OTC Drug Plaintiff Fit To Be Fryed In New York

Wednesday, December 14, 2011

Just when we're disgruntledly packing away our "Fry Mumia" buttons for the last time (guilty as sin, that one was), we get word from New York that the plaintiff in one of Dechert's Tylenol cases lost a Frye-based appeal. Unfortunately, because Ratner v. McNeil-PPC, Inc., ___ N.Y.S.2d ___, 2011 WL 5865657 (N.Y.A.D. Nov. 22, 2011), is one of our cases, we can't supersize this post. But we can give you an outline of what happened.

First, Ratner is an example of the philosophy behind this blog – that a defense win anywhere helps defendants everywhere. A few years ago we (well, Bexis) participated in an amicus brief filed by the Product Liability Advisory Council, Inc. ("PLAC") in a case called Parker v. Mobil Oil. That appeal turned out well, producing an excellent Frye-based expert opinion – Parker v Mobil Oil Corp., 857 N.E.2d 1114 (N.Y. 2006). Parker, in turn became the foundation for the recent win in Ratner.

So what happened?

Ratner involved a drug containing acetaminophen. Massive overdoses of this drug can cause liver failure, which is not disputed. Ratner, however, did not involve any sort of overdose – plaintiff claimed only routine, therapeutic doses of the drug, significantly expanding the scope of liability, if allowed . Fortunately, the trial court found no valid scientific basis for the claim and granted summary judgment. In Ratner, the Appellate Division affirmed, holding that none of the plaintiffs' four experts had scientifically valid causation opinions.

The key issue in Ratner was not any particular test or technique used by the plaintiffs' experts, but rather whether those tests could even be applied, given a fundamental lack of underlying scientific evidence. The court recognized this hurdle as a "separate inquiry" not tied to novelty:

> "[W]here there is no novel or innovative science involved, or where the tendered scientific deduction has been deemed generally accepted as reliable, there remains a separate inquiry applied to all evidence. This inquiry is "whether there is a proper foundation – to determine whether the accepted methods were appropriately employed in a particular case."

Ratner, 2011 WL 5865657, at *7 (quoting Parker). The plaintiff's "novel theory of causation" – "that therapeutic acetaminophen use caused the plaintiff's liver cirrhosis" – not any particular methodology, was at issue. Id. at *8

The plaintiff's experts claimed to be relying on "extrapolation" from the known hepatic risks of the drug in overdose situations. Id. The court held that there was nothing from which to extrapolate. Absent adequate underlying data, the claimed "extrapolation" was simply an expert's "*ipse dixit*." Ratner, 2011 WL 5865657, at *9. All the plaintiff really offered was a pair of widely separated case reports of people who, after taking the drug in therapeutic quantities, later suffered liver trouble. That was not enough:

> "[O]bservational studies or case reports are not generally accepted in the scientific community on questions of causation. . . . [T]he two aforementioned case studies relied upon by the plaintiff constitute merely observational data which are of a lesser caliber than controlled clinical studies from which results can be reviewed and verified."

Id. at *10.

Not only were case studies inherently insufficient, but these (even for case studies) were pretty weak. For one thing, their authors did not reach causation conclusions. "The two studies merely hypothesized that the liver injuries sustained by the patients therein were related to ingestion of therapeutic doses of acetaminophen and that further study was warranted." Id. Or, as another author:

> "state[d] that the clinical importance . . . was unclear, and the authors of the study did not interpret the finding . . . to be indicative of serious liver injury."

Id. at *10. Thus, the plaintiff's experts were attempting to draw conclusions from purported bases of their opinions that went well beyond what those initial authors felt was justified.

And more. Because acetaminophen had been around for a long time, there were plenty of (and much better) contrary data – "thousands of journal articles" – that "acetaminophen is safe in therapeutic doses, even for individuals suffering from liver disease." Ratner, 2011 WL 5865657, at *10.

Since the plaintiffs' experts' opinions were: (1) based upon minimal and comparatively weak data, (2) that was contradicted by large amounts of more powerful data, and (3) went beyond the conclusions that even the reporters of that weak data felt was justified, those opinions were "fundamentally speculative." Id. at *11. Thus, the trial court had properly excluded those opinions and entered summary judgment:

> "[W]hen an expert seeks to introduce a novel theory of medical causation without relying on a novel test or technique, the proper inquiry begins with whether the opinion is properly founded on generally accepted methodology, rather than whether the causal theory is generally accepted in the relevant scientific community. Here, the plaintiff failed to meet that burden."

Id.