

News from the Circuits

By Ben Massarsky and Sandra Seitman

Wyeth v. Levine, 2009 WL 529172

Diana Levine brought an action against the drug manufacturer Wyeth under Vermont's failure to warn statutes. She developed gangrene requiring the amputation of her arm after the company's drug Phenergan was administered to her using the IV-Push method. Ms. Levine alleged that the warning label for Phenergan did not adequately explain the dangers in using the IV-Push method to deliver the drug. The trial court rejected Wyeth's argument that Levine's failure to warn claim was pre-empted by the Food and Drug Administration's approval of the warning label at issue. The Vermont Supreme Court affirmed the lower court decision and Wyeth thus appealed to the Supreme Court of the United States.

In a 6-3 decision, with Justice Stevens writing the opinion and Justices Alito, Roberts, and Scalia dissenting, the Supreme Court held that the failure to warn claims were not pre-empted by the FDA's approval of the warning label. The Court rejected Wyeth's argument that it could not comply with federal and state laws because it was bound to display the exact label the FDA had already approved. In highlighting the FDA's "changes being effected" (CBE) regulation which allowed the manufacturer to add or strengthen an instruction about dosage and administration intended to increase the safe use of the drug product, the Court demonstrated that manufactures could make labeling changes upon filing a supplemental application with the FDA and need not wait for FDA approval. Wyeth argued that the CBE regulation stated that revisions could only be made to reflect newly acquired information, and that the company had no such new information. The Court rejected this "cramped reading" of the CBE regulation by pointing to the FDA's own interpretation of the provision, which explained that newly acquired information was not limited to new data, but also encompassed new analyses of previously submitted data and adverse event information. The Court noted that Wyeth had evidence of such adverse event information and could have used an appropriately stronger warning label without FDA pre-approval.

Wyeth's second argument, that requiring them to submit to state law claims regarding the warning label would obstruct the purpose and objectives of the FDA's labeling regulation, was also rejected. The Court explained that the FDA had always held the position that state law offered complimentary protection to its own regulations, and that such regulations were meant to be a floor and not a ceiling. Moreover, the Court stated that if state law did indeed endanger FDA regulation, Congress had ample time during the 70 years of Food, Drug, and Cosmetics Act (FDCA) to address the pre-emption question. The Court observed that Congress amended the FDCA in 1997 to address pre-emption and medical devices, but specifically declined to extend such express pre-emption to pharmaceutical products. The Court found this demonstrative of Congress's attitude towards the interaction of state law and FDA regulation.

This decision clarified the uncertain question of implied pre-emption with respect to the FDA and state law claims. The Court's reluctance to allow implied pre-emption and willingness to find suitable escape valves for state tort claims will likely be used in the future to support a basis for similar causes of action in federal administrative agency pre-emption cases. This could result in an increased pressure for prescription drug companies to more closely monitor both incoming and previously catalogued statistical data with an eye to continual reevaluation of the safety, side effects, and consequences of their products.

Second Circuit Hears Insider Trading Case – 2008 WL 126612

On April 3, 2008, the Second Circuit Court of Appeals heard an oral argument by the United States Securities Exchange Commission ("SEC"), the appellant in a pivotal insider trading case. The SEC appealed from a district court decision, *Securities and Exchange Commission v. Dorozhko*, No. 07 Civ. 9606(NRB), 2008 WL 126612 (S.D.N.Y. Jan. 8, 2008), which denied the SEC's motion for a preliminary injunction against Defendant-Appellee Oleksandr Dorozhko on alleged insider trading violations.

In its complaint, the SEC alleged that Dorozhko, a self-employed Ukrainian national residing in the Ukraine, violated §10(b) of the Securities Exchange Act of

1934 ("Act") (15 U.S.C. §78j (b)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5) by hacking into a secure computer network and stealing material non-public information which was used to trade in securities. At issue, was whether in the absence of a breach of a fiduciary (or similar) duty "in connection with" the purchase or sale of a security, the 'hacking and trading' activity could amount to violations of § 10(b) and Rule 10b-5.

The court examined the three elements of a Rule 10b-5 violation: (1) a "device or contrivance"; (2) which is "manipulative or deceptive"; and (3) used "in connection with" the purchase of securities. They found both elements (1) and (3) were met by Dorozhko's alleged hacking activity, but element (2) was not. First, on the facts available, Dorozhko's actions did not fit within the narrow definition of manipulative activity because his alleged stealing and trading did not "control" or "artificially affect" market activity. Second, turning to the historical development of insider trading fraud, the court found that a deceptive act in a §10(b) violation, regardless of whether the SEC relies on the traditional misappropriation or a separate scheme theory of insider trading, cannot be established absent a breach of fiduciary duty to disclose or abstain. Dorozhko owed no fiduciary or similar duty either to the source of his information or to those he transacted with in the market.

The SEC's reply brief on appeal to the Second Circuit argues that a breach of fiduciary or similar duty is not an element of every claim brought under §10(b) of the Act. See Reply Brief of Appellant, *SEC v. Dorozhko*, No. 08-0201-CV (2d Cir. Aug. 2008).

The pending result of this case has the potential to change insider trading cases dramatically. If the Second Circuit rules in favor of the SEC, violations of §10(b) and Rule 10b-5 will be much easier to prosecute, as the cause of action will be broadened to eliminate the previously required fiduciary or similar duty. This result would arguably reverse decades of insider trading litigation. If, however, the Second Circuit rules against the SEC, activities of an alleged hacking will have be absolved of §10(b) liability, and the SEC's authority to prosecute hackers who have stolen and traded in securities will be restricted. **BLB**