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Federal District Court Joins Second Circuit in Upholding Pharmaceutical Manufacturer’s Right to Truthfully Promote Off-Label Uses

On August 7, 2015, Judge Engelmayer of the Southern District of New York ruled that a pharmaceutical manufacturer's truthful and non-misleading statements about off-label drug uses are protected by the First Amendment. Amarin Pharma, Inc. v. FDA, No. 1:15-cv-03588. Amarin, the maker of the fish oil-based drug Vascepa, sought to make affirmative statements to physicians regarding the use of Vascepa for a patient population not currently approved by FDA. After unsuccessful negotiations with FDA, Amarin filed a complaint against FDA claiming that the threat of criminal prosecution chilled its commercial speech that was protected by the First Amendment. In the complaint, Amarin sought a ruling that the company may engage in truthful and non-misleading speech to doctors, both as to specific proposed statements and as a general matter, free from risk of criminal prosecution.

In addition to reviewing Amarin’s specific proposed statements, the District Court also analyzed whether Amarin had a general right to make truthful and non-misleading off-label promotional statements under the First Amendment. Relying heavily on the Second Circuit’s decision in United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), the Court found that “where the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under Caronia, cannot be the act upon which an action for misbranding is based.”

Although the Food, Drug, and Cosmetic Act (FDCA) does not expressly prohibit off-label promotion, FDA has long taken the position that a manufacturer who promotes or markets for off-label use risks criminal liability for “misbranding” under 21 USC 331(a). But this position was called into question when the Second Circuit overturned the criminal conviction of a sales representative for his truthful and non-misleading promotion of off-label uses of a drug in the 2012 Caronia decision on First Amendment grounds. FDA declined to appeal and has argued in Amarin that Caronia was limited to the facts, namely the government’s particular theory of prosecution and the jury instructions given in the underlying criminal trial, and accordingly would not impact the agency’s enforcement of off-label promotion.

The District Court squarely rejected FDA’s reading of Caronia, however, explaining that the Second Circuit decision was not about the specific facts at issue, but whether, consistent with the First Amendment, a misbranding prosecution can ever be based on truthful speech. And the Court found that, under Caronia, FDA may not base misbranding prosecution on speech alone without violating the First Amendment. The Court left the door open, however, to introducing evidence of speech to show the intent behind other non-speech conduct, such as company sponsored vacations for prescribing physicians.

The Court’s decision could free pharmaceutical manufacturers to promote drugs more broadly so long as
statements are truthful and not misleading. At the same time, companies should be mindful that the truthfulness of such off-label company statements could itself be a source of litigation. It's not yet known if FDA will appeal this decision.

An advisory providing a more in-depth analysis of the District Court’s decision is available here.

**Ninth Circuit Remands Diabetes Drug Lawsuits to State Court**

On August 6, 2015, the Ninth Circuit remanded five multi-plaintiff lawsuits alleging a link between a diabetes drug and pancreatic cancer to California state court. The Court held that the cases are not "mass actions" under the Class Action Fairness Act (CAFA) because Plaintiffs did not propose joint trials. *Briggs v. Merck Sharp & Dohme*, 2015 WL 4645605 (9th Cir. Aug. 6, 2015).

CAFA authorizes the removal to federal court of "mass actions," in which "monetary relief claims of 100 or more persons are proposed to be tried jointly" on the ground that the plaintiffs' claims involve common questions or law or fact." 28 U.S.C. § 1332(d)(11)(B)(i) (emphasis added). The statute excludes actions in which the claims are joined upon a defendant's motion or in which the claims are consolidated or coordinated only for pretrial proceedings. Id. § 1332(d)(11)(B)(ii)(II), (IV).

Congress enacted CAFA in 2005 to curb plaintiffs' attempts to circumvent removal in order to litigate multistate or national class actions in state courts. Since 2005, however, courts have repeatedly grappled with CAFA's scope in pharmaceutical mass tort cases, and specifically on the question whether plaintiffs have made the required "proposal" to try the cases jointly.

In *Briggs*, Plaintiffs filed five separate cases in California state court, each with fewer than one hundred plaintiffs. Defendant removed all five cases to federal court under CAFA, and Plaintiffs moved to remand the cases. The district court denied Plaintiffs' remand motions and held that Plaintiffs actions' constituted implicit proposals for joint trial. Specifically, Plaintiffs in three cases had told the district court that the cases, if remanded, would be transferred to a preexisting state coordinated proceeding and would be coordinated for all purposes there, including for trial. Plaintiffs in the fourth case similarly stated that remand would result in coordination. As to the fifth case, the district court determined that filing the case in the same court with the four other actions also constituted an implicit proposal to try the case jointly.

The Ninth Circuit panel unanimously reversed the district court's decision and held that Plaintiffs' actions did not rise to the level of proposing a joint trial. Although the Court agreed that implicit proposals may trigger CAFA jurisdiction, it determined that Plaintiffs' actions did not qualify for two reasons. First, to qualify as a proposal, a request for a joint trial must be addressed to the court that can effect the proposed relief. But the district court here to which the claimed proposals were made lacked any authority to transfer plaintiffs' cases to the state coordinated proceeding. Second, Plaintiffs' particular statements at most constituted predictions that the state court would consolidate these proceedings, not a proposal to do so. The panel thus distinguished the instant case from an earlier en banc decision in *Corber v. Xanodyne Pharmaceuticals, Inc.*, 771 F.3d 1218 (9th Cir. 2014), in which the Court held that a petition to initiate a state coordinated proceeding "for all purposes" was a proposal for a joint trial. Accordingly, the Court remanded all five cases to California state court.

*Briggs* reinforces that courts will finely parse plaintiffs' statements and actions in mass tort cases to make fine judgments about whether there has been a proposal to try cases jointly. Defendants should remain vigilant and look for opportunities to invoke federal jurisdiction when such a proposal is made.

**California Supreme Court Approves Class Action Arbitration Waiver in Closely Watched Post-Concepcion Case**

To combat class action abuses and to take advantage of the efficiencies of arbitration, businesses often include arbitration provisions in consumer agreements that not only call for private dispute resolution, but limit the ability of aggrieved parties to seek relief on behalf of a class. Although state courts historically often invalidated such provisions, the United States Supreme Court made clear in *Concepcion* that the Federal Arbitration Act precludes states from holding such waivers per se unconscionable. See *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333 (2011). But the Court left open to states the ability to apply general unconscionability principles, which do not discriminate against arbitration, to assess such contracts containing these arbitration provisions. In *Sanchez v. Valencia Holding Company*, 353 P.3d 741 (Cal. 2015), a case
closely monitored by stakeholders on both sides, the California Supreme Court upheld the validity of a class action arbitration waiver under Concepcion and state law.

In Sanchez, the plaintiff brought suit claiming, on behalf of himself and others similarly situated, that Valencia, a pre-owned luxury car dealership, engaged in numerous practices that violated California law. Valencia sought to compel the plaintiff to arbitrate based on a boilerplate contract of sale entered between them. The arbitration provision in the contract included: (i) a class action waiver with a “poison pill” provision declaring invalid the entirety of the arbitration provision if the class action waiver was found unenforceable; (ii) a limitation of appeals to a panel of arbitrators to only those cases in which a party was awarded no recovery or recovery in excess of $100,000; (iii) a provision requiring an appealing party to pay all costs of the appeal unless otherwise later apportioned; and (iv) the reservation of all self-help remedies, including small claims court and repossession.

The California Supreme Court reversed the Court of Appeal's determination that the arbitration provision was unenforceable. The Court first explained that while unconscionability was defined using a multitude of substantively similar formulations, at bottom there is “both a procedural and a substantive element, the former focusing on oppression or surprise due to unequal bargaining power, the latter on overly harsh or one-sided results.” The court cautioned: “All of these formulations point to the central idea that [the] unconscionability doctrine is concerned not with ‘a simple old-fashioned bad bargain,’ but with terms that are ‘unreasonably favorable to the more powerful party.’”

With the basic construct in place, the California Supreme Court then discussed each of the contract provisions in detail. The Court reasoned that the fact that the sale contract was one of adhesion, standing alone, did not render the agreement unconscionable. Neither did the other provisions, which the Court found in most instances benefitted both parties. For example, the agreement retained the right of the parties to bring suit in small claims court (which the Court viewed as likely benefitting the consumer) and the right to repossession (which benefitted the seller). Nor was the requirement to pay appeal fees unconscionable, at least in the context of a dispute about a luxury car where plaintiff produced no evidence of an inability to pay. The Court also pointed out that slight advantages to the party with more bargaining power are not fatal: contract provisions are not unconscionable when they “furnish a margin of safety that provides the party with superior bargaining strength a type of protection for which it has a legitimate commercial need.” This justified, for example, the right to appeal an injunction (which likely benefitted Valencia) because the far-reaching implications of an injunction could have an effect on Valencia’s business far in excess of the case being arbitrated.

Sanchez illustrates that the determination of whether a consumer arbitration contract is unconscionable will entail a detailed, context-specific analysis. Nevertheless, Sanchez provides some guidance as to the type of provisions that may be sustained and gives a modicum of comfort that state courts will increasingly uphold such provisions in the post-Concepcion world.

**Supreme Court to Address Use of Statistics in Class Liability and Damages Calculations**

In recent years, the Supreme Court has helped to rein in class action abuses with opinions reinforcing that class certification must be a rigorous process. See Dukes v. Wal-Mart, 564 U.S. ___ (2011); Comcast v. Behrend, 569 U.S. ___ (2013). The Supreme Court recently granted certiorari in another class action case that will be widely watched. Tyson Foods, Inc. v. Bouaphakeo, No. 14-1146. This time, the Court will address two important questions: use of statistical evidence as a basis for liability and damages calculations and whether a class can be certified despite the fact that some class members may not have suffered any injury at all.

In Tyson, plaintiffs brought a Fair Labor Standards Act case claiming they were illegally deprived of overtime pay for time spent “donning and doffing” protective equipment at an Iowa meat processing plant. The class was certified and ultimately tried to a plaintiffs' verdict of almost US$6 million. The key evidence Plaintiffs submitted to show damages were expert statistical models that extrapolated the average time spent donning and doffing based on a sample of class members. The class recovery was then to be distributed pro rata among the class despite the fact that different class members used different equipment taking different amounts of time to take on and off. The Eighth Circuit affirmed, with one Judge dissenting.

Tyson argued in its petition for certiorari that it was improper for the District Court to use statistics from a
sample of class members in light of the Supreme Court's holding in *Dukes*, which prohibited such "trial by formula" and similarly held that statistical evidence was insufficient to overcome individualized differences among class members. The case will accordingly give the Supreme Court an opportunity to interpret and apply *Dukes* outside of the employment discrimination context. In addition, the Supreme Court took up the separate but important question of whether a class can be certified even though it includes class members who may not have suffered any injury at all. There is a longstanding circuit split on that question, and a decision in the defendant's favor could have wide implications. Businesses facing class action lawsuits should keep a close eye on the Supreme Court's decision in *Tyson*.

For questions or comments on this newsletter, please contact the Product Liability group at product@aporter.com.