SUPREME COURT RULES IN TWO PHARMA CASES

June 29, 2011

To Our Clients and Friends:

Last Thursday, the Supreme Court issued two constitutional law decisions of significance to the pharmaceutical industry. The first found that state tort law "failure-to-warn" suits alleging injury from the use of generic drugs were preempted on grounds of "impossibility." The second invalidated on First Amendment grounds a Vermont law that restricted dissemination of prescriber identifying information for use by pharmaceutical companies (but not for numerous other uses), for the express purpose of disfavoring the companies' commercial message.

PLIVA, INC., ET AL. v. MENSING

In *Pliva v. Mensing*, a five-Justice majority held that federal law and regulations requiring generic drug manufacturers to use the same Food and Drug Administration ("FDA") -approved safety and efficacy labeling provided by the brand name manufacturer directly conflicted with and thus pre-empted state tort law requirements that generic manufacturers have a duty to provide a "different, safer" warning. Slip Op at 5. The drug at issue in *Pliva* was metoclopramide, the generic version of a digestive tract brand name drug called Reglan. The generic manufacturers asked the Court to reverse rulings from the Fifth and Eighth Circuit Courts of Appeals that allowed plaintiffs to allege that they received inadequate warnings of the risk that their long-term use of metoclopramide might result in severe neurological disorders. The generic manufacturers argued that federal statutes and FDA regulations required them to use the same labels approved for Reglan and that it was impossible for them to change the labels as plaintiffs alleged was required by state law. The case was closely watched in light of the Court's 2009 rejection of similar arguments made by a brand name manufacturer in *Wyeth v. Levine*. In *Pliva*, however, the Supreme Court (with Justice Thomas writing for the Court, joined by Justices Roberts, Scalia, Alito and Kennedy (who joined in all but one part)) found in the defendants' favor and remanded the cases.

The differences between the treatment of brand name and generic drugs centered on the 1985 Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act Amendments Act ("FDCA"). As the Court explained, to obtain FDA approval, the manufacturer of a generic drug need only propose "safety and efficacy labeling" that "is the same as the labeling approved for the brand name drug." Slip Op. 5-6. Moreover, the Court held that the federal scheme also required generic manufacturers to continue to use whatever labeling the FDA had approved for the brand name product. This holding was based in part on the Court's deference to the FDA,

which filed a brief asserting that warning labels on generic drugs were always to be the same as relevant brand name warning labels. Although the manufacturer in *Wyeth* also had argued that it could not change its labeling without FDA approval, the FDA explained in *Pliva*, and the Court held, that generic manufacturers could not use the agency's "changes-being-effected" process, which permits brand name manufacturers to add to or strengthen a warning label, before receiving FDA approval, nor could generic makers send "dear doctor" letters providing additional warnings. As such, the reasoning used in *Wyeth* did not apply in *Pliva*.[1]

The Court also rejected the FDA's argument that while the generic manufacturer could not use the "changes-being-effected" process or a "dear doctor" letter to unilaterally change the label, the generic manufacturer was required to propose stronger labels to the FDA and seek to have the FDA change the brand name label. The Court held that doing so "would not have satisfied their state tort-law duty to provide adequate labeling." Slip Op. at 12. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." Slip Op. at 17.

Pliva has a number of interesting implications for both generic and brand name pharmaceutical makers. The preemption defense recognized for the generic makers might result in attempts by users to sue brand name makers for failure to warn. In any event, it will likely reduce the potential liability of generic makers, who already enjoy limited exposure to the design defect claims faced by brand name makers. And, while this ruling has the greatest salience in the context of generic pharmaceuticals, it potentially applies in other areas where multiple participants, with different regulatory statuses, are involved in the design and sale of a regulated product. More broadly, *Pliva* signals that a majority of the Supreme Court is prepared to draw lines based on the comprehensive licensing and oversight system under the FDCA. It remains to be seen whether Congress will weigh in on this topic or how lower courts may address the differing treatment now to be accorded generic and brand name drugs and the potential conflicts between that regime and state-law duties.

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[1] *In Wyeth, the decision was also a close one. In that case, Justice Stevens, also writing for a 5-4 majority, delivered the opinion of the Court, in which Justices Kennedy, Souter, Ginsburg, and Breyer joined. Justice Thomas filed an opinion concurring in the judgment.*

SORRELL, ATTORNEY GENERAL OF VERMONT, ET AL. v. IMS HEALTH INC., ET AL.

In *Sorrell v. IMS Health*, a six-Justice majority affirmed a decision of the Second Circuit Court of Appeals, rejecting Vermont's controversial Prescription Confidentiality Law. The Court held that the law unconstitutionally infringed on the free speech rights of prescription information miners who collected the data and the pharmaceutical companies who used it to communicate with physicians.

The Vermont law involved information received by pharmacies about an individual physician's prescribing practices when filling prescriptions the doctor has written. This so-called "prescriber identifying information" is routinely collected by data mining companies and sold to pharmaceutical manufacturers, who use the data in part to target their sales efforts to address the personal practices of doctors. Vermont wanted to restrict the availability of prescriber data for these purposes; absent the prescriber's consent, the Prescription Confidentiality Law forbade the sale of such data by pharmacies and similar entities, and also prohibited the data's disclosure by potential sellers for marketing purposes as well as its use by pharmaceutical manufacturers for marketing.

Although denominated a "privacy" measure, the law included certain – and the Court noted, broad – exceptions. The data could be used without physician consent for health care research, educational purposes, and by law enforcement, insurance companies and journalists.

In invalidating the statute, the Court took issue with the fact that Vermont singled out a particular type of speech and speaker. Justice Kennedy's opinion took issue with both the operation of the law and Vermont's stated purpose in enacting the measure. Both, he wrote, made clear that the impermissible goal was to restrict speech disfavored by the State. In providing broad exceptions, the Vermont law disfavored certain speech – research, *e.g.*, was preferred to marketing, and disfavored certain speakers – journalists, *e.g.*, were preferred to pharmaceutical manufacturers. In addition, "[f]ormal legislative findings accompanying" the bill "confirm that the law's express purpose and practical effect are to diminish the effectiveness of marketing by manufacturers of brand name drugs." Slip Op. at 9. These targeted restrictions made the burden posed by the law more than "incidental," thus warranting heightened review.

The Court rejected the two justifications Vermont provided for its law – that it was designed to protect doctors' privacy, and that it would reduce healthcare costs by encouraging the use of generic drugs. The Court rejected the first justification in part because the information is available to an "almost limitless audience." It rejected the second, explaining that speech cannot

be stifled just because it is too persuasive, nor can it be burdened so as to "tilt public debate in a preferred direction." Slip Op. at 17-24.

Justice Breyer's dissent, joined by Justices Ginsburg and Kagan, would have reviewed the statute under a lower standard of scrutiny. It expressed concerns about the impact of the Court's ruling stating that – "[a]t best the Court opens a Pandora's box of First Amendment challenges to many ordinary regulatory practices that may only incidentally affect a commercial message…. At worst, it reawakens [the] pre-New Deal threat of substituting judicial for democratic decision-making where ordinary economic regulation is at issue." Slip Op. (dissent) at 24.

With *Sorrell*, the Court has emphasized that government cannot discriminate against speech simply because it disagrees with it – even if that speech is motivated by economic interests. Observers can expect that *Sorrell* will be the basis for additional challenges to commercial regulations.

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Please do not hesitate to call us if you have any questions or wish to discuss the decisions in greater detail.

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