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INTELLECTUAL PROPERTY ALERT

RECENT DECISION BY THE US COURT OF APPEALS FOR THE SECOND CIRCUIT: *UNITED STATES V. CARONIA*

In a much anticipated decision, the United States Court of Appeals for the Second Circuit, in *United States v. Caronia*, 09-5006-CR (2d Cir. December 3, 2012), reversed the conspiracy conviction of a pharmaceutical sales representative for his off-label promotion of an approved prescription drug. The Second Circuit held that the government's use of the misbranding provisions of the Food, Drug and Cosmetic Act (the "FDCA") to prosecute speech by a product manufacturer's representative who promotes an approved drug for an unapproved use violates the First Amendment. While doctors can prescribe approved products for unapproved uses without restriction, e.g., those indications not listed on the product's approved label, the government has taken the position for more than a decade that pharmaceutical and device companies, as well as their representatives, cannot promote these same products for off-label use. Government enforcement of the FDCA to prohibit off-label promotion has resulted in high profile prosecutions and convictions of drug and device companies as well as billions of dollars in payments by drug and device companies to both state and federal governments, qui tam relators, and civil plaintiffs.

In *Caronia*, a pharmaceutical sales representative was convicted of conspiracy to violate the misbranding provisions of the FDCA. His conviction was based primarily on conversations with physicians about unapproved uses of the drug Xyrem. Many of these conversations were recorded by a confidential informant and clearly touted the use of Xyrem for uses which were not within its approved labeling. Using both the heightened scrutiny test set forth in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), and the less restrictive commercial speech test set forth in *Cent. Hudson Gas & Elec. Corp. v. Pub.Serv. Comm'n of N.Y.*, 447 U.S. 557, 563-64 (1980), the Court held that the criminal prosecution under the FDCA of a pharmaceutical sales representative for promoting the sale of an approved drug for unapproved uses violates the First Amendment. Accordingly, the court overturned the misdemeanor conspiracy conviction of Caronia as unconstitutional.

Given the importance of this decision and the implications for the regulatory scheme of FDA, it is likely that *Caronia* will reach the United States Supreme Court on certiorari. In the interim, the decision is very important for manufacturers of prescription products which had hoped for some court recognition of First Amendment protections. The decision draws into question the government's unfettered ability to regulate speech by prescription product companies which promote off label use of their products. Further, civil litigants who have used qui tam actions asserting False Claims Act violations based upon simple allegations of off-label promotion would appear to face significant hurdles moving forward. Even civil litigants asserting tort claims against manufacturers based upon off label promotion without more would appear to be subject to challenge.

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We encourage you to forward the decision to any client or prospective client in the drug, device or biologics industry. We would be happy to discuss the implications of the decision should they have any questions.

A comprehensive discussion of off-label use and issues including First Amendment implications can be found in ***Off-Label Communications: A Guide to Sales & Marketing Compliance*** (3rd Ed. 2012) (FDLI, edited by Levy, M. C.).

The Intellectual Property Alert is intended to keep readers current on matters affecting intellectual property matters and is not intended to be legal advice. If you have any questions, please contact ***Mark Carlisle Levy*** *at 215.851.8404 or mlevy@eckertseamans.com, or any other attorney with whom you have been working.*