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# What's in a Label? FIFRA Regulations and the Preemption of State Tort Claims of Label Misrepresentation

*Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.*<sup>1</sup>

## I. INTRODUCTION

Products available for purchase in the United States have labels which people read and rely upon for their accuracy. This is particularly true for products that are potentially dangerous like pesticides. However, contrary to intuition, it is not always clear what constitutes a label. Some courts have even expanded the definition of a label to include information that is not necessarily attached to the product. In fact, there is little authority that can provide guidance on how to determine what is a label. In New Jersey, a group of blueberry farmers relied on verbal and oral representations based on a marketing brochure made about a pesticide when determining what pesticide to purchase and use.<sup>2</sup> The issue in the case was whether that marketing brochure was considered a “label” or “labeling,” and the circuit court’s decision determined whether or not the Plaintiffs could bring their claims against the pesticide company for misrepresentation and fraud.

## II. FACTS AND HOLDING

The Plaintiffs, a group of blueberry farmers from New Jersey, sued Novartis Crop Protection, Inc. (“Novartis”) claiming a pesticide manufactured by Novartis damaged their blueberry crops.<sup>3</sup> For several years prior to this suit, the Plaintiffs purchased Novartis pesticides and mixed them with two fungicides<sup>4</sup> called Captan and Captec in a process called tank mixing.<sup>5</sup> In 1997, Novartis began marketing a new pesticide

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<sup>1</sup> 617 F.3d 207 (3d Cir. 2010).

<sup>2</sup> *Id.* at 210.

<sup>3</sup> *Id.* at 211.

<sup>4</sup> A Fungicide is “an agent that destroys fungi.” Webster’s School & Office Dictionary 185 (1<sup>st</sup> ed.1995).

<sup>5</sup> *Novartis*, 617 F.3d at 210. Tank mixing is the process of mixing the fungicides and insecticides together before spraying the plants. *Id.*

called Diazinon AG600 ("AG600") using a brochure which claimed the product was safer for plants and the environment than the older pesticides.<sup>6</sup> The brochure was sent to scientists and retailers in the area, who relayed to the farmers through the "Blueberry Bulletin"<sup>7</sup> and a "twilight meeting,"<sup>8</sup> that AG600 was an effective product for their blueberries.<sup>9</sup>

The Plaintiffs purchased and applied AG600 utilizing the same tank mixing process they had applied to the older pesticides.<sup>10</sup> However, the farmer's blueberry plants that year suffered many problems and defects including plant death, blotches and spots.<sup>11</sup> They sued Novartis claiming the new pesticide caused these problems with the plants because of an ionic surfactant<sup>12</sup> not found in the older pesticides Novartis produced.<sup>13</sup> The farmers contend they did not know about the surfactant and had they known about this change to the pesticide, they would not have mixed it with the fungicides, due to incompatibility between the products.

The Plaintiffs sued Novartis in the District Court of New Jersey in 1999 for damages based on five claims: (1) strict liability under the New Jersey Products Liability Act ("NJPLA") for a design defect contending Novartis did not warn purchasers that if the pesticide was mixed with a fungicide it could damage crops; (2) negligence because Novartis did not adequately test AG600 before selling it; (3) negligent misrepresentation/fraud because Novartis advertised the product as safer and having no adverse effects on plants even though they should have known that it was potentially hazardous; (4) breach of the New Jersey Consumer Fraud Act ("NJCFA") because Novartis said the product was safe for blueberry plants; and (5) a breach of express warranty because

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<sup>6</sup> *Id.* at 210-11.

<sup>7</sup> *Id.* at 211. The Blueberry Bulletin is a newsletter published by Rutgers University.

<sup>8</sup> The twilight meeting was a meeting of scientists and farmers to discuss the new pesticide. *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 210.

<sup>11</sup> *Id.* at 211.

<sup>12</sup> Surfactant is defined by the court as a "surface-active agent" which helps the active ingredients in the pesticide to spread evenly across the plant. *Id.* at 211 n.2.

<sup>13</sup> *Id.* at 211.

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Novartis warranted on its label that AG600 would not injure plants.<sup>14</sup> Novartis filed for summary judgment claiming that the Federal Insecticide, Fungicide and Rodenticide Act<sup>15</sup> (“FIFRA”) preempted all of the Plaintiffs’ claims.<sup>16</sup> The District Court granted summary judgment for Novartis on each of the Plaintiffs’ claims and the Plaintiffs appealed.<sup>17</sup>

On appeal, the Third Circuit Court of Appeals determined the Plaintiffs’ claims for strict liability, negligence and breach of express warranty were not preempted by FIFRA and reversed the summary judgment for those claims.<sup>18</sup> However, the court remanded the two claims of negligent misrepresentation/fraud and violation of the NJCFA to the district court to determine whether the misrepresentations were oral or written.<sup>19</sup>

On remand, the district court granted summary judgment for Novartis on all of the Plaintiffs’ claims.<sup>20</sup> The district court held that the claims for negligent misrepresentation/fraud and the claim of a violation of the NJCFA based on the written material in the brochure were preempted by FIFRA because the brochure counted as “labeling” and therefore could not be attacked.<sup>21</sup> They also held that even if the claims were not preempted, the summary judgment still applied because the Plaintiffs never obtained or used any other written material about the product before purchasing and applying it.<sup>22</sup> The district court determined that to the extent the negligent misrepresentation/fraud and NJCFA claims were based on oral representations about the product, there was no claim because Novartis never made any oral representations about the product.<sup>23</sup>

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<sup>14</sup> *Id.* at 211–12.

<sup>15</sup> FIFRA is the system of regulation of the use, sale, and labeling of pesticides in the United States. *Id.* at 214.

<sup>16</sup> *Id.* at 212.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* This decision was based on *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) in which the Supreme Court determined the scope of FIFRA preemption.

<sup>19</sup> *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.*, 617 F.3d 207, 212 (3d Cir. 2010).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* (citing *Indian Brand Farms, Inc. v. Novartis Crop Protection, Inc.*, No. 99-2118, 2007 WL 4571087, at 7n. 5 (D.N.J. 2007)).

<sup>23</sup> *Id.*

As for the strict liability claim for failure to warn, the district court concluded it was preempted under FIFRA because success on the claim would introduce a new labeling requirement that goes further than the requirements set forth in FIFRA.<sup>24</sup>

Finally, with respect to the pesticide design defect claim that Novartis should have known about, the district court concluded that testing for chemical interactions was unnecessary because there were too many possible combinations of chemicals to test, and thus “tank mixing” was not reasonably foreseeable.<sup>25</sup> The Plaintiffs then appealed again to the Third Circuit Court of Appeals.<sup>26</sup>

On this second appeal, the appellate court considered all five of the Plaintiffs’ claims individually and held that the district court erred when it decided Novartis’s brochure qualified as “labeling” under FIFRA. Therefore, the claims of negligent misrepresentation/fraud and violation of the NJCFA were not preempted by FIFRA,<sup>27</sup> and the court reversed the grant of summary judgment for those issues.<sup>28</sup> However, that reversal only applied to the written representations made by Novartis, namely the brochure, and not to the oral representations.<sup>29</sup> Regarding these claims of oral misrepresentation, the circuit court affirmed the summary judgment granted by the lower court.<sup>30</sup> The circuit court reversed the district court’s summary judgment as to the failure to warn claims.<sup>31</sup> Finally, concerning the claim regarding the alleged design defect in the product, the circuit court reversed the summary judgment granted to Novartis because the evidence had shown the risk of harm was foreseeable and the damage could have been avoided with a pesticide that did not have an ionic surfactant.<sup>32</sup>

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<sup>24</sup> *Id.* (citing *Indian Brand Farms*, 2007 WL 4571087, at 9).

<sup>25</sup> *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.*, 617 F.3d 207, 212–13 (3d Cir. 2010).

<sup>26</sup> *Id.* at 213.

<sup>27</sup> *Id.* at 217.

<sup>28</sup> *Id.* at 220–21.

<sup>29</sup> *Id.* at 220–21.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 225.

<sup>32</sup> *Id.* at 228.

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Thus, the Third Circuit Court of Appeals reversed and remanded all findings, except for the summary judgment granted for Novartis against Indian Brand Farms, one specific group of farmers, because there was no proof any oral representations were made or relied upon.<sup>33</sup>

### III. LEGAL BACKGROUND

#### A. FIFRA Regulations

The FIFRA statutes present a series of regulations stipulating what pesticides may be sold on the market and explaining all the requirements pesticides must meet before being sold.<sup>34</sup> Under FIFRA regulations each pesticide must be registered with FIFRA to determine if it effectively does what the manufacturer claims, to verify its label complies with FIFRA's prohibition on misbranding, and to ensure it will not harm the environment "when used with widespread and commonly recognized practice."<sup>35</sup>

There are several ways a pesticide can be misbranded, all due to label inadequacy. The "label" refers to "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers."<sup>36</sup> Under FIFRA, a pesticide is misbranded if its label has a "false or misleading" statement.<sup>37</sup> A pesticide is also misbranded if its label does not have adequate instructions for use of the product or it fails to caution a consumer of possible dangers.<sup>38</sup> It may be misbranded if the label does not contain an "ingredient statement" on the package.<sup>39</sup> The ingredient statement must contain all active and inert (inactive) ingredients and their percentages.<sup>40</sup> Manufacturers are responsible for complying with the requirements of every FIFRA regulation, and it is illegal to sell any pesticide that is misbranded.<sup>41</sup>

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<sup>33</sup> *Id.* at 229.

<sup>34</sup> *Id.* at 214 (citing 7 U.S.C. § 136a(c)(1)(C), (F) (2006)).

<sup>35</sup> 7 U.S.C. § 136a(c)(5)(A)–(D) (2006).

<sup>36</sup> 7 U.S.C. § 136(p)(1).

<sup>37</sup> 7 U.S.C. § 136(q)(1)(A).

<sup>38</sup> 7 U.S.C. § 136 (q)(1)(F)–(G).

<sup>39</sup> 7 U.S.C. § 136(q)(2)(A).

<sup>40</sup> 7 U.S.C. § 136(m)–(n).

<sup>41</sup> 7 U.S.C. § 136j(a)(1)(E) (2006).

Prior to FIFRA's passing, each state individually regulated pesticides. However, FIFRA was enacted to create uniform federal regulations on the use of pesticides.<sup>42</sup> Under FIFRA, states can continue regulating the use and sale of pesticides registered with the Environmental Protection Agency ("EPA"), but they cannot allow pesticides that are prohibited by the EPA to be used or sold in the state.<sup>43</sup> States also cannot create or enforce labeling requirements different from, or in addition to, the requirements of the Act.<sup>44</sup> Therefore, while the states share control of the sale and use of pesticides with the federal government, the EPA, via the FIFRA regulations, has exclusive control of the labeling requirements and can prevent a state from changing or adding to the requirements laid out in FIFRA.<sup>45</sup> Under these rules, the federal regulations can only preempt the state rules regarding labeling if two conditions are met: first, the state requirement must be "for labeling or packaging," and second, these requirements must be "in addition to or different from" the requirements established under FIFRA.<sup>46</sup>

### B. *Relevant State Laws*

In New Jersey, the state law regulating the adequacy of labels states only that the manufacturer of the product is liable for damages if the product "failed to contain adequate warnings or instructions."<sup>47</sup> Under the state law, if the plaintiff brings an action for fraud because the label was inadequate, the plaintiff must only prove five elements: "(1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5)

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<sup>42</sup> Ann K. Wooster, Annotation, *Federal Preemption of State Common-Law and Statutory Claims Pertaining to Herbicides*, 2 A.L.R. FED. 2d 265, § 2 (2005).

<sup>43</sup> 7 U.S.C. § 136v(a) (2006).

<sup>44</sup> 7 U.S.C. § 136v(b).

<sup>45</sup> *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.*, 617 F.3d 207, 214 (3d Cir. 2010) (citing 7 U.S.C. § 136v(b) (2006)).

<sup>46</sup> *Id.* (citing 7 U.S.C. § 136(v)(b) (2006)).

<sup>47</sup> N.J. STAT. ANN. § 2A:58C-2 (2000). The Court of Appeals for the Fifth Circuit compared these regulations to the FIFRA regulations. *Novartis*, 617 F.3d at 222–223.

resulting damages.”<sup>48</sup> Similarly, when trying to prove a claim of negligent misrepresentation, the plaintiff must show there was “an incorrect statement, negligently made and justifiably relied upon, [and] may be the basis for recovery of damages for economic loss . . . sustained as a consequence of that reliance.”<sup>49</sup>

When trying to prove reliance under either of these causes of action under New Jersey state law, it is sufficient if the plaintiff shows “indirect reliance,” which “allows a plaintiff to prove a fraud action when he or she heard a statement not from the party that defrauded him or her but from that party’s agent or from someone to whom the party communicated the false statement with the intention that the victim hear it, rely on it, and act to his or her detriment.”<sup>50</sup>

### C. Federal Preemption of Claims Made Under State Statutes

The United States Supreme Court first encountered the issue of whether a local regulation is preempted by FIFRA in *Wisconsin Public Intervenor v. Mortier*.<sup>51</sup> In *Mortier*, the issue was whether FIFRA preempted a local regulation that required people to get a permit in order to apply pesticides to public land, to private land used by the public, or for the application of pesticides to private land by airplanes.<sup>52</sup> The Court noted the Supremacy Clause of the Constitution declares state laws invalid if they “interfere with or are contrary to the laws of congress.”<sup>53</sup> However, the Court previously ruled the only way federal regulations preempt state laws is through explicit preemptive language, or if the regulation is written so there is clearly no allowance for state rules to also apply.<sup>54</sup> Additionally, preemption occurs when federal and state laws conflict.<sup>55</sup> Applying these well-established rules together with the text of

<sup>48</sup> *Novartis*, 617 F.3d at 218 (quoting *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 367 (N.J. 1997)).

<sup>49</sup> *Id.* (quoting *H. Rosenblum, Inc. v. Adler*, 461 A.2d 138, 142–43 (1983)).

<sup>50</sup> *Id.* (quoting *Kaufman v. I-Stat Corp.*, 754 A.2d 1188, 1195 (N.J. 2000)).

<sup>51</sup> 501 U.S. 597 (1991).

<sup>52</sup> *Id.* at 602–03.

<sup>53</sup> *Id.* at 604 (quoting *Gibbons v. Ogden*, 22 U.S. 1, 82 (1824)).

<sup>54</sup> *Id.* at 605 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

<sup>55</sup> *Id.* (citing *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)).



the statute itself<sup>56</sup> and the legislative history, the Supreme Court decided FIFRA did not preempt the state regulation of pesticide use, because FIFRA does not expressly dictate that it supersedes local or state regulations.<sup>57</sup>

The Supreme Court in *Bates v. Dow Agrosciences LLC*<sup>58</sup> clarified whether FIFRA regulations preempt state regulations for issues of claims for damages.<sup>59</sup> In *Bates*, a group of peanut farmers in Texas sued the manufacturer of a pesticide that they claim damaged their crops.<sup>60</sup> After considering the Court's previous decision in *Mortier* that "the statute leaves ample room for states and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a),"<sup>61</sup> the Court concluded that FIFRA does not prevent a state from making violations of FIFRA labeling provisions a state offense with state-imposed sanctions.<sup>62</sup> The Court concluded that since § 136v(b)<sup>63</sup> only prohibits states from adopting labeling requirements that are "in addition to or different from" FIFRA requirements, a state rule is not preempted as long as it is consistent or parallel to FIFRA regulations.<sup>64</sup> The Court adopted this "parallel requirements" for future use.<sup>65</sup>

#### IV. INSTANT DECISION

Upon reviewing the District Court's findings, the Third Circuit Court of Appeals made decisions on each of the Plaintiffs' claims in turn.

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<sup>56</sup> See 7 U.S.C. § 136v (2006) ((a) "[ . . . ] 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 of use prohibited by this subchapter." (b) "[ . . . ] 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.").

<sup>57</sup> *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 606 (1991).

<sup>58</sup> 544 U.S. 431 (2005).

<sup>59</sup> See *id.*

<sup>60</sup> *Id.* at 434.

<sup>61</sup> *Id.* at 441–42. (citing *Wis. Pub. Intervenor*, 501 U.S. at 613).

<sup>62</sup> *Id.* at 442.

<sup>63</sup> 7 U.S.C. § 136v(b) (2006).

<sup>64</sup> *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005).

<sup>65</sup> *Id.*

## WHAT'S IN A LABEL?

### A. *FIFRA Preemption Claim*

The court's first finding addressed the Plaintiffs' assertion that none of their claims against Novartis could be preempted by FIFRA regulations because the EPA, which enforces FIFRA regulations, waived its authority to have jurisdiction over pesticide efficacy issues.<sup>66</sup> The court concluded however, that the claims could be preempted for several reasons. The main reason was that the EPA did not waive its jurisdiction over *efficacy* issues because Congress had not authorized them to do so.<sup>67</sup> The EPA can only waive its authority to force companies to submit data requirements related to efficacy when registering a new pesticide.<sup>68</sup>

Secondly, the court concluded that while the efficacy claims could be preempted, the main issue in this case is not the efficacy of the pesticide, but its alleged labeling defects.<sup>69</sup> Therefore, because the case is not about efficacy but about mislabeling the Plaintiffs' claims about the alleged mislabeling of the product and their dependence on the written representations Novartis gave to them were not preempted.<sup>70</sup> The court then went on to discuss the Plaintiff's claims of negligent misrepresentation/fraud.

### B. *Negligent Misrepresentation/Fraud Claims*

The district court granted summary judgment in favor of Novartis on all of the Plaintiffs' fraud and negligent misrepresentation claims, but the Third Circuit reversed, finding it to be a material question of fact whether the Plaintiffs could show they relied on the brochure and other representations of Novartis in choosing the product and believing it safe for tank mixing.<sup>71</sup> First, the appellate court determined the marketing brochure Novartis gave to the retailers and to Rutgers University did not

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<sup>66</sup> *Indian Brand Farms, Inc. v. Novartis Crop. Prot. Inc.*, 617 F.3d 207, 213 (3d Cir. 2010).

<sup>67</sup> *Id.* at 213–14.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 214.

<sup>71</sup> *Id.* at 220–21. The Third Circuit did, however, affirm the district court's granting of summary judgment against Indian Farms. *Id.*

qualify as a “label” under FIFRA.<sup>72</sup> The brochure did not meet the requirements of a “label” because it was not on or attached to the product, but was distributed prior to sale.<sup>73</sup> Because the brochure did not constitute a label, the plaintiffs claims are not preempted by FIFRA regulations.<sup>74</sup>

However, the court concluded that the Plaintiffs could sustain a claim of fraudulent misrepresentation if they could show they relied on a written representation given by Novartis.<sup>75</sup> The brochure created by Novartis could constitute such a written representation.<sup>76</sup> In New Jersey, to establish fraud the Plaintiffs had to prove they reasonably relied on the representation<sup>77</sup> along with the other four elements.<sup>78</sup> Here, the element of reasonable reliance was in question because the Plaintiffs claimed they relied on written and oral representations made by Novartis.<sup>79</sup> The court determined that in order to prove reliance, it was enough for the Plaintiffs to show “indirect reliance.”<sup>80</sup> Indirect reliance occurs when a plaintiff can prove that the statement relied upon came not from the party directly, “but from that party’s agent or from someone to whom the party communicated the false statement with the intention that the victim hear it, rely on it, and act to his or her detriment.”<sup>81</sup>

Because the Plaintiffs could show they chose to use the product AG600 because they indirectly relied upon the marketing brochure, the recommendations of the product by Rutgers University scientists, the information given at the “twilight meeting,” and from reading an article

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<sup>72</sup> *Id.* at 216. A “label” under FIFRA is any “written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers. *Id.* (quoting 7 U.S.C. § 136(p)(1) (2006)).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 218.

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> There are five elements of fraud in New Jersey: “(1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages.” *Id.* (quoting *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 367 (N.J. 1997)).

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at 218–19.

<sup>80</sup> *Id.* at 218.

<sup>81</sup> *Id.* (quoting *Kaufman v. I-Stat Corp.*, 754 A.2d 1188, 1195 (N.J. 2000)).

about the product in the “Blueberry Bulletin,” the court determined that the Plaintiffs could make a claim for fraud and therefore have enough evidence to get past summary judgment.<sup>82</sup> This ruling only reversed the summary judgment on the fraud claims based on the written representations.<sup>83</sup> Because Plaintiffs could not show any specific oral representations Novartis made to them, the summary judgment against claims of oral misrepresentations was affirmed.<sup>84</sup>

### C. *Failure to Warn Claim*

The Plaintiffs also argued before the district court that Novartis was liable for the damage to the blueberry plants because Novartis failed to warn purchasers of the dangers of tank mixing.<sup>85</sup> The Plaintiffs claimed that Novartis’s failure to warn of the dangers was a violation of the FIFRA requirement that labels have sufficient warnings.<sup>86</sup> The circuit court first considered if this claim was preempted by FIFRA regulations.<sup>87</sup> The court determined that failure to warn claims are only preempted by the FIFRA regulations if a ruling in favor of the plaintiff would impose labeling requirements “in addition to or different from” the requirements in FIFRA.<sup>88</sup>

To establish whether the Plaintiffs’ failure to warn claim would impose new regulations, the court looked to the state law of New Jersey to determine what labeling requirements are necessary.<sup>89</sup> In New Jersey, a manufacturer is only liable for misbranding if the product “failed to contain adequate warnings or instructions.”<sup>90</sup> The court ascertained that the New Jersey legislation does not impose any new or inconsistent duty that is not imposed by FIFRA’s requirements of sufficient labeling.<sup>91</sup>

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<sup>82</sup> *Id.* at 220.

<sup>83</sup> *Id.* at 220–21.

<sup>84</sup> *Id.* at 221.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 221–22 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005)).

<sup>89</sup> *Id.* at 222.

<sup>90</sup> *Id.* (quoting N.J. STAT. ANN. § 2A:58C-2 (2000)).

<sup>91</sup> *Id.* at 222–23.

Because no new requirements would be imposed, the Plaintiffs' claims for failure to warn were not preempted by FIFRA. Since the claim was not preempted, the Plaintiffs were allowed to bring their claim and the summary judgment granted by the district court to Novartis had to be reversed.<sup>92</sup>

Novartis contended, however, that an EPA "Notice" discussing the policy of labeling for appropriateness of tank mixing, titled Revised Policy on Label Claims for Tank Mixing issued in 1982, indicates that manufacturers only have to warn of potential dangers of tank mixing if the company is holding the product out as appropriate for tank mixing.<sup>93</sup> The court concluded that the Notice did not apply for several reasons. For starters, there is a strong presumption against preemption of state law in failure to warn cases.<sup>94</sup> Additionally, the court noted the Notice was actually issued to applicators/purchasers of pesticides and was not technically related to the labeling requirements for manufacturers.<sup>95</sup>

However, regardless of what purchasers are expected to know about the products they buy, manufacturers are required to avoid misbranding.<sup>96</sup> The Plaintiffs' claims of failure to warn against Novartis were not preempted by FIFRA regulations because holding for the Plaintiffs would not impose any new or different standards of labeling on the Defendants. In view of the fact that Novartis could not show it had no duty to label, the Third Circuit reversed the summary judgment against failure to warn claims.<sup>97</sup>

#### D. Design Defect Claims

Finally, the Plaintiffs claimed the product AG600 was defectively designed because of the ionic surfactant, which caused the damage to the plants when tank mixed with the fungicides.<sup>98</sup> The district court granted summary judgment to Novartis on this claim, but the Third Circuit

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<sup>92</sup> *Id.* at 224–25.

<sup>93</sup> *Id.* at 223.

<sup>94</sup> *Id.* at 224 (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 225.

<sup>98</sup> *Id.*

reversed this decision, finding a genuine issue of material fact existed due to the evidence available.<sup>99</sup> The Third Circuit began by looking at New Jersey law about strict liability design defect claims and found the plaintiff must prove the product was not fit for a reasonably foreseeable purpose.<sup>100</sup> Whether a product was fit for a reasonably foreseeable purpose is decided by determining if the use to which it was put was “objectively foreseeable.”<sup>101</sup> Essentially, a defendant is not liable for damages caused by misuse unless the misuse was “objectively foreseeable.”<sup>102</sup> The court also noted that not all misuses are reasonably foreseeable, but misuses that are considered normal and not extraordinary are reasonably foreseeable.<sup>103</sup> In New Jersey, the determination as to whether a misuse of a product is objectively foreseeable is for a jury to decide.<sup>104</sup>

Next, the court determined there was sufficient evidence for a reasonable jury to find the misuse was foreseeable.<sup>105</sup> The court found four pieces of evidence that suggested the tank mixing was reasonably foreseeable.<sup>106</sup> First, based on the testimony of the Plaintiffs, tank mixing was almost inevitable because it is more economical for farmers to apply all products at once than to apply them one at a time.<sup>107</sup> Second, the Plaintiffs testified that tank mixing is a “common practice among farmers.”<sup>108</sup> Third, there was evidence that several groups of people, including product retailers and Rutgers University scientists, recommended that the farmers tank-mix AG600 with fungicides.<sup>109</sup> Fourth, the record showed that Novartis’s own representatives knew tank mixing was a common practice among farmers.<sup>110</sup>

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<sup>99</sup> *Id.* at 228.

<sup>100</sup> *Id.* at 225.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* (quoting *Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 314 (3d Cir. 1999)).

<sup>103</sup> *Id.* at 227 (citing *Arcadian Corp.*, 189 F.3d at 314).

<sup>104</sup> *Id.* at 225 (quoting *Jurado v. W. Gear Works*, 619 A.2d 1312, 1319 (N.J. 1993)).

<sup>105</sup> *Id.* at 225–26.

<sup>106</sup> *Id.* at 226.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

Based on these evidentiary findings, the court concluded that it was possible for a jury to determine tank mixing of AG600 was a reasonably foreseeable use of the product and this was a normal and not extraordinary use; therefore, the summary judgment was reversed and remanded for the Plaintiffs to bring their claims of design defect.<sup>111</sup>

#### V. COMMENT

The Supreme Court in *Bates* clarified the issue of when FIFRA regulations preempt state laws on the matter of pesticides and labeling.<sup>112</sup> However in making this ruling, the Supreme Court did not clarify what exactly qualifies as a label. Since *Bates*, a new issue has arisen as to what is and is not a label. Determining what constitutes a label is essential to manufacturers, sellers and buyers because the ambiguity leaves many parties open to civil, and possibly even criminal liabilities, if a mistake is made.

In deciding the claim against Novartis, the Third Circuit relied on the precedent established in *Bates* and determined that any of the blueberry farmers' claims of a flawed label would be preempted if the state regulations regarding labels imposed any supplemental duties on the manufacturer other than those outlined in FIFRA.<sup>113</sup> However, the issue was more complicated because the farmers did not rely on a label attached to the product, but on an oral representation of the product and a written report called the "Blueberry Bulletin," both of which were given by third parties who relied on pamphlets supplied by Novartis.<sup>114</sup> The court had to determine if the advertising literature about the product fell within the label category, because if it did then the representations given to the farmers would be considered labels and the claims would be preempted.<sup>115</sup> To accomplish this, the court had to focus on the FIFRA regulations.<sup>116</sup>

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<sup>111</sup> *Id.* at 228.

<sup>112</sup> *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444 (2005).

<sup>113</sup> *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207, 214 (3d Cir. 2010).

<sup>114</sup> *Id.* at 211.

<sup>115</sup> *Id.* at 215.

<sup>116</sup> *Id.* at 215–16.

## WHAT'S IN A LABEL?

Under FIFRA, a “label” is “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.”<sup>117</sup> FIFRA then defines “labeling” as “all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device . . . .”<sup>118</sup> The court noted that while the brochure was clearly not “on or attached to” the product, it still qualified as “all other written, printed, or graphic matter.”<sup>119</sup> However, since the brochure was not referenced on the label attached to the product, the only way to determine if the brochure qualified as “labeling” is to discover if it was “accompanying” the product.”<sup>120</sup>

This presents the crux of the issue that could potentially affect manufacturers, sellers and buyers across the country; when a case boils down to whether a potential label is “accompanying” a product, the authority is sparse as to what exactly “accompanying” means.

The Supreme Court has not ruled as to what “accompanying” means under FIFRA regulations, however the Court has established the Federal Food, Drug and Cosmetic Act’s definition of “labeling” to mean “all labels and other written, printed, or graphic matter[ . . . ]accompanying such article.”<sup>121</sup> The Court concluded a drug label “accompanying such article” is something that “supplements or explains it,[ . . . ]No physical attachment one to the other is necessary. It is the *textual* relationship that is significant.”<sup>122</sup> The Court noted Congress did not intend the Federal Food, Drug and Cosmetic Act to cover drug advertising material, but it did intend to cover advertising material that “performs the same function as if it were on the article or on the containers or wrappers.”<sup>123</sup> Therefore, under *Kordel v. United States*<sup>124</sup>, drug advertising that instructs users how to use the drugs, though not attached to or given with the drug itself, is considered labeling.

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<sup>117</sup> 7 U.S.C. § 136(p)(1) (2006).

<sup>118</sup> 7 U.S.C. § 136(p)(2).

<sup>119</sup> *Novartis*, 617 F.3d at 216.

<sup>120</sup> *Id.*

<sup>121</sup> *Kordel v. United States*, 335 U.S. 345, 347–48 (1948); *see* 21 U.S.C. § 321(m) (2006).

<sup>122</sup> *Kordel*, 335 U.S. at 350 (emphasis added).

<sup>123</sup> *Id.* at 351.

<sup>124</sup> 335 U.S. 345 (1948).



In *New York State Pesticide Coalition, Inc. v. Jorling*,<sup>125</sup> the Second Circuit determined that, "labeling is better understood by its relationship, rather than its proximity, to the product" and that labeling "is designed to be read and followed by the end user."<sup>126</sup>

The Third Circuit in *Novartis* considered both the Supreme Court in *Kordel* and the Second Circuit in *Jorling* and determined the marketing brochure was not a label because it was not intended to supplement the label.<sup>127</sup> The purpose of the brochure was not to tell prospective buyers how to use the product, but only to advertise the product and inform buyers about the benefits of the product.<sup>128</sup> Therefore, because the brochure did not contain instructions for use, the court determined it was not a label and the farmer's claim of reliance on the brochure was not preempted by FIFRA.<sup>129</sup>

The lack of case law on the meaning of "accompanying" leaves room for various circuits to interpret the term differently, which could potentially lead to splits among the courts in determining whether state law claims are preempted by FIFRA regulations. For FIFRA to preempt state law, a court has to find that the alleged label actually be a label accompanying the product. If circuits can vary on how they interpret the term "accompanying," this might lead to inequitable application of federal regulations across the country.

In Missouri and the Eighth Circuit, no court has yet determined how the word "accompanying" will be interpreted and applied. The Missouri Supreme Court has not even heard a case on pesticide claim preemption by FIFRA. Two cases from the Missouri Court of Appeals for the Southern District indicate how Missouri courts might determine when pesticide label claims are preempted.<sup>130</sup> In *M & H Enterprises v. Tri-State*

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<sup>125</sup> 874 F.2d 115 (2d Cir. 1989). *Jorling* is the only federal appellate decision specifically about the meaning of "accompanying" under FIFRA.

<sup>126</sup> *Id.* at 119.

<sup>127</sup> *Indian Brand Farms, Inc. v. Novartis Crop Prot., Inc.*, 617 F.3d 207, 216–18 (3d Cir. 2010).

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> See *M & H Enters. v. Tri-State Delta Chems., Inc.*, 984 S.W.2d 175 (Mo. App. S.D. 1998); *Yowell v. Chevron Chem. Co.*, 836 S.W.2d 62 (Mo. App. S.D. 1992).

## WHAT'S IN A LABEL?

*Delta Chemicals, Inc.*<sup>131</sup>, the court held that label based state common law claims are always preempted by FIFRA regulations.<sup>132</sup> The plaintiffs argued the label stated that the product would kill certain insects. However, after using the product the insects were not killed and proceeded to destroy the plaintiffs' crops.<sup>133</sup> The court concluded the claims were based solely on the label itself, and thus were preempted because the label complied with FIFRA standards and was approved by the EPA.<sup>134</sup>

The same court made a similar decision in *Yowell v. Chevron*<sup>135</sup> when it determined that the plaintiff's claim against the defendant company was based entirely on the label, and therefore preempted.<sup>136</sup> Consequently, the only way in Missouri to avoid federal preemption is to plead the case in such a way as to avoid discussion of the label. One way to do this is to make a claim under the Missouri products liability statute.<sup>137</sup>

While Missouri and the Eighth Circuit have yet to rule on a case where the controversy is whether something other than what is attached to the product is a label, it is likely the courts will follow the persuasive authority of the Second and Third Circuits. However, there is a possibility of a split among the circuits. If this happens the federal regulations will be applied inconsistently, which could cause difficulties for companies wanting to sell their product in many states across the country.

Since state regulations cannot be more intrusive than FIFRA regulations,<sup>138</sup> a company need only comply with FIFRA to be in compliance with state regulations. However, if the regulations are applied inconsistently across the country, it becomes increasingly difficult to conduct business effectively. It will cost manufacturers more money to

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<sup>131</sup> *M & H Enters. v. Tri-State Delta Chems., Inc.*, 984 S.W.2d 175 (Mo. App. S.D. 1998)

<sup>132</sup> *Id.* at 180.

<sup>133</sup> *Id.* at 177.

<sup>134</sup> *Id.* at 177, 183.

<sup>135</sup> *Yowell v. Chevron Chem. Co.*, 836 S.W.2d 62 (Mo. App. S.D. 1992).

<sup>136</sup> *Id.* at 66.

<sup>137</sup> In Missouri, the contents of a products liability claim are listed in MO. REV. STAT. § 537.760 (2000). The statute provides that a plaintiff can bring a claim against a manufacturer on the theory that the manufacturer put the product into the stream of commerce, the plaintiff used the product in a reasonable manner and the product was either defective or unreasonably dangerous.

<sup>138</sup> 7 U.S.C. § 136(v)(b) (2000).

make and distribute products if they have to use different marketing, selling and labeling practices across the country. It could add to the already overburdened dockets in federal courts. All of this will cost businesses more money, causing purchasers to pay more for products, which could potentially raise the cost of food.

While this scenario might seem unlikely, it would be helpful if the Supreme Court would deliver a ruling declaring specifically how to interpret the word “accompanying” and state explicitly what it does and does not cover. The possible consequences of not having a controlling precedent for every circuit are potentially problematic, and a decision would make these cases much easier for the lower courts, or even prevent these cases from arising in the first place.

## VI. CONCLUSION

The potential for confusion over what does and does not qualify as a label shows that there is a need for controlling precedent by the Supreme Court to clarify what the term “accompanying” means under the FIFRA regulations. The blueberry farmers’ case was recently remanded back to the district court for the second time because of the confusion created in determining what qualifies as a label. Controlling precedent would solve this problem, conserve judicial economy and save farmers and pesticide manufacturers time and money.

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