Legal Backgrounder

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IN RE PEPSICO PROVIDES GUIDANCE ON ARGUING EXPRESS PREEMPTION

by

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In two recent opinions, the United States Supreme Court issued seemingly divergent views on the extent to which federal statutes with express preemption provisions should preclude state law products liability claims. It suggested in *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431 (2005) that state tort law can serve as a useful complement for federal safety standards for pesticides under FIFRA. More recently, the Court found in *Riegel v. Medtronic Inc.*, 128 S. Ct. 999 (2008) that state tort law impermissibly interferes with FDA safety standards for Class III medical devices. A closer analysis of the facts in these cases, however, reveals that the Court was guided by a common standard: If federal regulators have specifically addressed the question raised by the state law claim, the claim is preempted; if not, the claim is allowed to proceed.

Thus understood, the Court's anti-preemption ruling in *Bates* was driven not by a philosophical conclusion about the interplay between state and federal law, but by its determination that EPA did not regulate the issue of pesticide efficacy that was the specific focus of plaintiff's state law claims. *See Bates*, 544 U.S. at 440 ("EPA confirmed that it had stopped evaluating pesticide efficacy for routine label approvals") (internal quotes omitted). When faced three years later in *Riegel* with a state tort claim that addressed the issue of medical device safety which was squarely within federal regulatory oversight, the Court did not hesitate to hold the claim preempted. *See Riegel*, 128 S. Ct. at 1007 ("FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application.").

The Court's guidance on express preemption following *Bates* and *Riegel* parallels the guidance the Court provided nearly a decade ago on implied preemption, when the Court likewise issued two seemingly divergent opinions on the scope of federal regulatory oversight in each case. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000) (NHTS decision not to require automobile airbags preempts state law claims); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (Coast Guard's decision not to regulate motor boat propeller guard was not federal action requiring preemption). While these four cases involve four different federal regulatory schemes, different analyses under express and implied preemption, and different express

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preemption language in *Riegel* and *Bates*, the cases provide a common guidepost to preemption analyses. The key question in preemption – more important than debates over the proper role of state and federal government in protecting public health and safety – is whether the federal government has spoken on the specific issue raised by a state law claim. If the court determines that the federal government has spoken, state law will generally be required to give way.

Of course, this black-or-white pronouncement is subject to a world of grays. As demonstrated by the Court's recent opinion in *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172 (Mar. 4, 2009), defendants asserting implied preemption arguments will face a higher hurdle in demonstrating a conflict between state tort law and the federal regulatory action at issue. Defendants asserting express preemption arguments following *Riegel* and *Bates* have an easier argument, but still cannot rest on the mere fact that their product was subject to federal safety regulation. They must proffer to the court any and all evidence of federal decision-making on the specific issue raised by the state law claim. In approaching this task, defendants would be well served to review a recent opinion out of the Southern District of New York in which Pepsico Company went beyond the simple language of the governing federal regulation to identify the specific evidence needed to convince the court that plaintiff's state law claim should be preempted. *See In re Pepsico, Inc., Bottled Water Mktg & Sales Practices Litig.*, 588 F. Supp. 2d 527 (S.D.N.Y. 2008).

In re Pepsico involved a consumer class action brought against the manufacturer of Aquafina bottled water alleging that the manufacturer (Pepsico) had fraudulently misrepresented the source of the water. Plaintiffs claimed that Pepsico's label unlawfully created the impression that the water came from a mountain spring when it in fact was "tap water" drawn from public water supplies. Plaintiffs pointed to graphics on the Aquafina label, including a cartoon-like squiggle allegedly evoking a mountain range and a red-orange circle allegedly evoking a rising or setting sun. Plaintiffs also pointed to the labeled slogan "Pure Water-Perfect Taste" and the product description "Purified drinking water." The only reference on the label to the actual source of the water was an ambiguous statement "BOTTLED AT THE SOURCE P.W.S." Although P.W.S. was not defined, plaintiffs contended that it was an abbreviation for "Public Water Supply." *See* 588 F. Supp. 2d at 529.

Pepsico responded that Aquafina was treated water, thereby satisfying the definition for "purified water" in 21 C.F.R. § 165.110(a), and that the Aquafina label conformed with the standard of identity for bottled water set forth in the Nutritional Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat 2533. That standard of identity included a requirement that manufacturers of bottled water identify the source of the water (*e.g.* "from a community water system"), but explicitly exempted water meeting the definition of purified drinking water from this disclosure requirement. Pepsico thus argued that the plaintiff's claim was expressly preempted by Section 403A of the Federal Food, Drug, and Cosmetics Act (FDCA), which states:

> (a) [N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce –
>
> > (1) any requirement for food which is the subject of a standard of identity established under [the NLEA] that is not identical to such standard of identity or that is not identical to the requirement of [FDA's misbranding provision] section 403(g).

Section 403(g) in turn provides that a food is misbranded if (1) it does not conform with the applicable

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standard of identity; or (2) its label does not bear the name of the food specified in the definition and standard. 21 U.S.C. § 343(g).

While not disputing the fact that Aquafina was purified, plaintiffs argued that their claims were not preempted. Plaintiffs noted that there was nothing in the standard of identity or the exemption for purified water from the source disclosure requirement that permitted Pepsico to include what plaintiffs alleged were affirmative misrepresentations as to the source of the water. Plaintiffs thus sought to place themselves on the *Bates* and *Sprietsma* side of the preemption divide, arguing that their state law claim focused on an issue that was not squarely addressed by the federal regulation and thus should be allowed to proceed.

Rather than resting solely on its compliance with the federal regulatory standard, however, Pepsico presented the court with evidence establishing that the FDA had not only exempted purified water from its source disclosure requirements but that the FDA had further specifically concluded that the presence of graphics suggesting a mountain source for municipal water was irrelevant and hence not misleading if the water was purified. Pepsico pointed first to the regulatory history behind the FDA's standard of identity for bottled water. In setting forth its proposed rule for the labeling of bottled water, the FDA had directly addressed the issue of misleading graphics similar to those at issue in plaintiffs' complaint: "[A] picture of a blue-green mountain spring on a label of a bottled water product may indicate to consumers that the water comes from a mountain spring. Such a label is misleading to consumers if the water actually comes from the municipal water supply of an urban area located far from any mountains." *Beverages: Bottled Water*, 58 Fed. Reg. 393, 395 (1993). Later in that same proposed rule, however, the FDA explained that it exempted purified water from this source disclosure requirement, concluding that "consumers purchase this water because of its treatment and subsequent purity rather than because of its source." *Id.* at 399.

While advancing Pepsico's position, these two statements did not definitively demonstrate a specific FDA decision that it is acceptable for suppliers of purified municipal water to affirmatively include label graphics which suggest that the water came from a mountain spring. Pepsico strengthened its case by presenting evidence from the FDA's written responses to comments on its proposed rule. Included among these 430 comments was one comment that directly raised the claim central to plaintiffs' complaint, *i.e.*, that "it would be misleading if a country setting is shown on the label … and the product is drinking water processed [to standards of purity] from municipal supplies." 60 Fed. Reg. 57076-01, 57104 (1995). In its response, the FDA reiterated its view that such label graphics would be misleading if used with untreated municipal water, but also reasserted the exemption of purified water from the source disclosure requirements, making clear its view that any concern about misleading graphics was irrelevant in the context of purified water. While plaintiff objected to the use of the comments to determine the preemptive scope of federal law, the district court disagreed, stating "[i]t is appropriate for Courts to consider the FDA's published responses to commentators during the rule drafting process in determining the meaning of FDA regulations promulgated in furtherance of the FDCA." 588 F. Supp. 2d at 536 n.7.

Armed with this evidence from the regulatory history, the court correctly held that plaintiffs' state law claims were preempted. As the court explained, contrary to plaintiffs' assertion, federal law was "not silent on the subject of implied labeling misrepresentations regarding the municipal source of bottled water." *Id.* at 536-37. The court also rejected plaintiffs' attempts to limit the scope of preemption based upon the specific language of the federal regulatory standard of identity. The court explained:

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> [A]lthough the standard of identity does not define the term "pure" or specify when it is permissible to place a cartoon-like image of a mountain range on a purified water label, the FDA considered misrepresentations regarding source and chose to regulate the labeling requirements for the disclosure of source information, and in so doing it determined that purified water should be exempted.

Id. at 538. Pepsico's plumbing of the regulatory record left plaintiffs with no room to maneuver.

In re Pepsico provides an important template for express preemption litigation and a useful tutorial for preemption-minded defendants. While the federal government speaks through its final statutes and regulations, the evidence of the specific determinations made by the federal government in issuing those edicts can often only be found in secondary materials, like the comments provided in response to public inquiry or the correspondence between the regulators and the regulated entity in connection with a specific product. It is from these secondary materials that a successful preemption ruling can be built.

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