

## [What's In Them For Us?](#)

Tuesday, June 21, 2011

The Supreme Court decided the climate change case, [American Electric Power Co. v. Connecticut](#), No. 10–174, [slip op.](#) (U.S. June 20, 2011), and the class action case, [Wal-Mart Stores, Inc. v. Dukes](#), No. 10–277, [slip op.](#) (U.S. June 20, 2011), yesterday. We can't hope to compete with the deluge of general comment on these two behemoths (nor would we be particularly competent to do so), so we'll focus on what, if anything, we've found in these decisions that's relevant to prescription medical product liability litigation.

### [Wal-Mart v. Dukes](#)

First [Dukes](#) – initially because it was released a few minutes before [AEP](#), and ultimately because there's more there there (apologies to Oakland) for us.

As everyone who cares to know already knows, [Dukes](#) was (before yesterday) a gigantic employment discrimination case. As a substantive matter, there's not a whole lot of overlap between [Dukes](#) and what we do here. Everybody knew that the [Dukes](#) class action was so huge and polyglot that its certification had a target on its back. Indeed, not a single justice was willing to uphold the Ninth Circuit's decision that there was a certifiable class. But while part of [Dukes](#) (Part III, to be exact) was unanimous, another part (Part II) is only 5-4, and the Part II split was the usual "liberal/conservative" one with Kennedy siding with the Court's right wing.

Interestingly, the 5-4 part of the opinion was decided on commonality grounds. Previously, that prong of Rule 23(a) had been sort of a "gimme" in class action litigation. Most courts had held commonality satisfied if any plausible "common" issue existed, no matter how many individualized issues existed nor how weighty they were.

Well, no longer – and this is a ruling applicable to all class actions, including those involving prescription medical products. Commonality now has some teeth. If you don't believe us, check out the dissent. See [Dukes](#), [dissenting slip op.](#) at 8 (the majority "elevates the (a)(2) inquiry so that it is no longer easily satisfied"). Right on. Simply "reciting" a few common

questions “is not sufficient to obtain class certification.” Dukes, [opinion of the Court](#), slip op. at 9.

“Commonality requires the plaintiff to demonstrate that the class members have suffered the same injury. This does not mean merely that they have all suffered a violation of the same provision of law. . . . Their claims must **depend upon** a common contention. . . . That common contention, moreover, **must be of such a nature that it is capable of classwide resolution** – which means that determination of its truth or falsity will resolve an issue that is **central to the validity of each one of the claims in one stroke**.

Id. (citation and quotation marks omitted – both here and in the quotes that follow) (emphasis added). In other words, commonality now requires that all the class claims have a “central” common issue upon which every class member's claim rises or falls.”

This sounds like an essential element test, but to what extent? A claim could have more than one essential element, some common some not. That's something that happens all the time in litigation. But the absence of either would be enough to tank the claim. Knock out any essential element of a cause of action, and the whole claim falls, regardless of the other elements (that's why they're “essential”). So, under Dukes, how “central” is a common issue, if the same cause of action also contains an individualized element that by itself could defeat the claims? If any essential element of a claim is individualized, do other “common” elements satisfy the “in one stroke” test? We can't say, but it's something we'll be litigating.

And that's just commonality, formerly the easy one.

As a matter of personal prerogative, we have to point out that, as support for this change in the law – and it's as much of an emphasis shift as Twlqbal was for Rule 8 – the Court relies upon the work of our departed friend, Professor Richard Nagareda, whom we eulogized [here](#). His work truly lives on.

There's more good stuff. The old Eisen “don't look at the merits” prohibition – already in tatters – is now definitively interred:

“[C]ertification is proper only if the trial court is satisfied, after a rigorous analysis, that the prerequisites of Rule 23(a) have been satisfied. Frequently that rigorous analysis will entail some overlap with the merits of the plaintiff's underlying claim. That cannot be helped.”

Dukes, [slip op.](#) at 10. Thus, in our neck of the woods, as in all others, plaintiffs “must affirmatively demonstrate” entitlement to certification. Id. Just so nobody misses the point, the Court drops a footnote at the end of that paragraph, which explicitly buries the prior “mistaken” view of Eisen. Id. at n. 6 (characterizing the former view of Eisen as “purest dictum” and “contradicted by our other cases”).

So as to Eisen, it’s the end of an error. It was a long time coming; may it be a long time gone.

The fundamental factual problem for the plaintiffs in Dukes was the defendant’s lack of centralized employment decision-making. That process atomized the class, as it’s pretty difficult to assert credibly that disuniformity can be uniform throughout a class. Hence the Court’s statement:

“Without some glue holding the alleged reasons for all those decisions together, it will be impossible to say that examination of all the class members’ claims for relief will produce a common answer.”

Dukes, [slip op.](#) at 12.

We’re not employment lawyers on this blog, but we see a definite analogy to the individualized role of learned intermediary prescribers in prescription medical product cases. Just as in Dukes – and indeed, *a fortiori*, since **every** doctor’s prescription is an exercise in patient-specific medical judgment – there is no “glue” holding together any significant number of separate drug/device prescriptions.

We always viewed all those marketing-based class actions as phony. In light of Dukes, we think the Supreme Court would, too.

Also of great interest is the Court’s treatment of the purported “statistical proof” of discrimination – some sort of regression analyses that allegedly identified regional differences in the kind of stuff relevant to employment discrimination. The Court essentially holds that this type of attenuated statistical modeling doesn’t prove squat about each and every member of the class, as required by the Court’s beefed up commonality analysis:

“There is another, more fundamental, respect in which respondents’ statistical proof fails. Even if it established . . . [a] pattern that differs from the nationwide figures or the regional figures . . . , that would still not demonstrate that commonality of issue exists. . . . [R]espondents have identified no specific . . . practice

– much less one that ties all their 1.5 million claims together. Merely showing that [defendant’s] policy . . . has produced an overall . . . disparity does not suffice.”

Dukes, [slip op.](#) at 16-17. We deliberately stripped this quote of all its Title VII-related employment specifics to see how the Court’s holding would look as a general statement of class action law. We like it. It looks like a pretty broad indictment of attempts to prove commonality (and probably other Rule 23 elements, too) by means of bare statistical associations.

This aspect of Dukes looks like an application, at the Supreme Court level, of what Judge Weinstein called (not altogether fondly) the “individualized proof rule.” See In re Zyprexa Products Liability Litigation, 671 F. Supp.2d 397, 434-48 (E.D.N.Y. 2009). If our view of Dukes proves accurate, then there’s not much of a future for those experts, whom we all know and love, who peddle similar statistical analyses in support of marketing-based class actions in drug/device cases.

Finally, one more goodie out of Part II. Another currently raging class action battle is whether Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), applies to class certifications. While the Court did not explicitly decide that question in Dukes – it gave a pretty strong hint: “The District Court concluded that Daubert did not apply to expert testimony at the certification stage of class-action proceedings. We doubt that is so. . . .” Dukes, [slip op.](#) at 14.

We can use that in future battles. Praise the Court and pass the ammunition.

We reiterate: **All** of the above analysis is of the Rule 23(a) commonality factor. That’s a factor that must be met in any proposed class action of any sort under Rule 23. In these ways Dukes is relevant to every class action asserted against a manufacturer of prescription medical products.

Part III of the Dukes opinion – the unanimous part (Part I is simply a factual/procedural history) – is narrower because it only concerns when an “injunctive” class can also seek forms of monetary relief. As to Rule 23(b)(2), even the Court’s liberal wing could not stomach the Dukes certification. The Court did not reach the question whether monetary relief is “ever” allowed under Rule 23(b)(2), but decided the case on back pay awards being a prohibited form

of “individualized” relief.

Professor Nagareda must be smiling down upon us today, because again the Court relies on his writings:

“The key to the (b)(2) class is the indivisible nature of the injunctive or declaratory remedy warranted – the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them.”

Dukes, [slip op.](#) at 20 (quoting one of his many articles on the subject). In short, individualized and class-wide relief cannot be joined together in a Rule (b)(2) action. Id. at 21. Rule (b)(2) class members simply can’t seek “an individualized award of monetary damages.” Id. at 20-21. It doesn’t matter whether the monetary claims “predominate” or not – if they’re individualized, Rule 23(b)(2), and very likely Due Process itself, cannot accommodate them. Id. at 23-25. Whether or not some unspecified form of “incidental” monetary relief would be allowable in such classes, whenever such relief is “individualized,” Rule 23(b)(2) is unavailable. Id. at 26.

Right about there, we were looking for another citation to the ALI’s Principles of Aggregate Litigation. We didn’t see it.

We think that the Court’s holdings about Rule 23(b)(2) have implications for medical monitoring class actions. In most, if not all such classes, entitlement to relief varies greatly depending upon how much, how long, and how often an individual was exposed to a particular substance (which is sometimes alleged to be a drug – only rarely a medical device) claimed to threaten future harm. Combined with the Court’s broad criticism of statistical proof of injury, we would expect courts to take a harder look at medical monitoring class actions under Rule (b)(2) after Dukes.

Another thing that we’ve occasionally seen in drug/device class actions is an attempt by the plaintiffs to use a class action to extrapolate the results of a few plaintiffs’ cases to everybody else in the class. That’s usually called a “Castano” issue (at least by our side) – so named after a 1990s asbestos case out of the Fifth Circuit that’s been the most well-reasoned case rejecting class-action based extrapolation.

Now we can call that a Dukes problem – except that we shouldn't have to worry about it much at all anymore. In the last part of Part II, that's the unanimous part, the Court looked at the concept of "Trial by Formula" and recoiled. Class actions cannot be used to extrapolate results from the few to the many:

"We disapprove that novel project [referencing a Dukes-specific version of extrapolation]. Because the Rules Enabling Act forbids interpreting Rule 23 to abridge, enlarge or modify any substantive right, a class cannot be certified on the premise that [the defendant] will not be entitled to litigate its statutory defenses to individual claims."

Dukes, [slip op.](#) at 27.

Whoa! The Rules Enabling Act. That's pretty heavy artillery. The Court usually finds some way to avoid going there. Not this time.

As we've mentioned in [other posts](#), we once participated in Dukes, but only with respect to punitive damages, an item that was knocked out of the class action before it got to the Supreme Court. But in that last quote, it's as if the Court were channeling our position on punitives – and expanding it to all class actions. Our position (supported by the holding in Philip Morris USA v. Williams, 549 U.S. 346 (2007)), was that class actions cannot deprive defendants of their right to litigate individualized defenses to punitive damages.

Well, in Dukes, it appears that the unanimous Court has taken that "individualized defense" point and broadened it to all class actions of every sort. To deprive a defendant of individualized defenses would "modify" substantive rights and thus would be an improper application of the class action as a procedural device. While the PM v. Williams holding was narrowly grounded in constitutional Due Process law, by attaching the same proposition to the Rules Enabling Act (the statute that permits courts to promulgate any federal procedural rules), the Court has expanded our right-to-individualized-defenses argument to all class actions, including those involving prescription medical products.

Not a bad decision at all.

### **American Electric Power v. Connecticut**

What we were looking for out of the climate change case was: (1) an application of the

“Political Question Doctrine” to curb judicial triumphalism (that is, the judicial tendency to decide issues best left to the other branches of government), and failing that, (2) for the Court to say as many critical things as possible about the plaintiffs’ purported common-law “public nuisance” cause of action.

Well, we got very little on the first point. The Court split 4-4 (Justice Sotomayor was recused) on that issue (phrased as “standing” and also possibly encompassing a variety of other arguments), and thus didn’t decide anything. [AEP](#), [slip op.](#) at 6. Later on, there is some language disapproving of judicial triumphalism in the generic sense, but not tied to a specific ruling:

“The expert agency is surely better equipped to do the job than individual district judges issuing ad hoc, case-by-case injunctions. Federal judges lack the scientific, economic, and technological resources an agency can utilize in coping with issues of this order. . . . [J]udges are confined by a record comprising the evidence the parties present. Moreover, federal district judges, sitting as sole adjudicators, lack authority to render precedential decisions binding other judges, even members of the same court.”

[Id.](#) at 14-15. Nice, but – unlike [Dukes](#) – no teeth.

However, as in [Dukes](#), not a single member of the Court was willing to affirm the expansive ruling below, and thus give a green light for private plaintiffs and defendants to litigate climate change in the courts.

Nor did we score much on the second issue. The Court decided that federal environmental statutes had occupied the field, and that eliminated any need to turn to the “unusual” power to create federal common law. [AEP](#), [slip op.](#) at 9. Thus the Court did not critique, one way or the other, the merits of a public nuisance cause of action that would (among other things) let courts in one state reach across state lines to enter orders affecting activities in other states.

Rather, the Court posed a couple of interesting questions for the lower courts to chew on: (1) was there even such a public nuisance claim under state law? and (2) if so, was it preempted by federal environmental laws? [AEP](#), [slip op.](#) at 15-16. As to the first, we sound like a broken record, but federalist [Erie](#) principles should prohibit adventuresome predictions of state law - particularly when the supposed “nuisance” arises from conduct occurring wholly in another, equally sovereign, state. As to the second, the defense will have to cope with [Levine](#) and its “clear evidence” test. So what the EPA does in the next year or so will loom quite large.

While AEP was surely a big deal in some precincts, unfortunately it doesn't turn out to affect our area of the law very much. Such is life in the big city. The remanded questions could, however, prove to be more interesting.