United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 98-1055

Richard Symens; Joyce Symens, *

*

Plaintiffs - Appellees, *

*

v. *

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SmithKline Beecham Corporation, *

*

Defendant - Appellant. *

No. 98-1056

Ivan Sjovall, *

*

Plaintiff - Appellee, *

*

v. *

*

SmithKline Beecham Corporation, *

*

Defendant - Appellant. *

Appeals from the United States
District Court for the
District of South Dakota.

Submitted: June 8, 1998
Filed: August 27, 1998

Before LOKEN, GODBOLD,* and HEANEY, Circuit Judges.

LOKEN, Circuit Judge.

In the last half of 1992, cattle feedlot operators Richard and Joyce Symens and Ivan Sjovall vaccinated their cattle with "BoviShield 4" and "Ultrabac-7/Somubac," vaccines manufactured by SmithKline Beecham Corporation (SBC). They commenced these diversity actions, alleging that the cattle "contracted debilitating and mortal infections and diseases" from the vaccines, and asserting South Dakota common law claims for strict liability, breach of implied warranties, false advertising, failure to warn, and fraud on the licensing agency. SBC moved for summary judgment, arguing that plaintiffs' claims are preempted by the Virus-Serum-Toxin Act (VSTA), 21 U.S.C. §§ 151-59. The district court denied the motion and certified the issue for interlocutory appeal under 28 U.S.C. § 1292(b). We reverse in part and remand.

VSTA authorizes the United States Department of Agriculture (USDA) to license and regulate the preparation and sale of "viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals." 21 U.S.C. § 154. USDA has delegated this authority to its Animal and Plant Health Inspection Service (APHIS). See 9 C.F.R. § 101.2. APHIS in turn has "promulgated an extensive regulatory scheme governing the design, manufacture, distribution, testing, and labeling of animal vaccines." Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620, 624 (7th Cir.), cert. denied, 117 S. Ct. 178 (1996), citing 9 C.F.R. §§ 101-24.

APHIS licenses all animal vaccines and vaccine manufacturers. See 9 C.F.R. §§ 102.1, 102.2. The application for an animal vaccine license must include an

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*The HONORABLE JOHN C. GODBOLD, United States Circuit Judge for the Eleventh Circuit, sitting by designation.

"Outline of Production" that details the vaccine's composition, manufacture, preparation, testing, and packaging. See 9 C.F.R. §§ 102.3(b)(2)(i), 114.8-.9. The regulations detail ingredient requirements, such as the types of cell lines that must be used to produce biologics. See 9 C.F.R. §§ 113.50-.55. APHIS-mandated testing procedures ensure the "purity, safety, potency, and efficacy" of the vaccine. See 9 C.F.R. §§ 102.3(b)(2)(ii), 113.25-.55, 113.64-.332. APHIS approves all product labels and package inserts; even minor changes in label size and color must be resubmitted for review and approval. See 9 C.F.R. §§ 101.4, 112.5. Packaging must contain instructions, warnings, the license number, and prescribed storage temperatures. See 9 C.F.R. § 112.2(a). Once approved, the Outline of Production may not be changed without resubmission to APHIS. See 9 C.F.R. § 114.8(d). Before marketing, the manufacturer must test a licensed vaccine to ensure that it is "pure, safe, potent, and efficacious." 9 C.F.R. § 113.5. Any serial (lot) that does not pass the prescribed premarket tests may not be sold. See 9 C.F.R. § 113.6(b). The manufacturer must forward samples of each serial and subserial to APHIS. See 9 C.F.R. § 113.3. APHIS may test the product for "purity, safety, potency, or efficacy" before it is marketed. See 9 C.F.R. § 113.6(a).

BoviShield 4 and Ultrabac-7/Somubac are APHIS-licensed vaccines. SBC's records reflect that each serial of the vaccines administered to plaintiffs' cattle was tested by SBC before release. The test results were "satisfactory," and those results were reviewed by APHIS. After the Symens's cattle sickened, they complained to APHIS. The agency tested two BoviShield 4 serials and concluded they met purity standards and were not contaminated.

The Preemption Question.

Under the Supremacy Clause of the Constitution, federal legislation may preempt state law. Congress may express an intent to preempt in the federal statute. An intent to preempt may also be implied, for example, when federal and state laws directly

conflict, when state law stands as an obstacle to accomplishing the purposes of federal law, or when federal law is so pervasive that it reflects an intent to occupy a regulatory field. See Heart of Am. Grain Inspection Serv., Inc. v. Missouri Dep't of Agric., 123 F.3d 1098, 1103 (8th Cir. 1997). Congress may also delegate the preemption question -- expressly or by implication -- to the agency it authorizes to administer or enforce a federal statute. When agency preemption is at issue, the inquiry focuses on whether the agency intended to preempt state law and whether it had the statutory authority to do so. See City of New York v. F.C.C., 486 U.S. 57, 63-64 (1988). This appeal raises an issue of agency preemption. VSTA does not expressly address the preemption question, but it delegates broad powers to APHIS, and the agency has expressed a clear intent to preempt inconsistent state "requirements." We must consider whether APHIS has the power to preempt, and if so, whether it has preempted all or part of plaintiffs' common law claims.

A. Is There VSTA Preemption?

Prior to 1985, VSTA did not clearly apply to intrastate vaccines. Congress amended VSTA in the Food Security Act of 1985. See Pub. L. No. 99-198, Title XVII, § 1768, 99 Stat. 1654-56. The 1985 amendments authorized USDA to license and regulate intrastate vaccines, broadened the Secretary's authority to issue regulations "to carry out" the Act, and granted the agency enhanced enforcement powers. See 21 U.S.C. §§ 151, 154, 159. The legislative history observed that "[t]he need for uniform national standards has become recognized widely in recent years." H.R. Rep. No. 99-271, pt. 2, at 339, reprinted in 1985-3 U.S.C.C.A.N. 1660, 2005.

In 1990, APHIS proposed to modify its regulations to clarify that licensees must comply with state regulation "based on local disease conditions." See 55 Fed. Reg. 42,392 (1990), proposing to amend 9 C.F.R. § 102.5(d)(2). In promulgating the final rule, APHIS responded to comments that States should have broader authority:

> Seven commentators indicated that States should have the authority to add to Federal restrictions, as appropriate . . . . APHIS, however, does not agree . . . . The legislative history relating to the 1985 amendments . . . clearly expresses Congressional intent that Federal regulation of veterinary biologics is needed to prevent and eliminate burdens on commerce and that there is a need for uniform national standards regarding these products. Therefore, *States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States*. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent, and efficacious.

APHIS, Final Rule Pertaining to Restrictions Which May Be Imposed by States on the Distribution and Use of Veterinary Biological Products, 57 Fed. Reg. 38,758, 38,759 (1992) (emphasis added).

Despite this clear expression of intent to preempt state law requirements, the district court concluded that APHIS has no statutory authority to preempt. We disagree. The Commerce Clause grants Congress power to preempt state regulation of animal vaccines. While an intent to preempt state law will not lightly be implied from an ambiguous statute, see, e.g., Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 146-47 (1963), the question whether Congress intended to authorize a federal agency to preempt is reviewed somewhat differently:

> [M]any of the responsibilities conferred on federal agencies involve a broad grant of authority to reconcile conflicting policies. Where this is true, the Court has cautioned that even in the area of pre-emption, if the agency's choice to pre-empt "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the

> statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."

City of New York, 486 U.S. at 64, quoting United States v. Shimer, 367 U.S. 374, 383 (1961); see also Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1982). The 1985 VSTA amendments granted USDA authority to license intrastate vaccines, enhanced the agency's enforcement powers, and broadened its authority to issue implementing regulations. The legislative history noted the "truly national markets for the live animals and their products" and the "need for uniform national standards." 1985-3 U.S.C.C.A.N. at 2005. In these circumstances, we agree with the Seventh Circuit "that APHIS acted rationally and within the scope of the authority granted to it by Congress in issuing the above statement seeking to preempt state law." Lynnbrook Farms, 79 F.3d at 625; accord Murphy v. SmithKline Beecham Animal Health Group, 898 F. Supp. 811, 815-17 (D. Kan. 1995); Brandt v. Marshall Animal Clinic, 540 N.W.2d 870, 874-76 (Minn. Ct. App. 1995).

Whether state laws that add to federal regulatory requirements are inconsistent with the purposes of the federal statute is often a complex issue. Here, for example, Congress intended to create a regulatory regime that establishes uniform national standards and has the ability to meet "an emergency condition, limited market or local situation, or other special circumstance." 21 U.S.C. § 154a. It is reasonable to infer that Congress intended to delegate to the federal licensing agency the question of whether and to what extent preemption is necessary to further these policies. Therefore, APHIS made a "reasonable accommodation . . . that Congress would have sanctioned," the test under City of New York, when it concluded that the 1985 amendments granted it power to preempt, and that additional state requirements regarding product safety, efficacy, potency, purity, and labeling "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991).

B. What Is the Extent of VSTA Preemption?

Having concluded that APHIS validly preempted state laws that "impose requirements which are different from, or in addition to, those imposed by USDA" regarding the safety, efficacy, potency, purity, or labeling of licensed vaccines, we must determine the effect of that preemption on plaintiffs' common law claims. SBC argues that "requirements" include common law remedies and therefore plaintiffs' claims are totally preempted. Plaintiffs argue that APHIS did not intend to preempt common law remedies and therefore their claims are entirely unaffected by federal regulation of the vaccines in question. We reject both contentions.

SBC argues for total preemption of state common law remedies. Congress does on occasion fashion a comprehensive scheme of federal remedies that preempts inconsistent remedies under state law. See Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142-45 (1990) (ERISA preempts all state law remedies). But VSTA confers no federal right of action on those who may be injured by animal vaccines that are, for example, unlicensed, defective, or mislabeled. Therefore, SBC's contention would leave vaccine purchasers and users without any remedy, a preemptive intent we should be most reluctant to infer. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 486-87 (1996) (plurality opinion); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984). Here, there is strong evidence that APHIS did not intend to entirely preempt common law remedies. When the agency implemented its preemption declaration in 1992, it left in place the labeling regulation that prohibits licensed manufacturers from publishing "disclaimers of merchantability, fitness for the purpose offered, or responsibility for the product." 9 C.F.R. § 112.2(b). That regulation is an express recognition that common law remedies are not entirely preempted.

On the other hand, plaintiffs' contention -- that preemption of state law "requirements" relating to vaccine safety, efficacy, purity, potency, and labeling leaves common law claims unaffected -- is equally misguided. Two recent Supreme Court

decisions confirm that state common law damage actions are within the scope of a federal statute or regulation preempting state law "requirements." In Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521, 548-49 (1992), a majority of the Court concluded that the federal statute preempting all state law requirements relating to cigarette labeling preempted some state common law claims. Similarly, in Medtronic, five Justices agreed that a federal statute preempting state law requirements regarding medical devices applied to state common law damages actions as well as to state statutes and regulations. See 518 U.S. at 503-04 (Breyer, J., concurring in the judgment), 509-12 (O'Connor, J., concurring in part and dissenting in part).

VSTA as construed by APHIS preempts inconsistent substantive state law "requirements" but not state common law remedies. In this situation, common law claims are *not* preempted *to the extent that* they seek relief for alleged violations of the federal substantive standards. All the Supreme Court opinions in Medtronic agreed on that.[1] It is also a logical interpretation of the APHIS preemption statement, viewed in light of the regulation prohibiting the disclaimer of implied warranties. Indeed, we have direct evidence this was APHIS's intent. When United States Senator Paul Wellstone requested clarification of the preemption statement, the agency responded:

> Our intent in promulgating the rule was, and continues to be, to preempt States from imposing requirements either through statutes, regulations, *or other means* that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product.

[1]Justice Stevens for the Court stated, "Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. Justice Breyer's concurring opinion explained that a state law tort suit is not preempted if its "liability-creating-premises" do not conflict with federal requirements. Id. at 508. Justice O'Connor's separate opinion declared that "the Lohrs' claims are not pre-empted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements." Id. at 513.

Such requirements would include, but are not limited to production, testing, distribution, or labeling requirements. *We did not intend to preempt common law actions for damages arising from noncompliance with USDA regulatory standards.*

Letter from APHIS Acting Administrator to Senator Wellstone (Dec. 22, 1995) (emphasis added).[2]

There remains the question of how to dispose of this appeal. The district court flatly denied SBC's motion for summary judgment, and its opinion seems to conclude that plaintiffs' common law claims are unaffected by the APHIS declaration of preemption. As we have explained, this is incorrect. Plaintiffs' broadly pleaded claims are preempted to the extent that they rely upon "liability-creating-premises" that are

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[2]SBC has moved to supplement the record with the abstract of a speech by an APHIS official at the annual meeting of the American Veterinary Medical Law Association on July 26, 1998. The abstract states in part:

> The Seventh Circuit Court of Appeals properly interpreted APHIS' intent . . . when it held in Lynnbrook Farms . . . that: ". . . State tort claims are available when APHIS regulatory standards are violated or disregarded . . . and that when APHIS regulations are heeded, state tort claims involving the safety, efficacy, potency, or purity of animal vaccines do not survive."
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> APHIS' policy on Federal preemption attempts to strike a balance between maintaining uniform national standards for veterinary biologics and allowing State tort actions when there is noncompliance with Federal standards.

David A. Espeseth, Center for Veterinary Biologics, APHIS Licensing and Policy Development, Federal Preemption of Product Liability Litigation -- Rationale and Result (July 26, 1998). We grant the motion to supplement. We give the abstract little weight, but it is consistent with other evidence of APHIS' intent.

different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, purity, or labeling of SBC's licensed vaccines.[3] We cannot determine from the record on appeal whether plaintiffs' claims are entirely preempted. These kinds of preemption issues "require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope" of the federal regime. Medtronic, 518 U.S. at 500. Such an analysis may result in total or only partial preemption. Compare Lynnbrook Farms, 79 F.3d at 630, with Gresham v. Boehringer Ingelheim Animal Health, Inc., 1996 WL 751126 at *3 (N.D. Ga. Aug. 7, 1996); see also National Bank of Commerce of El Dorado v. Kimberly-Clark Corp., 38 F.3d 988, 994 n.4 (8th Cir. 1994) ("actual [federal] agency approval eliminates any possible claims under state tort law for failure to comply with federal requirements"). Therefore, we reverse in part the district court's order of December 10, 1997, and remand the case for further proceedings not inconsistent with this opinion.

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[3]Plaintiffs argue that preemption would violate the APHIS declaration that its 1992 final rule was "not intended to have retroactive affect" because plaintiffs started using the SBC vaccines before the rule's effective date. 57 Fed. Reg. at 38,759. We disagree. Even assuming the retroactivity comment applied to the agency's preemption declaration, and not simply to the amendments to 9 C.F.R. § 102.5, there is no retroactive effect in this case because plaintiffs did not file suit until long after September 1992. We must apply the law now in effect to plaintiffs' tort and implied warranty claims because plaintiffs had no vested rights in these unasserted claims at the time VSTA preemption was modified. See Landgraf v. USI Film Products, 511 U.S. 244, 269, 273 (1994); In re TMI, 89 F.3d 1106, 1113 (3d Cir. 1996), cert. denied, 117 S. Ct. 739 (1997); Hammond v. United States, 786 F.2d 8, 12 (1st Cir. 1986).