.

CONCLUSION

[8] Because CreAgri’s admitted violation of 21 C.F.R. § 101.9(g)(4) cannot be deemed collateral to use of the Olivenol mark under *Satinine*, 209 U.S.P.Q. at 967 (Kera, concurring), excused under 21 C.F.R. § 101.36(f)(2), or

¹²At the time, failing to lawfully use a mark in commerce before applying for trademark registration would render the mark ineligible for such registration. The “intent to use” system has since supplanted the system that was in place when General Mills’ application was processed. See Pub. L. No. 100-667 § 103, 102 Stat. 3935 (1988) (codified as amended at 15 U.S.C. § 1051).

overlooked as immaterial under *General Mills*, 24 U.S.P.Q.2d at 1274, it follows that the Olivenol mark was not lawfully used in commerce prior to Olivol's June 18, 2002 priority date. As such, USANA's mark has priority over CreAgri's mark, and a trademark infringement action by CreAgri against USANA cannot stand. The district court correctly granted summary judgment in favor of USANA on CreAgri's trademark infringement claims.¹³

[9] Additionally, the district court correctly cancelled "Olivenol" from the supplemental register. A mark is only eligible for supplemental registration if it was in "lawful use in commerce" prior to the date on which the holder applied for such registration. 15 U.S.C. § 1091(a); *In re Pepcom*, 192 U.S.P.Q. at 401. As explained above, "Olivenol" was not lawfully used in commerce prior to June 18, 2002, and CreAgri admits that Olivenol's labels on October 9, 2002—when CreAgri filed its amended application for registration on the supplemental register—were no different from those in use on June 18, 2002. Thus, the Olivenol mark was properly cancelled from the supplemental register.¹⁴

AFFIRMED.

¹³Summary judgment was also properly granted as to CreAgri's non-trademark-infringement claims and USANA's request for declaratory judgment, as these claims also hinged on Olivenol's trademark priority—or lack thereof—over Olivol.

¹⁴It should be noted that cancellation of Olivenol's *current* supplemental registration does not necessarily render "Olivenol" forever incapable of being registered on either the principal or supplemental registers.