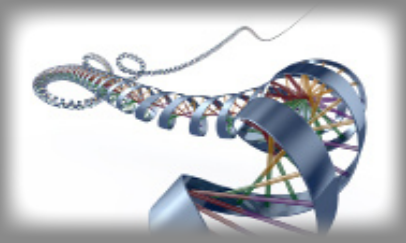
Life Sciences News

November 2008



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Wyeth v. Levine

An Eyewitness Report on the Oral Arguments before the U.S. Supreme Court

by Tripp Haston and Anne Marie Seibel

Wyeth v. Levine, preceded by *Riegel v. Medtronic* and *Warner-Lambert v. Kent*, is the final chapter in a trilogy of F.D.A. federal preemption cases taken up by the Court over the past sixteen months. In *Riegel*, the Court ruled in favor of preemption in the narrow setting of pre-market approved medical devices. *Kent*, on the other hand, resulted in a four-four draw due to Chief Justice Roberts' Pfizer stock ownership and consequent recusal. That case concerned the potential preemption of a Michigan statute barring most pharmaceutical products liability claims, save for cases of fraud on the F.D.A. At its core, the *Levine* case concerns the potential preemptive effect of the F.D.A's decisions concerning a medicine's label and attendant warnings upon claims for alleged personal injury due to use of that medicine.

Levine has been:

- Hyped by the U.S. Chamber of Commerce as "the most important business case of the Century."
- The beneficiary of over thirty amicus briefs from interests as diverse as the U.S. Government, Attorneys General from forty-seven States, former F.D.A. Commissioners, and economics professors at MIT, Vanderbilt and Emory.
- The subject of editorials in both the *New England Journal of Medicine* and the *Journal of the American Medical Association*.

Clearly, something is special about the *Wyeth v. Levine* case in legal, medical and financial circles. And, oral argument before the United States Supreme Court on Monday, November 3, 2008 did not disappoint, as this eye-witness report from Tripp Haston of Bradley Arant's Birmingham office details.

READING TEA LEAVES

After months of anticipation of the *Levine* argument and in the wake of *Riegel* and *Kent*, what did the questions from the bench suggest as a likely outcome?

First, and most importantly, it appears that the Court has a clear basis to recognize some form of F.D.A. conflict preemption if a majority concludes that the record supports the fact that the F.D.A. considered the risks of the medication administration method at issue here and concluded that Phenergan's labeling was adequate. The opening for this conclusion to be reached would be Levine's counsel's concession that certain pharmaceutical claims challenging the adequacy of the label could be preempted. Such a case may arise when the F.D.A. had considered and decided upon a specific label issue and no new or different information existed concerning this label issue. This is a significant concession because, to this author's knowledge, plaintiffs have never before conceded that the F.D.A.'s labeling decisions could have potential preemptive impact.

Second, any preemption finding is likely to be narrow and heavily conditioned. While the Court's questions suggested that Chief Justice Roberts, Justice Scalia and possibly Justice Breyer favored preemption, the questions of Justice Kennedy, Justice Souter and, to some extent, Justice Alito expressed skepticism of preemption in this context. Justice Thomas is a wild card as he remained silent in the session and his record on preemption has been mixed. Finally, based on their historic jurisprudence and questions today, Justices Ginsberg and Stevens are unlikely to join in any opinion favoring preemption.

In the end, perhaps a fragile 5-4 or 6-3 opinion favoring preemption in a narrow context will be the result. Given the fragility of this result and the time that it will require to build consensus, an opinion should not be expected until well into 2009.

A more in-depth analysis of this week's oral argument by Tripp Haston of our Birmingham office is available by clicking here.

The firm's newsletter of October 7, 2008, which has a more complete description of the case, can be provided upon request or is available here.

For further analysis, please contact Tripp Haston of our Birmingham office.

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