7-15-1999

Hawkins v. Leslie Pool Mart Inc

Filed July 15, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 98-5229

DAWN-MARIE HAWKINS; JAMES E. HAWKINS,

Appellants

v.

LESLIE'S POOL MART, INC.

APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

(D.C. No. 96-cv-01869)
District Judge: The Honorable Mary Little Cooper

ARGUED March 9, 1999

BEFORE: MANSMANN, SCIRICA, and NYGAARD,
Circuit Judges.

(Filed July 15, 1999)

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OPINION OF THE COURT

NYGAARD, Circuit Judge.

Appellants Dawn-Marie and James Hawkins (referred to collectively as Hawkins) appeal the District Court's summary judgment. It had concluded that Hawkins's claims that Leslie's Pool Mart (1) negligently failed "to provide adequate directions or precautions regarding the opening, closing and/or storage of the package containing the product" and (2) negligently failed "to package the product in a manner adequate to prevent excessive chemical decomposition, contamination, combustion, or generation of fumes and gases" were preempted by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. S 136 et seq. We have jurisdiction under 28 U.S.C. S 1291 and will exercise plenary review to determine whether "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact" such that Leslie's Pool Mart is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; see Olson v. General Elec. Astrospace, 101 F.3d 947, 951 (3d Cir. 1996). We will affirm in part and reverse in part.

I.

Dawn-Marie Hawkins suffered a burning sensation in her throat and lungs, and breathing difficulty when she opened a container of Leslie's Chlorinator Tablets 1<!DAG> purchased from Leslie's Pool Mart. Hawkins filed a diversity action in federal court against Leslie's Pool Mart alleging negligence, strict liability, breach of warranty and loss of consortium. Germane to this appeal, Hawkins asserts that Leslie's Pool Mart:

* failed to warn of sudden decomposition and chemical reactions which could generate harmful fumes;

* failed to provide adequate directions regarding the opening, closing and/or storage of the container; and

* failed to package the product in a manner adequate to prevent excessive decomposition contamination, combustion, or generation of fumes.

Compl. PP 9, 18, 21, 22 and 25; App. 2a-6a.

The District Court employed the preemption analysis established by the Supreme Court in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S. Ct. 2608 (1992), and held that Hawkins's failure to warn claims, failure to provide adequate directions claims and failure to adequately package the product claims were preempted by FIFRA. The District Court reasoned that imposing liability would require Leslie's Pool Mart to alter the label and packaging approved by the Environmental Protection Agency (EPA). Hawkins appeals, relying on the Supreme Court's most recent case on preemption, Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240 (1996).

On appeal, Hawkins first argues that FIFRA neither requires directions for opening a package nor information about the chemical reactivity of a pesticide be included therein. Appellant's Br. at 12. Second, she suggests that directions on a container's lid are neither required or approved under FIFRA nor are they registered with the EPA. Third, she asserts that FIFRA's regulations concerning directions for use are general, and therefore, her claims do not impose requirements that are in addition to, or different from, FIFRA's. As to Hawkins's defective/negligent packaging claim, she argues that because the EPA has regulated packaging only in the area of child-resistant packaging, her claim for defective packaging is not preempted. We will affirm as to the labeling based claims but reverse as to the packaging claim.

II.

Preemption is based on the Supremacy Clause. See U.S. Const. art. VI, cl. 2 ("This Constitution, and the Laws of the

United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any thing in the Constitution or Laws of any State to the contrary notwithstanding."). The doctrine preempts state laws that conflict with or are contrary to federal law. See Cipollone, 505 U.S. at 516, 112 S. Ct. at 2617. There are three types of preemption: express, implied and conflict preemption. However, these "categories are not `rigidly distinct.' " Gade v. National Solid Wastes Management Ass'n, 505 U.S. 88, 104 n.2, 112 S. Ct. 2374, 2386 n.2 (1992) (quoting English v. General Elec. Co., 496 U.S. 72, 79 n.5, 110 S. Ct. 2270, 2275 n.5 (1990)). Here, the language of FIFRA expressly preempts state law.

The preemptive provision of FIFRA states:

> S 136v. Authority of States
>
> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. S 136v.

Even though "the pre-emptive language of [section 136v] means that we need not go beyond that language to determine whether Congress intended [FIFRA] to pre-empt at least some state law, we must nonetheless `identify the domain expressly pre-empted.' " Medtronic, 518 U.S. at 484, 116 S. Ct. at 2250 (quoting Cipollone, 505 U.S. at 517, 112 S. Ct. at 2618). To do so, we "begin with [the statute's] text" as "informed by two presumptions about the nature of preemption." Id. at 484-85, 116 S. Ct. at 2250 (citing Gade, 505 U.S. at 111, 112 S. Ct. at 2389-90 (Kennedy, J., concurring in part and concurring in judgment)). Thefirst presumption is " `that the historic police powers of the

States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' " Id. at 485, 116 S. Ct. at 2250 (quoting Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230, 67 S. Ct. 1146, 1152 (1947)). The second long-standing presumption is that " `the purpose of Congress is the ultimate touchstone' in every pre-emption case." Id., 116 S. Ct. at 2250 (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103, 84 S. Ct. 219, 222 (1963)). Therefore, a proper analysis of a statute's preemptive scope "rest[s] primarily on`a fair understanding of congressional purpose' " as "discerned from the language . . . and the `statutory framework.' " Id. at 485-86, 116 S. Ct. at 2250-51 (quoting Cipollone, 505 U.S. at 530 n.27, 112 S. Ct. at 2624 n.27, and Gade, 505 U.S. at 111, 112 S. Ct. at 2390 (Kennedy, J., concurring in part and concurring in judgment)).

A proper analysis must also consider "the `structure and purpose of the statute as a whole,' as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." Id. at 486, 116 S. Ct. at 2251 (quoting Gade, 505 U.S. at 98, 112 S. Ct. at 2383).

In Wisconsin Public Intervenor v. Mortier, the Supreme Court concluded that section 136v of FIFRA resulted in a "narrow preemptive overlap" and that Congress did not intend "to occupy the entire field of pesticide regulation." 501 U.S. 597, 613, 111 S. Ct. 2486 (1991). The Supreme Court observed, albeit in dicta, that although FIFRA was "a comprehensive regulatory statute," the preemption provision was narrow and preempted state regulation of labeling. Id. at 601, 111 S. Ct. at 2480 (quoting Ruckleshaus v. Monsanto Co., 467 U.S. 986, 991, 104 S. Ct. 2862, 2867 (1984)). This conclusion is supported by the House Committee Report on the 1972 amendments to FIFRA. The Report notes that "[i]n dividing the responsibility between the States and the Federal government for the management of an effective pesticide program, the Committee has adopted language which is intended to completely preempt State authority in regard to labeling and packaging." H.R. Rep. No. 92-511, at 16 (1971).

However, the pre-emptive effect of FIFRA is dependent on agency regulations. See id. at 1 (explaining that "[t]he Federal Government sets the program standards the States must meet. State authority to change Federal Labeling and packaging is completely preempted" and noting that the EPA has "[g]eneral authority . . . to write regulations to carry out the Act and recognize the use of specialty chemicals"); 7 U.S.C. S 136v(a) (permitting state regulation of pesticides "but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter"); id. S 136v(b) (prohibiting state imposed labeling or packaging requirements that are "in addition to or different from those required under this subchapter").

We therefore begin by noting that FIFRA expressly preempts state imposed requirements in the areas of labeling and packaging that are "in addition to or different from those required" by the EPA. 7 U.S.C. S 136v(b). We also note that the term "requirements" in section 136v includes not only state statutory law but also state common-law damages claims. See Medtronic, 518 U.S. at 487-88, 116 S. Ct. at 2251; see also Cipollone, 505 U.S. at 521, 112 S. Ct. at 2620 (concluding that the term "requirements" "sweeps broadly" and"easily encompass[es] obligations that take the form of common-law rules" and that an award of damages can be " `a potent method of governing conduct and controlling policy' " (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247, 79 S. Ct. 773, 780 (1959))). However, that does not in turn automatically preclude all state common-law damages claims. As the Supreme Court observed in Medtronic, "if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it." 518 U.S. at 487, 116 S. Ct. at 2251. The word " `requirement' appears to presume that the State is imposing a specific duty upon the manufacturer." Id., 116 S. Ct. at 2251. If Congress's true intention was to preclude all common law causes of action, it could have stated that all remedies, rather than requirements, under state law pertaining to pesticides, fungicides and rodenticides are precluded. Cf. id. at 487-88, 116 S. Ct. at 2251.

A. Labeling Claims

Although FIFRA's language is fairly general as to some aspects of pesticide regulation, EPA rules and regulations

set forth specific labeling requirements. See 40 C.F.R. S 156.10; Lewis v. American Cyanamid Co. , 715 A.2d 967, 973 (N.J. 1998) (noting that "[a]lthough FIFRA does not prescribe the exact contents of labels, manufacturers are not free . . . to create pesticide labels in any manner they choose. . . . FIFRA cannot impose a specific requirement for warning labels like the 1969 Cigarette Act because FIFRA regulates a wide variety of products that cannot be serviced by a single statement."). The EPA requirements address, inter alia, label contents and proper label placement. Required warning and precautionary statements are based in part, on the toxicity of the pesticide. The EPA has established "typical precautionary statements" for the different categories of toxicity. 40 C.F.R.S 156.10(h)(2)(i)(B). However, "[t]hese statements must be modified or expanded to reflect specific hazards." Id. Thus, Hawkins's claim that Leslie's Pool Mart failed to warn of sudden decomposition and sudden reactivity of the pesticide is, on its face, preempted by the pesticide-specific labeling requirements established by the EPA.

Hawkins contends that her "claims based on failure to provide adequate directions for opening and closing the container are not preempted because they do not impose requirements that are different from or in addition to federal requirements." Appellant's Br. at 6. We disagree.

First, " `labeling' means all labels and all other written, printed, or graphic matter . . . accompanying the pesticide or device at any time." 7 U.S.C. S 136(p)(2) (emphasis added). Thus, a plain reading of the statute reveals that Congress intended the term "labeling" to include all printed matter--whether appearing on a front or back "label" or some other portion of the container. Hawkins attempts to make the distinction that her claim is based not on the label, but on instructions placed on the lid of the container. We reject such a hair-splitting reading of the statute, and instead conclude that, under a literal reading of FIFRA, labeling requirements include any and all printed matter that "accompan[ies] the pesticide." Id.

Hawkins also argues that "[t]he applicability of [Medtronic's] logic to this case is inescapable" because the language of FIFRA "is virtually identical" to that of the

Medical Device Amendments.1 Appellant's Br. at 11. However, even assuming that FIFRA is analogous to the Medical Device Amendments addressed by the Supreme Court in Medtronic, contrary to Hawkins's assertions, we do not read that case as standing for the overarching premise that tort claims fall outside "preempted requirements." Further, the Court's holding in Medtronic does not alter our analysis as to Hawkins's labeling-based claims. In Medtronic, the Food and Drug Administration approved a pacemaker device without performing an extensive evaluation. See 518 U.S. at 480, 116 S. Ct. at 2248. In stark contrast, here the EPA withheld approval of the chlorinator tablets and accompanying labels until Leslie's Pool Mart incorporated specific labeling language mandated by the EPA. For example, in 1975, the EPA approved the following language for Leslie's chlorinator tablets 1<!DAG> labels and warning:

> DANGER: KEEP OUT OF REACH OF CHILDREN.
>
> Corrosive, causes eye damage. May be fatal if swallowed. Do not get in eyes, on skin or on clothing. Irritating to nose and throat. Avoid breathing dust. May cause burns to broken skin. Wash hands after handling.
>
> DANGER: STRONG OXIDIZING AGENT.

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1. The preemptive provision of the Medical Device Amendments Act states in pertinent part:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different form, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the ddAdevice or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. S 360k(a). Subchapter (b) then lists the exempted requirements. See id. S 360k(b).

> Mix only with water. Use clean dry utensils. Contamination by moisture, organic matter, or other chemicals may liberate hazardous gases. Store in cool, dry, well-ventilated area away form heat or openflame. Decomposes at 350F with liberation of harmful gases. In case of decomposition, if possible, isolate container in open air. Flood with large amounts of water. Keep container tightly closed when not in use. Rinse empty container thoroughly with water to dissolve all material before discarding.

App. at 15a (emphasis added). In 1988, the EPA notified Leslie's Pool Mart that its labeling was unacceptable and needed to be revised to read as follows:

> Danger: corrosive. Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles and rubber gloves when handling. Harmful if swallowed. Avoid breathing dust. Wash thoroughly with soap and water after handling.

App. 35a (emphasis added). Finally, in 1994, the EPA again changed the wording requirements to read:

> CORROSIVE: Causes irreversible eye damage and skin burns. May be fatal if absorbed through skin. May be fatal if inhaled. Do not breathe dust or spray mists. Irritating to nose and throat. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing and rubber gloves when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

App. 58a (emphasis added).

Additionally, in 1994, the EPA approved the following language concerning the storage and disposal of the chlorinator tablets:

> STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Keep product dry in tightly closed container when not in use. Store in cool dry, well ventilated area away from heat or openflame . . .

app. at 38a (emphasis added), and the following precautionary statements under the heading "Physical or Chemical Hazards: Strong Oxidizing Agent":

> Mix only with water. Use clean dry utensils. Do not add this product to any dispensing device containing remnants of any other product. Such use may cause a violent reaction leading to fire or explosion. Contamination with moisture, organic matter, or other chemicals may start a chemical reaction, with generation of heat, liberation of hazardous gases, and possible generation of fire and explosion. In case of contamination or decomposition, do not reseal container. If possible isolate container in open air or well ventilated area. Flood with large volumes of water if necessary.

Id. (emphasis added). The Record shows that each time the EPA evaluated the labels and made recommendations pertaining to the language on the labels, Leslie's Pool Mart cooperated with the EPA and changed the labels as instructed.

"In sum, the EPA's requirements for labeling pesticides are sufficiently specific to mandate preemption of claims based on state statutes or common law." Lewis, 715 A.2d at 973; see also Taylor AG Indus. v. Pure-Gro, 54 F.3d 555, 560 (9th Cir. 1995) ("[U]nder 7 U.S.C. S 136a(c)(5), the EPA approves each label only after a careful review of the product data and the draft label. FIFRA cannot impose a specific language requirement for warning labels like the 1969 Cigarette Act because FIFRA regulates a wide variety of products that cannot be serviced by a single statement."). The EPA categorizes each pesticide according to its toxicity and then sets forth the warning language required on the pesticide's label. See Lewis, 715 A.2d at 973. FIFRA disallows any changes to an EPA-approved label unless the EPA approves the change. This absolute control of labeling regulation indicates that Hawkins's claim that labeling different from that approved by the EPA should have been included on the container is preempted.2

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2. This conclusion "comports with the decisions of an overwhelming majority of federal and state courts that have interpreted the extent of

Moreover, Hawkins mischaracterizes the EPA labeling requirements concerning directions for use. We agree that the General Requirements are just that--general. 3 The

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FIFRA preemption in light of Medtronic." Lewis, 715 A.2d at 973 (citing Kuiper v. American Cyanamid Co., 131 F.3d 656, 662 (7th Cir. 1997), and Grenier v. Vermont Log Bldgs., Inc., 96 F.3d 559, 563-64 (1st Cir. 1996)); see, e.g., Taylor AG Indus., 54 F.3d at 561; Welchert v. American Cyanamid, Inc., 59 F.3d 69, 73 (8th Cir. 1995); Lowe v. Sporicidin Int'l, 47 F.3d 124, 129 (4th Cir. 1995); MacDonald v. Monsanto Co., 27 F.3d 1021, 1025 (5th Cir. 1994); Papas v. Upjohn Co. , 985 F.2d 516, 518 (11th Cir. 1993); Arkansas-Platte & Gule Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1177, 1179 (10th Cir. 1993).

3. The General Requirements mandate:

> (i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide.
>
> When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.
>
> (ii) Placement of directions for use. Directions may appear on any portion of the label provided that the are conspicuous enough to be easily read by the user of the pesticide product
>
> . . .
>
> (2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use"
>
> (i) The statement of use classification . . .
>
> (ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling"
>
> . . .
>
> (ix) specific directions concerning the storage and disposal of the pesticide and its container . . . . These instructions shall be grouped and appear under the heading "Storage and disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning
>
> (x)(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the

environment.

40 CFR S 156.10.

record, however, makes clear that the EPA scrutinized Leslie's Pool Mart's proposed labels, and withheld approval until the required language was incorporated. Therefore, we agree with Leslie's Pool Mart's observation that"[h]ad the EPA felt that additional language on the opening, closing, storage or use of the tablets was necessary, it would have required that Leslie's include such language." Appellee's Br. at 19 n.7.

Finally, Hawkins asserts that her labeling claims relate to areas not addressed by FIFRA or the EPA regulations because "[n]owhere do the regulations address the appropriate directions for opening a package in any given condition." Appellant's Br. at 12. We disagree. The EPA-mandated and approved language on the labels specifically instructed the user on protective actions to take when opening the container and using the pesticide. Among the federal requirements are directions for the proper storage and disposal of the product and the potential reactivity of the product. These instructions necessarily implicate "opening instructions." Although the approved instructions and warnings do not specify how the user is to pry the lid off the container, they do instruct the user to avoid breathing any fumes and to wear protective clothing and a face shield or eye goggles. Again, the comprehensiveness of the regulations leads us to conclude that Hawkins's labeling claims are preempted. To hold otherwise would be to impose labeling requirements additional to those mandated by the EPA. See Welchert v. American Cyanamid, Inc., 59 F.3d 69, 73 (8th Cir. 1995) ("Where Congress has so clearly put pesticide labeling regulation in the hands of the EPA, [a] claim challenging the accuracy of the . . . label's federally-mandated and approved statement cannot survive. To hold otherwise would be to allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations.").

B. Defective Packaging Claims

Hawkins also alleges that Leslie's Pool Mart "negligent[ly] fail[ed] to package the product in a manner adequate to prevent excessive chemical decomposition, contamination,

combustion, or generation of fumes and gases." Compl. P 18(c); App. at 4a. During oral argument, Hawkins contended that Leslie's Pool Mart's failure to individually wrap the chlorinator tablets facilitated the generation of fumes. The District Court read section 136v as preempting all state law claims based on packaging and labeling. Accordingly, the District Court granted summary judgment for Leslie's Pool Mart. On appeal, Hawkins asserts that because the only area of packaging the EPA has regulated is child-resistant packaging, her claims alleging inadequate packaging would not impose a requirement in addition to, or different from, federal packaging requirements. Therefore, Hawkins argues, the preemption doctrine does not apply.

Leslie's Pool Mart responds that the EPA's limited exercise of authority is of no consequence to the broad preemptive scope of FIFRA. Leslie's Pool Mart argues that because section 136v specifically mentions state imposed labeling and packaging requirements, these areas are the "exclusive domain" of the federal government and any state requirement concerning labeling or packaging is preempted. Thus, our task is to determine whether the scope of federal preemption of packaging claims under FIFRA is limited to the discrete area of child-resistant packaging when the EPA has not evaluated and approved the packaging methods in dispute.

Once again, we begin our preemption analysis by identifying the domain preempted. When identifying the domain preempted, we first acknowledge that the text of FIFRA makes it clear that the EPA has authority to regulate all aspects of packaging. See 7 U.S.C. S 136q(e) (stating that the Administrator of the EPA "shall . . . promulgate regulations for the design of pesticide containers that will promote safe storage and disposal of pesticides"); id. S 136w(a)(1) (authorizing the Administrator of the EPA "to prescribe regulations to carry out the provisions of[FIFRA]"; id. S 136w(c)(3) (authorizing the Administrator of the EPA "to establish standards . . . with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting

from accidental ingestion or contact with pesticides or devices regulated by this subchapter as well as to accomplish the other purposes of this subchapter"). We also consult FIFRA's legislative history to glean Congress's intent. The legislative history notes that "Subsection (b) [of section 136v] preempts any State labeling or packaging requirements differing from such requirements under the Act." Sen. Rep. No. 92-838 (1972) reprinted in 1972 U.S.C.C.A.N. 3993, 4021 (emphasis added). It also allows for the inference that state and federal labeling and packaging requirements might coexist. See id. at 4111 (commenting that "[t]he amended language would prohibit local governments from imposing requirements as to labeling and packaging which differ from those imposed by Federal and State authorities (emphasis added)). Finally, we must also consider the appropriate EPA regulations because, as explained supra, the preemptive reach of FIFRA is dependent on agency regulations.

With these guideposts, we now turn to the pertinent federal statutes and regulations. In contrast to the numerous regulations and statutes governing pesticide labeling requirements, only one EPA regulation governs pesticide packaging. See 40 C.F.R. S 157.20. Section 157.20 states in pertinent part:

> This subpart prescribes requirements for child-resistant packaging of pesticide products and devices. The requirements are established under the authority of FIFRA section 25(a)(1)4, which authorizes the Administrator to issue regulations to carry out the purposes of the Act, and FIFRA section 25(c)(3) 5, which authorizes the Administrator to establish standards with respect to the package, container or wrapping in which a pesticide or device is enclosed in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated under the Act.

Id. Accordingly, despite a potentially broad scope of

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4. FIFRA section 25(a)(1) can be found at 7 U.S.C. S 136w(a)(1).

5. FIFRA section 25(c)(3) can be found at 7 U.S.C. S 136w(c)(3).

authority, the EPA has thus far limited its exercise of power to the area of child-resistant packaging. We conclude that this limited exercise of power is significant and seriously undermines Leslie's Pool Mart's argument. In sum, we hold that where, as here, a preemption provision is dependent on government regulations, we cannot extend the reach of that provision to areas not actively regulated by the federal government. In other words, the EPA's failure to promulgate packaging regulations outside the area of child-resistant packaging is fatal to Leslie's Pool Mart's preemption argument. When no federal packaging requirements have been established, logic dictates that a state law packaging requirement cannot be different from or in addition to the absent federal requirement. We believe this decision is consistent with the Supreme Court's recent pronouncement on preemption in Medtronic, 518 U.S. at 470, 116 S. Ct. at 2240 (1996).6

In Medtronic, the Court analyzed the preemptive effect of the Medical Device Amendments of 1976 on state law claims for common-law negligence and strict liability brought against the manufacturer of an allegedly defective pacemaker. See id. at 474, 116 S. Ct. at 2245. The Court concluded that defective design claims were not preempted even though the Food and Drug Administration approved the pacemaker. See id. at 492, 116 S. Ct. at 2254. The Court reached its decision after noting that the Food and Drug Administration "did not `require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the [premarket approval] process." Id. at 494-95, 116 S. Ct. at 2254. As such, the federal requirements did not reflect "an unambiguous conclusion" that was reached after a deliberate weighing of competing interests. Id. at 501, 116 S. Ct. at 2258. Rather, the requirements "reflect[ed] important but entirely generic concerns about device

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6. Our reliance on Medtronic should not be read as implying that the Supreme Court effectively overruled Cipollone. To the contrary, Cipollone remains good law and provides the basic background for preemption analysis.

regulation generally." Id., 116 S. Ct. at 2258. Therefore, the recipient's manufacturing and labeling based claims were not preempted. We read Medtronic as instructing that only when the "Federal Government has weighed the competing interests . . . [and] reached an unambiguous conclusion about how those competing considerations should be resolved in a particular cases . . . and implemented that conclusion via a specific mandate" are general state common-law claims preempted. Id., 116 S. Ct. at 2258.

Here, the record reveals no evidence that the EPA considered the packaging methods at issue. Additionally, it is undisputed that no federal requirements exist in the area of pesticide packaging, exclusive of child-resistant packaging. Accordingly, we will not infer that the EPA approved the packaging for the chlorinator tablets after weighing the competing interests and reaching an "unambiguous conclusion." Therefore, in keeping with the reasoning underlying the Supreme Court's decision in Medtronic, we conclude that allowing Hawkins's defective packaging claims would not impose state law requirements that are in addition to or different from federal regulations. We recognize that our holding might be viewed as conflicting with Lowe v. Sporicidin International, 47 F.3d 124, 129 (4th Cir. 1995), Worm v. American Cyanamid Co., 5 F.3d 744, 747 (4th Cir. 1993), and Papas v. Upjohn Co., 985 F.2d 516, 518 (11th Cir. 1993). However, none of these cases was decided after the Supreme Court's decision in Medtronic. Moreover, these cases do not stand for the blanket proposition that all packaging claims are preempted. In Lowe, the Fourth Circuit Court of Appeals limited its mention of defective packaging based claims to the comments that "any state law claim that would require the defendant to alter its EPA-approved warning label, labeling, or packaging to avoid liability is preempted." 47 F.3d at 129. In Worm, the court focused on failure to warn and labeling requirements, not design requirements. Similarly, the Eleventh Circuit Court of Appeals in Papas limited its discussion of defective packaging to labels and/or warnings located on the package and concluded that "to the extent [those] claims require a showing that [the defendant's] labeling or packaging `should have included additional, or more clearly stated, warnings, those

claims are pre-empted.' " 985 F.2d at 518 (quoting Cipollone, 505 U.S. at 524, 112 S. Ct. at 2621). 7

Except for these cases that peripherally mention preemption of packaging claims, no courts of appeal have addressed the preemptive reach of FIFRA to allegations of inadequate packaging. Despite Leslie's Pool Mart's contention that all packaging claims are preempted, we conclude that unless the EPA has specifically considered the packaging methods for a pesticide product, the domain preempted is the narrow area of child-resistant packaging. As such, Hawkins's claims for defective packaging are not preempted.

III.

The preemption provision of FIFRA, attendant EPA rules and regulations, and the Supreme Court's decision in Medtronic guide our analysis of whether the labeling and packaging based claims are preempted. Hawkins's claim that Leslie's Pool Mart failed to adequately warn about the sudden decomposition of chlorinator tablets is expressly preempted by EPA regulations. Further, Hawkins's claim that Leslie's Pool Mart failed to provide appropriate directions concerning the opening of the container falls within the realm of pesticide labeling. Because the EPA carefully reviewed all printed matter that accompanied the chlorinator tablets and even mandated specific language, allowing this claim would impose a state requirement in addition to or different from federal labeling regulations.

In contrast, the EPA has chosen to regulate only the area of child-resistant packaging. We are unwilling to hold that

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7. As an alternative argument, Leslie's Pool Mart contends that although Hawkins couches her claim as "defective packaging," it is actually a challenge to the sufficiency of the precautionary and warning statements contained on the labels and packaging and is therefore preempted by FIFRA. Appellee's Br. at 24. This argument is unavailing and Leslie's Pool Mart's interpretation of Hawkins's claim is misleading. The Complaint specifically accuses Leslie's Pool Mart of failing to package the
product in a manner adequate to prevent excessive decomposition, contamination, combustion, or generation of fumes. See Compl. P 18(c); App. 4a.

an area is preempted when the government has not acted in that particular area. Therefore, we will not construe the preemption provision of FIFRA so broadly as to preclude Hawkins's packaging based claims. Accordingly, we affirm that portion of the District Court's order that the labeling claims are preempted by FIFRA and reverse as to the packaging claims.

MANSMANN, Circuit Judge, dissenting.

Although I join in Parts I (except as to its affirmance as to labeling-based claims) and II(B) of the majority's opinion and agree with the majority's holding in Part II(A) that claims based on labeling actually reviewed and approved by the Environmental Protection Agency and claims based on matters addressed therein are preempted under the Federal Insecticide, Fungicide and Rodenticide Act, I must nonetheless dissent from the majority's determination that Plaintiffs-Appellants' (collectively, "Hawkins") claims based on opening directions on the top of the package are also preempted.

Hawkins contends that Mrs. Hawkins was injured as a result of following allegedly faulty opening instructions provided on the top of the container of pool chlorinator tablets supplied by Defendant-Appellee Leslie's Pool Mart ("Leslie's").1 The majority rejects Hawkins's attempt to distinguish these instructions from other package labeling as "hair-splitting" because, under FIFRA,"labeling" includes all "written, printed or graphic matter" accompanying the product, wherever it appears on the container.2 While it is undoubtedly true that the instructions on the top of the package constitute labeling and are subject to EPA regulation under FIFRA, I believe that the majority has misconstrued Hawkins's argument. Hawkins contends that claims based on the package top opening instructions escape preemption not because of the instructions' location but because they were never reviewed and approved by the EPA.

The majority appears to have rejected Hawkins's real argument concerning the opening instructions on factual, rather than legal, grounds. According to the majority, "[t]he

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1. The printed material on top of the container begins with the following:

TO OPEN:
PLACE COIN IN GROOVE -
PRY AND LIFT LID OFF

2. See Majority Opinion at p. 7 (rejecting Hawkins's "attempt[ ] to make the distinction that her claim is based not on the label, but on instructions placed on the lid of the container").

record . . . makes clear that the EPA scrutinized Leslie's Pool Mart's proposed labels . . . ." Majority Opinion at pp. 11-12; see also Majority Opinion at p. 17 ("[T]he EPA carefully reviewed all printed matter that accompanied the chlorinator tablets . . . .").3 There is, however, no demonstration in the record that the EPA reviewed and approved the package top instructions at issue. As the party with the burden of proof on its affirmative defense of preemption,4 Leslie's is responsible for this deficiency in the record. Cf. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 254 (1986) (on motion for summary judgment, evidence is to be read in light most favorable to the non-moving party).5 Moreover, Hawkins expressly asserts that the top opening instructions were not part of the EPA approved labeling,6 and Leslie's has not disputed this assertion.7

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3. But see Majority Opinion at p. 12 (acknowledging that "the approved instructions and warnings do not specify how the user is to pry the lid off the container").

4. See, e.g., Williams v. Ashland Eng'g Co., 45 F.3d 588, 592 n.7 (1st Cir.), cert. denied, 516 U.S. 807 (1995) (recognizing that federal preemption is affirmative defense as to which defendant has burden of proof).

5. See also Avirgan v. Hull, 691 F. Supp. 1357, 1368 (S.D. Fla. 1988) (when defendant moving for summary judgment bears burden of proof because he is asserting affirmative defense, "he must establish beyond peradventure all of the essential elements of the . . . defense to warrant judgment in his favor").

6. See Brief of Appellants at 12 (alleging that front and back EPA-registered labels do not refer to opening or closing, while the package lid
instructions - not registered with the EPA - do). Hawkins specifically asserts that "The allegedly defective directions on the lid are neither required nor approved under FIFRA, nor registered with EPA." Id.
7. Indeed, the documentation provided by Leslie's in its Appendix appears to support Hawkins's assertion. See Appendix at 13a-16a (Affidavit of Cynthia G. Watts, Leslie's Vice President and General Counsel, attaching as Exhibit A "a true and accurate copy of the original label for Leslie's Chlorinator Tablets 1<!DAG> approved by the EPA in August
1975"). Exhibit A consists of two pages (15a-16a)- the front and back labels of the container, each stamped as "ACCEPTED" under FIFRA on August 19, 1975; Appendix at 37a-39a (a portion of Exhibit C, correspondence from the EPA during Leslie's process of modifying and reregistering its labels, showing that Leslie's Certification with Respect to
Citation of Data submitted in its application for registration attached two

labels only – front and back); Appendix at 60a–62a (Exhibit E, the EPA's Notice of Reregistration issued on June 20, 1994, which again contains two labels only – front and back).

In the present posture of this case, i.e., on review of summary judgment, I believe we must assume that the package top instructions were not reviewed and approved by the EPA. Thus, EPA approval gave rise to requirements only with respect to the storage and general handling instructions on the approved labels. Because no statutory or regulatory provision governs the content of opening instructions, I would hold that in the absence of agency review and approval there is no applicable federal "requirement" to which a state law duty as to claims for faulty opening instructions may be different or additional, and therefore there is no preemption under FIFRA. 8 Moreover, as the majority indicates and as Leslie's concedes, the inclusion of unapproved labeling material - unilaterally added by the manufacturer - is itself a violation of FIFRA and its implementing regulations.9 State law causes of action which provide a remedy for conduct that violates FIFRA are not preempted. See, Worm v. American Cyanamid Co., 5 F.3d 744, 748 (4th Cir. 1993) ("If a state elects to recognize that a breach of a FIFRA-created duty forms the basis for a state remedy, . . . it is permitted to do so by 7 U.S.C. S 136v(b).").10 Cf. Medtronic, 518 U.S. at 495

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8. See Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (holding that preemption depends upon agency promulgation of a relevant requirement); see also Majority Opinion at p. 6 (explaining that "pre-emptive effect of FIFRA is dependent on agency regulations"); 7 U.S.C. S136v(b) (prohibiting state imposed labeling or packaging requirements that are "in addition to or different from those required under this subchapter").

9. See Brief of Appellee at 11 (citing 7 U.S.C. S 136j(a)(2)(A) and observing
that "Thus, no one in the chain of commerce is free to add additional warnings, information or instructions on its own after a particular label has been approved by the EPA."); see also Majority Opinion at p. 10 ("FIFRA disallows any changes to any EPA-approved label unless the EPA approves the change.").

10. See also Moss v. Parks Corp., 985 F.2d 736, 741 (4th Cir. 1993) (following Worm in concluding that FHSA does not preempt claim for non-compliance with federally mandated labeling requirements); Nat'l Bank of Commerce of El Dorado v. Kimberly-Clark Corp., 38 F.3d 988, 993 (8th Cir. 1994) ("We agree with the conclusions of the Worm and Moss courts and of the district courts cited above that when a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with federal requirements.").

("The presence of a damages remedy does not amount to the additional or different `requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing `requirements' under federal law.").

For these reasons, I believe that Hawkins should be permitted on remand to pursue claims based on the opening instructions if indeed they were not reviewed and approved by the EPA. I express no opinion on whether Hawkins would be able to establish that a defect in those instructions caused her injuries. Because I conclude, however, that FIFRA does not preempt such a claim in these circumstances, I respectfully dissent from this aspect of the majority's opinion.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit