United States Court of Appeals for the Federal Circuit

ALLERGAN, INC., AND DUKE UNIVERSITY,
Plaintiffs-Appellees,

AND

MURRAY A. JOHNSTONE, M.D.,
Plaintiff,

v.

ATHENA COSMETICS, INC.,
Defendant-Appellant,

AND

PHARMA TECH INTERNATIONAL, INC., PRODUCT INNOVATIONS, LLC, NORTHWEST COSMETIC LABORATORIES, LLC, AND R & G BUSINESS LLC,
Defendants.

2013-1286

Appeal from the United States District Court for the Central District of California in consolidated Nos. 07-CV-1316 and 09-CV-0328, Judge James V. Selna.

Decided: December 30, 2013

MARK A. PERRY, Gibson, Dunn & Crutcher LLP, of Washington, DC, argued for plaintiffs-appellees. With him on the brief were JEFFREY T. THOMAS and BLAINE H. EVANSON, of Irvine, California.

STEVEN A. ZALESIN, Patterson Belknap Webb & Tyler LLP, of New York, New York, argued for defendant-appellant. With him on the brief were TRAVIS J. TU, JONAH M. KNOBLER and JANE M. METCALF. Of counsel was STEPHEN P. BENSON, Katten Muchin Rosenman, LLP, of Chicago, Illinois.

Before RADER, *Chief Judge*, MOORE, and WALLACH, *Circuit Judges*.

MOORE, *Circuit Judge*.

Athena Cosmetics, Inc. (Athena) appeals from the district court's grant of summary judgment that Athena violated California's unfair competition law (UCL) by marketing, distributing and selling, without regulatory approval, products that qualify as drugs. Athena also challenges the court's entry of a nationwide injunction and the denial of a motion for judgment on the pleadings that the Federal Food, Drug, and Cosmetic Act (FDCA) preempts Allergan, Inc.'s (Allergan) UCL claim. We hold that the FDCA does not preempt Allergan's UCL claim and that there is no genuine dispute that the products at issue are drugs under California law, and thus *affirm* the grant of summary judgment. We also hold that the district court abused its discretion by entering an overbroad injunction, and thus *vacate* the injunction and *remand*.

BACKGROUND

The products at issue in this appeal are formulations of Athena's RevitaLash line, all of which contain a

prostaglandin derivative as an active ingredient. The Food and Drug Administration (FDA) has not taken enforcement action against, or otherwise regulated, the products at issue. Allergan sells a product called Latisse, which also contains a prostaglandin derivative. Latisse is a FDA-approved prescription drug used for the treatment of a condition that affects eyelash growth.

Allergan sued Athena for patent infringement and a violation of the UCL, California Business and Professions Code § 17200 *et seq*. Allergan alleged that Athena competed unfairly by violating, *inter alia*, California's Health and Safety Code (California Health Code) § 111550[1] by "marketing, selling, and distributing [its] hair and/or eyelash growth products without [a new drug] application approved by the FDA or California State Department of Health Services." Complaint at ¶¶ 82, 84, *Allergan, Inc. v. Athena Cosmetics, Inc.*, No. 8:07-cv-1316 (C.D. Cal. Sept. 30, 2011).

The district court denied Athena's motion for judgment on the pleadings that the FDCA preempts Allergan's UCL claim. Allergan moved for summary judgment that the products at issue qualify as new drugs that lack the requisite approval under the California Health Code, giving rise to a UCL violation. The court granted summary judgment and entered a permanent injunction. Athena appeals.

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[1] "No person shall sell . . . any new drug . . . unless it satisfies either of the following: (a) It is . . . [a] new drug, and a new drug application has been approved for it and that approval has not been withdrawn or suspended under Section 505 of the [FDCA] . . . . [or] (b) The [California Health Department] has approved a new drug application for that new drug . . . ."

JURISDICTION

While this appeal does not present any patent issues, Allergan's amended complaint alleged infringement of three patents of which it is the exclusive licensee, including U.S. Patent No. 6,262,105. The parties did not initially contest our jurisdiction, but "every federal appellate court has a special obligation to satisfy itself . . . of its own jurisdiction." *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541 (1986) (internal quotation marks omitted). Therefore, we ordered supplemental briefing on our jurisdiction.

Athena argued that we have jurisdiction over this appeal. Sept. 20, 2013 Supp. Br. It argued that, as a result of actions in the underlying district court litigation, the parties' legal relations were altered with respect to the patent claims. *Id.* Allergan disputed our jurisdiction. Sept. 20, 2013 & Oct. 11, 2013 Supp. Brs.

We have exclusive jurisdiction over an appeal from a final decision of a district court (including one unrelated to patent issues) when "patent law is a necessary element of one of the well-pleaded claims" in the complaint. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988); 28 U.S.C. § 1295(a)(1). In some circumstances, a district court's dismissal without prejudice of a patent claim serves as a constructive amendment to the complaint, effectively removing the patent claim. *See Chamberlain Grp. v. Skylink Techs., Inc.*, 381 F.3d 1178, 1189–90 (Fed. Cir. 2004). We have explained, however, that "[d]ismissals divest this court of jurisdiction only if '[t]he parties were left in the same legal position with respect to [all] patent claims as if they had never been filed.'" *Id.* at 1190 (quoting *Nilssen v. Motorola, Inc.*, 203 F.3d 782, 785 (Fed. Cir. 2000)). Moreover, "[n]either the specific rule under which the District Court dismissed the claims nor the wording of the dismissal alters the funda-

mental basis of our jurisdiction." *Chamberlain*, 381 F.3d at 1190.

In this case, following the district court's issuance of a Final Claim Construction Order, the parties proposed that the court grant summary judgment of noninfringement of the '105 patent, while preserving their full appellate rights regarding claim construction. *Allergan,* No. 8:07-cv-1316, ECF No. 679 (C.D. Cal. May 9, 2012). The court entered summary judgment "in accordance with the terms of the Stipulation." *Id.*, ECF No. 691 (C.D. Cal. May 29, 2012). Thereafter, pursuant to the parties' further agreement, the court dismissed all of the patent claims "without prejudice." *Id.*, ECF No. 1075 (C.D. Cal. Mar. 28, 2013).

We have jurisdiction over this case because the parties were not left in the same legal position as if the '105 patent claim had never been filed. The court's dismissal "without prejudice" merely reflects the parties' agreement that the '105 patent claim could be re-filed in future litigation between these parties. Should that occur, however, the parties will be bound by the court's summary judgment ruling—which the court did not vacate. Indeed, Allergan, whose decision it is whether to reassert the '105 patent against Athena, concedes on appeal that the summary judgment ruling "would bind the parties in future district court litigation against each other." Oct. 11, 2013 Supp. Br. at 2. The court's dismissal of the '105 patent claim did not undo this alteration in legal status, and therefore we have jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1).[2]

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[2] Athena contends that the district court altered the legal status of the parties with respect to each of the other

ANALYSIS

Where an issue is not unique to patent law, we apply the law of the regional circuit from which the case arises. *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004). The Ninth Circuit reviews grants of summary judgment and determinations regarding preemption *de novo*. *Engine Mfrs. Ass'n v. S. Coast Air Quality Maint. Dist.*, 498 F.3d 1031, 1035 (9th Cir. 2007). The Ninth Circuit reviews the decision to grant a permanent injunction, as well as its scope, for abuse of discretion, and underlying factual findings for clear error. *Columbia Pictures Indus., Inc. v. Fung*, 710 F.3d 1020, 1030 (9th Cir. 2013).

I. Preemption

The California Health Code incorporates various provisions of the FDCA, which does not itself allow a private right of action. *See* 21 U.S.C. § 337(a). The district court held that the FDCA did not preempt Allergan's UCL claim. It stated that "mentions of the FDCA throughout" its order were "referential" because "[i]n order to determine if the [California Health Code] is violated, the Court looks to whether the federal regulations incorporated therein are violated." *Allergan*, No. 8:07-cv-1316, slip op. at 4 (C.D. Cal. Oct. 11, 2012). On appeal, the parties agree that the FDCA does not expressly preempt Allergan's claim—the dispute before us concerns implied preemption.

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two patent claims. Sept. 20, 2013 Supp. Br. at 2–3. Because the change in legal status with respect to the '105 patent claim is sufficient to supply our jurisdiction, we need not address the other patents.

Athena argues that the FDCA impliedly preempts Allergan's UCL claim. It contends that, under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), a state law claim is impliedly preempted if it does not implicate a traditional state law tort principle and exists solely by virtue of a federal statute. Athena argues that Allergan's claim involves the violation of a California statute that simply incorporates FDCA provisions and is not rooted in state law tort principles.

Athena argues that the Ninth Circuit's application of *Buckman* in *PhotoMedex, Inc. v. Irwin,* 601 F.3d 919 (9th Cir. 2010) governs this case. In that case, the court found that the plaintiff's claim based on alleged misrepresentations to the FDA about a medical device was impliedly preempted because it would have impermissibly circumvented the agency's exclusive enforcement authority. *Id.* at 926–30. Athena argues that Allergan's claim interferes with the FDA's discretionary authority whether to regulate an article in interstate commerce as a drug. Athena also argues that, under the prudential doctrine of primary jurisdiction, the district court abused its discretion by declining to stay this case pending the FDA's determinations about the products at issue.

Allergan responds that the FDCA does not impliedly preempt its UCL claim. It argues that the FDCA contains express preemption provisions for "certain narrow topics inapplicable," including medical devices and non-prescription drugs. Resp. Br. at 17–18 (citing 21 U.S.C. §§ 360k(a), 379r). Allergan argues that there are no similar preemption provisions for prescription drugs, indicating that Congress intended that the FDCA should not preempt by implication state law claims related to this category.

Allergan argues that, under *Wyeth v. Levine*, 555 U.S. 555 (2009), there is no implied preemption where simul-

taneous compliance with state and federal law is possible, and the state law is not an obstacle to the realization of federal goals. It argues that the California Health Code's requirements parallel the FDCA's, making compliance with both regimes possible. Allergan also argues that the district court did not abuse its discretion by retaining jurisdiction because the resolution of this case did not require the FDA's specialized knowledge.

We agree with Allergan and hold that the FDCA does not impliedly preempt its UCL claim. "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Id.* at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). "'In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.* (quoting *Medtronic*, 518 U.S. at 485) (alterations omitted).

The fact that the California Health Code parallels certain FDCA provisions does not mean that it does not implicate an historic state power that may be vindicated under state law tort principles. The Supreme Court acknowledged "the historic primacy of state regulation of matters of health and safety," *Buckman*, 531 U.S. at 348, which is precisely the California Health Code's subject matter.

We do not find a clear purpose by Congress to preempt the state law claim at issue. Congress expressed its intent to preempt state-law causes of action regarding, for example, non-prescription drugs and medical devices. Allergan's contention, however, is that the products at issue must ultimately be regulated as prescription drugs—about which Congress "declined to enact such a

provision." *Wyeth*, 555 U.S. at 567; *see also Farm Raised Salmon Cases*, 175 P.3d 1170, 1179 (Cal. 2008) ("[D]eference should be paid to Congress's detailed attempt to clearly define the scope of preemption under the FDCA."). Moreover, the California Health Code is not an obstacle to realizing federal objectives. To the contrary, it contains provisions that parallel the FDCA, such that the statutes have consistent goals.

Athena's principal authorities are distinguishable. *Buckman* involved a claim based on fraud before the FDA, which existed—unlike Allergan's claim—"solely by virtue of the FDCA disclosure requirements." 531 U.S. at 352–53. The Court described fraud on the FDA as—unlike state regulation of health and safety—"hardly a field which the States have traditionally occupied . . . such as to warrant a presumption against finding federal preemption of a state law cause of action." *Id.* at 347 (internal quotation marks omitted). *PhotoMedex* concerned an issue that does not involve federal preemption of a state law claim: "whether the FDCA limits claims under the [federal] Lanham Act." 601 F.3d at 924. The decision was limited to "particular circumstances" that are also not before us: alleged misrepresentations to the FDA about a medical device, which implicated the Medical Device Amendments of 1976 to the FDCA. *Id.* at 922, 924–28.

We see no error in the district court's determination that the FDCA does not preempt Allergan's UCL claim.

II. Summary Judgment

The California Health Code incorporates the FDCA's definition of "drugs" to include "any article other than food that is used or intended to affect the structure . . . of the body of human beings." Cal. Health Code § 109925(c); *cf.* 21 U.S.C. § 321(g)(1)(C). An article's intended use is determined based on "the objective intent of the persons legally responsible for the labeling of drugs." 21 C.F.R.

§ 201.128. Objective intent "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article," including "labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id.*

The district court found no genuine dispute that Athena objectively intended to market past and present formulations of the products at issue to affect the structure of eyelashes—*i.e.*, as drugs. The court found that Athena's founder, a physician, developed an initial formulation using a prostaglandin derivative with the intent to cause users' eyelashes to grow longer and fuller. It found that Athena's marketing of subsequent formulations containing different derivatives continued to discuss eyelash growth. The court acknowledged that Athena's marketing of the most recent formulation discussed eyelash *appearance*, but concluded this did not negate an objective intent to cause *growth*.

Athena argues that there is a genuine issue of material fact about its objective intent. Athena argues that its intent should turn only on labeling and marketing materials related to its most recent formulation, and that the physical properties of the products at issue and marketing of past formulations are irrelevant. Athena contends that, within a year of its founding, it limited its marketing to claims about eyelash appearance. It argues that statements by resellers about eyelash growth do not reflect Athena's objective intent. Athena points to the testimony of a former employee that she always referred to eyelash appearance when training resellers about the products at issue. It argues that authorized resellers must acknowledge that the products at issue may only be sold as cosmetics and may not be marketed for eyelash growth.

Allergan responds that there is no genuine factual dispute that Athena objectively intends for the products

at issue to be used as drugs. It argues that the physical properties and claims about past and present formulations are relevant, particularly because Athena has not materially altered the properties of, or marketing about, its various formulations. Allergan argues that Athena and its resellers advertise that the products at issue were developed by Athena's founder to treat his wife's eyelash loss. It argues that Athena's founder testified that he had reason to think the product he developed would cause eyelashes "to grow thick and long," J.A. 670–71, and sought to sell the product for that purpose. J.A. 684, 687. Allergan argues that Athena's marketing consistently references eyelash length, which depends on growth.

We agree with Allergan and hold that there is no genuine dispute that Athena objectively intends for the products at issue to be used to affect the structure of eyelashes—*i.e.*, as drugs. Athena's intent as to its line-up of products may be "derived or inferred from labeling, promotional material, advertising, or any other relevant source." *United States v. Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985). As an initial matter, we disagree with Athena that the only relevant evidence is labeling and marketing, or that the only relevant formulation is the most recent one. Athena's website collectively refers to the RevitaLash "line-up of products," and describes formulation changes as "improve[ments]" to the intended use of "one or more of our products." J.A. 878.

Athena's marketing of the products at issue consistently discusses physical changes to eyelashes. There is no dispute that Athena made drug-related claims about an early formulation—and it never expressly disavowed such claims as it reformulated its products. Instead, the company continued to suggest that the products at issue change eyelash structure. For example, the company's website contained a message from the founder referring to

his wife's "fragile, sparse and thin" eyelashes, and his development of a formula to achieve "the look of *renewed health*, *strength* and beauty." J.A. 875 (emphasis added). An advertisement about the most recent formulation states that the product is "both dermatologist and ophthalmologist reviewed," and describes "improved appearance" of eyelashes in the context of a "clinical study." J.A. 750; *see also* J.A. 871.

Athena's training of resellers similarly references eyelash structure. An Athena representative led a webinar for resellers in which she discussed achieving "fuller and thicker" eyelashes. J.A. 820. She discussed a "maintenance program" to retain "the desired length" after "achiev[ing] longer, fuller-looking eyelashes." J.A. 822. She stated that "eyelashes will grow naturally or with RevitaLash." J.A. 824. One reseller's marketing materials displayed a before-and-after photograph of eyelashes and promoted "dramatically thicker, longer, and lusher lashes." J.A. 960. Athena's claims invariably link eyelash appearance to physical changes caused by the products at issue.

Athena's argument that it markets *only* cosmetic benefits fails. We need not decide whether the products at issue could *also* be cosmetics—it is sufficient to resolve this case that there is no dispute that Athena objectively intends that the products at issue be used as drugs. We therefore affirm the district court's grant of summary judgment.

III. Injunction

The district court entered a permanent injunction barring Athena from manufacturing, marketing, selling, and/or offering for sale "any and all" "eyelash growth product(s)" "anywhere within the United States." *Allergan*, No. 8:07-cv-1316, slip op. at 15 (C.D. Cal. Mar. 6, 2013). It determined that nationwide coverage was

justified because Athena's UCL violation resulted from sales and advertising "throughout the United States," and "wherever the unfair competition occurs, it affects Allergan in California." *Id.* at 7–8. The court concluded that the injunction's regulation of out-of-state commerce did not violate the Commerce Clause of the United States Constitution. *Id.* at 8–10. Specifically, it found "substantial indications that other jurisdictions define 'drug'" like the California Health Code. *Id.* at 9–10. The court stated that Athena did not "demonstrate that there would be a conflict with other states' laws," and "proffer[ed] no facts to suggest that [it] would encounter contrary" law in other states. *Id.* at 7, 9–10.

Athena argues that it was an abuse of discretion for the court to issue a nationwide injunction. It argues that the injunction impermissibly reaches outside of California to remedy a violation of California law. Athena argues that the injunction violates the Commerce Clause by regulating commerce that occurs wholly outside of California. It emphasizes that California is not part of the supply chain for the most recent formulation of the products at issue.

Allergan responds that the court did not abuse its discretion. It argues that the injunction properly applies to out-of-state conduct that causes Allergan an injury under the UCL in California. Allergan argues that the record evidence demonstrated that the injunction's nationwide scope was a practical necessity. It argues that, after Athena volunteered to stop sales of the products at issue in California before the court issued an injunction, such sales persisted within the state. Allergan also argues that there is no Commerce Clause violation because the injunction does not impose obligations on Athena that conflict with another state's law and Athena has not shown any conflict with the laws of other states. It contends that, in any event, other states could not adopt laws

that are inconsistent with the California Health Code because it incorporates a regulatory floor set by the FDCA.

We agree with Athena and hold that the district court abused its discretion by entering an injunction that regulates any and all out-of-state conduct. As the California Supreme Court has stated, "[n]either the language of the UCL nor its legislative history provides any basis for concluding the Legislature intended the UCL to operate extraterritorially." *Sullivan v. Oracle Corp.*, 254 P.3d 237, 248 (Cal. 2011). The injunction impermissibly imposes the UCL on entirely extraterritorial conduct regardless of whether the conduct in other states causes harm to California. This injunction is so broad that it would bar Athena from making its product in Idaho, distributing it from a facility in Nevada, and selling it to Connecticut consumers.

Allergan argues that *Norwest Mortgage, Inc. v. Superior Court of San Diego County*, 72 Cal. App. 4th 214 (1999), supports the court's imposition of a nationwide injunction in this case. It does not. In *Norwest Mortgage*, the California Court of Appeals held that UCL claims could be filed by California residents regardless of where they purchased their mortgage product and by non-California residents who purchased it in California, but not by non-California residents who purchased it outside of California (entirely extraterritorial conduct). *Id.* at 222–24. The conduct enjoined here is exactly the sort of purely extraterritorial conduct that the California Court of Appeals expressly held could not be regulated by the UCL. This injunction prevents sales that are entirely extraterritorial. It is not limited to purchases made by California residents that are being shipped into California or to sales emanating from California.

Neither the California courts nor the California legislature are permitted to regulate commerce entirely out-

side of the state's borders. To do so would violate the Commerce Clause, which "precludes" such extraterritorial application of state law "whether or not the commerce has effects within the state." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982)). The Commerce Clause "dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another." *Id.* at 337. This rule applies regardless of whether Athena can demonstrate that the laws of other states do—or even could—conflict with the UCL or the California Health Code. In short, California may, as it has in this case, conclude that its own unfair competition law has been violated, and it may prohibit any future conduct within its borders that would cause continued violation of its law. California is not permitted, however, to extend its unfair competition law to other states.[3]

The FDA—and the FDA alone—has the power and the discretion to enforce the FDCA. 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"). California does not have the authori-

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[3] There may be instances when a court in one state may issue an injunction that applies beyond the state's boundaries such as when a federal law has been violated. The Ninth Circuit recognized such a possibility in *United States v. AMC Entertainment, Inc.*, 549 F.3d 760 (9th Cir. 2008), but nonetheless vacated the nationwide injunction because the Fifth Circuit had a different interpretation of the federal law at issue. *Id.* at 770–73. Such is not the case here. California has no obligation or right to enforce the FDCA. The only law at issue here is California's UCL.

ty to stand in the shoes of the FDA to determine whether Athena's sale of the products at issue amounts to the sale of an unapproved drug under the FDCA. This enforcement authority relies exclusively with the FDA. California has chosen to enact the UCL, which prevents marketing, distributing, and selling, without regulatory approval, products that qualify as drugs. While it is true that a state is not free to enact laws that do not meet the minimum requirements of the FDCA, a state is free to have no comparable state law if it chooses. The FDA does not require states to enact laws that parallel federal requirements. Thus, if other states have no laws that parallel relevant provisions of the UCL and California Health Code, there would be no mechanism at all in those states to challenge Athena's sales of the products at issue. In short, imposing the UCL on other states would violate their sovereignty, and usurp the discretionary enforcement authority of the FDA.

Allergan's reliance on Athena's purported failure to voluntarily cease sales of the products at issue in California does not justify a nationwide injunction. After summary judgment, Athena offered to voluntarily cease sales to California. An attorney for Allergan submitted a declaration stating that, after Athena's purported cessation of sales in California, she was still able to purchase a product at issue from Athena's and a reseller's website for delivery in California, as well as directly from a reseller's store in California. *See* J.A. 2729–34. This record demonstrates that these sales were isolated occurrences. Athena recognized these infractions and instituted better procedures to ensure no further sales of the products at issue in California, instructed its online resellers not to sell those products for delivery in California, and ceased to ship those products to brick-and-mortar resellers in California. *See* J.A. 3098–101. If Athena violates a properly tailored injunction, Allergan's remedy lies in a contempt proceeding. But Athena's failure to entirely

stop sales in California pursuant to its voluntary efforts cannot, as Allergan argues, justify a nationwide injunction that violates the Commerce Clause.

We vacate the permanent injunction. On remand, the district court should limit the scope of the injunction to regulate conduct occurring within California.[4]

CONCLUSION

We have considered the parties' remaining arguments and do not find them persuasive.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

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[4] Athena also argues that the district court did not make findings to support irreparable harm, and abused its discretion by drafting the injunction to cover any product containing a prostaglandin derivative applied to eyelashes. We hold that the district court made an express finding of irreparable harm that was not clearly erroneous, *see, e.g.*, J.A. 1542–43, and the scope of the products covered was not an abuse of discretion.