How Is Generic Preemption Like Fraud On The FDA?

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A couple of months ago, we provided our stream-of-consciousness impressions of the Mensing/Demahy generic preemption argument to the Supreme Court. As we mentioned then, we were all set to write an obituary on generic preemption. After all, since Wyeth v. Levine, 555 U.S. 555 (2009), generic preemption had lost in every court of appeals to consider the issue, and the government (the Solicitor General) had weighed in on the anti-preemption side as well.

As we remarked then, the generic side appeared to do much better than expected during the oral argument. Not only were they sympathetically received by the three justices (Roberts, Scalia, Alito) who had dissented in Levine, but two critical swing justices (Kennedy, Breyer), seemed to be of the view - we say "seemed" because oral argument prognostication is only a little better than reading tea leaves - that Mensing fell under the aegis of preemption as recognized in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). Here are some excerpts from that post:

Justice Kennedy made a startling statement – that this case may even be "a fortiori" from Buckman. Whoa. Justice Kennedy is another crucial swing preemption vote. If that was really what he thinks, then that sounds like good news indeed for the generics, since he voted against preemption in Levine.

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We then get an interesting observation from Justice Breyer that, rather than Levine, the case is more like Buckman, because any supposed duty to tell the FDA something, amounts to a claim that private plaintiffs can enforce that duty, as opposed to the FDA "enforcing their own stuff."

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So two key swing justices, Kennedy and Breyer, each made comments during oral argument equating generic preemption, and the "take steps" rationale, with Buckman rather than Levine. That bears watching.

Since then, we've had the opportunity to discuss this aspect of Mensing with a couple of lawyer friends whose opinions on these sorts of issues we respect a lot. They'll have to remain nameless because we don't have permission to identify them, and can't get it on short notice. But the upshot is that they also noticed the same thing and think that there's a good chance, maybe even 50-50, that enough members of the Court might buy the Buckman argument to tip the balance in Mensing.

We thought we'd explain how that can be in a little more coherent fashion, that is more coherently than in our oral argument post. The major way in which, functionally, Mensing is different from Levine is that, to enforce the statutory (Hatch-Waxman amendments to the FDCA) mandate that generic labeling be the "same" as the label carried by the original branded drug that the generics are copying, generic manufacturers are not permitted to change their labels through the "changes being effected" (CBE) process. That was a big deal in the Levine debacle because CBE doesn't require FDA pre-approval.

At least that's the government's position, as well as the plaintiff's fallback in Mensing. Note that this is not completely nailed down as a statutory/regulatory matter, and the smoothest path for the plaintiffs to win in Mensing, would be for the Court to hold that that the CBE exception applies to generic drugs.

But for present purposes, that's neither here nor there.

Anyway, the FDA had previously taken the position that CBE did not apply to generics, and after getting lambasted in Levine for position switching, it wasn't about to execute another about face. Since the current administration is anti-preemption (at least in product liability cases), it had to come up with another rationale to get to that result.

That rationale was referred to at the Mensing oral argument as the "take steps" theory. In a very simplified fashion, it goes like this: Even though the generics couldn't be forced to change their label without FDA pre-approval due to the unavailability of the CBE loophole, they could have done other things - taken other steps - to get the FDA to agree that the label (including, if necessary, the label for the branded drug at issue) should be strengthened in the way plaintiffs wanted. These "steps" were somewhat ill-defined, but that hardly matters. Basically, the argument is that nothing prevented the generic defendants from, in a variety of ways, in effect lobbying the FDA to beef up the relevant warnings.

That's not "impossible," right? After all anybody can always lobby. The constitution protects the right to "petition" (what lobbying was called in the 18th century) the government.

But let's think about "take steps" for a minute. For one thing, it potentially has extremely broad scope, which may be why an anti-preemption administration invented it. Like we just said, anybody can lobby about anything. If all that's necesary to make a direct conflict with a government regulation - any regulation about anything - melt away is to argue that the defendant could have lobbied the relevant agency to change the offending regulation to eliminate the conflict, then there isn't a whole lot left of conflict preemption. And could that argument be extended further to the notion of lobbying Congress to change statutes? We don't know, but that nose poking into the tent in Mensing has an awfully big camel behind it.

That's one.

Second, when we're talking about a cause of action centering on a supposed state-law tort duty (that's what all these cases are, at bottom, about), upon defendant manufacturers to lobby the FDA, then state tort law is invading the regulatory space - the relationship between the regulated defendant and the agency regulating it. There's where Buckman comes in. One aspect of Buckman is that the Court was unwilling to give state tort-based intrusions of the regulatory space the benefit of the doubt:

> [T]he relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law. . . . Accordingly - and in contrast to situations implicating federalism concerns and the historic primacy of state regulation of matters of health and safety - no presumption against pre-emption obtains in this case.

Buckman, 531 U.S. at 347-48 (citations and quotation marks omitted).

So the "take steps" rationale for avoiding preemption runs into Buckman problems because the nature of the duty embraced by the purported state-law theory tells the defendant that it should have done something more or different with respect to its dealing with the FDA, as opposed to, in Levine, its dealing with the plaintiff or the prescribing physician.

Note that we said "purported." That's another possible point of Buckman vulnerability for the "take steps" argument. Forget for a moment about the FDA and prescription drugs. Have you ever heard of a state-law tort duty, anywhere, that imposes on the defendant a duty to change existing government policy? We've heard about warnings, design, and manufacture, and even more exotic (and generally rejected) things like duty to test, but we sure haven't heard of a duty to lobby. Analyzing "take steps" as some sort of "parallel violation" claim, it would fail because there's no pre-existing state-law tort duty that parallels what the plaintiffs are asserting. Rather, it's a purely regulatory claim. Buckman had something to say about that, as well:

> We must also reject respondent's attempt to characterize both the claims at issue in Medtronic . . . and the fraud claims here as claims arising from violations of FDCA requirements. . . . [I]t is clear that the Medtronic claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although Medtronic can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

531 U.S. at 352-53 (citations and quotation marks omitted). If Buckman stands for anything, it's that Congress prohibited private rights of action under the FDCA, and attempts to assert such private rights in the guise of tort claims are preempted.

So a second area where the "take steps" theory of liability - or of evading preemption - runs into Buckman trouble is that it involves a novel state-law duty that couldn't exist in the absence of the FDCA and the FDA. After all, if there wasn't a statutorily created federal agency in the first place, then there couldn't be any duty to lobby it.

A third possible collision point between "take steps" and Buckman has to do with the administrative interference rationale expressed in that case. See 531 U.S. at 351 (concluding that agency fraud claims would create "an incentive [for manufacturers acting defensively] to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application"). While the government in Mensing, unlike the SG's position in Buckman, disclaimed any fear of additional administrative burden, the question was posed in oral argument that "take steps" would create an incentive to lobby the FDA about a variety of things, including attaching "boilerplate" requests for label changes to every adverse event report. A large amount of defensive lobbying would seem to have the same, if not more, potential for gumming up the agency's works as the flood of unnecessary information invoked in Buckman. At least, that's the argument.

Finally, there's another way in which the "take steps" theory in Mensing bears troubling resemblence to the fraud-on-the-FDA claims held preempted in Buckman. That's causation. To find liability on a fraud-on-the-FDA theory would required a causal chain running through the FDA. A jury would have to conclude that, but for the fraud, the FDA would have come to a different regulatory conclusion than it in fact did, and that this different regulatory outcome would have in some way (such as keeping a product off the market altogether) prevented the plaintiff's injury.

But postulating liability on a counterfactual hypothetical that the FDA would have done something other than it in fact did is not only speculative, but creates a very real conflict with the real world - that is, the hypothetical inherently conflicts with what the FDA actually did.

Well, the "take steps" theory requires the same sort of FDA-based causation chain. In order for "take steps" to be causal as to either plaintiff Mensing or plaintiff Demahy, the lobbying that the manufacturers hypothetically could have done must have, again hypothetically, caused the FDA to do something other than what it actually did - in Mensing, say, to have ordered the manufacturers to change their label in some way that would have led to plaintiffs not receiving the drug (presumably because their prescribers would have read the hypothetically different label and made different prescribing decisions). In fact, the FDA did no such thing.

That's the same questionable FDA-based causation as in Buckman, dependent on a hypothetical set of facts in which the FDA would have done something different - something that conflicts, that is - from what it actually did.
Anyway, we don't know if, once the process of putting pen to paper (or whatever is the computer-based equivalent), the Buckman analogy will in fact muster enough votes to produce a pro-preemption ruling in Mensing, but we can see how, by creating and arguing the "take steps" theory of liability, the plaintiffs and the SG created the potential for a head-on collision with Buckman in a case that started out as a relatively simple warning case that did not not seem to implicate Buckman very much.

Mensing could be decided any day now. We're watching with a lot more interest now than we had when the Supreme Court originally accepted the appeals.