Top Ten Best Prescription Drug/Medical Device Decisions Of 2011

Thursday, December 29, 2011

Happy Christmas/Hanukkah/solstice and Merry New Year to all our readers. May your 2012 be filled with winning arguments, Twlqbal dismissals, and summary judgments. There's not much of 2011 left now, although we'd be overjoyed for one or more last-minute decisions to come down and warrant a change to the list that follows.

What list is that?

Why our list of our favorite drug/medical device judicial decisions of 2011, of course. And what a list it is. Between three United States Supreme Court decisions, four (maybe five, depending on how we count) court of appeals decisions, and two more by state supreme courts, only one federal trial court opinion was able to make this year's cut.

We've even heard tell that some firms (we won't name names) have actually advertised their involvement with cases on our past top ten list. We should be flattered at that – we suppose. But such considerations don't enter into our rankings, which are purely subjective opinions. Anyway, without further ado, here are our best of 2011 – the decisions that made us rush to our computers to blog about, and cases that we hope will help our (and your) clients in the coming year.

1. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011). It's such a big win for preemption that it has to be number one, even though generic manufacturers are the only immediate beneficiaries. Not only was it a win, but after Wyeth v. Levine, 555 U.S. 555 (2009), a lot of commentators had written generic preemption off – but not us, as we pointed out here almost a month before Mensing was decided. Mensing also reveals a Court that is about as evenly split as it is possible to be on the presumption against preemption, with four justices saying no, four saying yes, and Justice Kennedy (who else on this Court?) supporting preemption without feeling the need to address that issue. What shoots Mensing into the top spot is it being an implied preemption case. This means that its principles are not limited to generic drugs. So keep in mind Mensing's test for impossibility preemption: "whether the private party could independently do under federal law what state law requires of it." Id. at 2579. It's usable elsewhere. Consider how that test might play in the context of, say, black box warnings,

design defect claims (both drugs and non-PMA devices), Dear Doctor letters, and any other situation where our clients are required to get the FDA's (or some other federal agency's) sign off before doing this or that. Also supporting the #1 ranking is that the reservations we have about some aspects of Mensing have not materialized (see #9 below). We blogged about Mensing here and here.

2. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068 (2011). We're #2! We're #2! This blog has been following Bruesewitz since it was in the district court. Vaccine defendants effectively ran the table in Bruesewitz. The main holding is that Congress totally preempted design defect claims as part of the Vaccine Act (the statute creating the current federal administrative compensation scheme for vaccine-related injuries). As in Mensing, the purported presumption against preemption goes on walkabout. Bruesewitz also rejected each and every of the plaintiff's hair-splitting arguments. After Bruesewitz, there shouldn't be much left of common-law vaccine litigation, with both warning (assuming the vaccine carries FDA-approved warnings – not a hard thing to do) and design claims preempted. Bruesewitz also makes a number of useful statements concerning common law issues that, while not binding, we are pleased to add to our defense armamentarium. The only reason Bruesewitz doesn't rank higher is because vaccines are a narrower category of litigation than drugs or medical devices. We listed our favorite bits of Bruesewitz here.

3. Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP, 634 F.3d 1352 (11th Cir. 2011). The best third-party payer/economic loss decision of the year. "Third-party" and "three" go together well, we think. A defense hat trick, with Rule 12 (no expensive discovery) dismissals affirmed against RICO, consumer fraud, and common-law claims under the law of – get this – 46 different states. That's just about every theory plaintiffs advance in this kind of case. As to each, the basic rationale is pretty much the same, simply paying a theoretically higher price for a safe and effective drug isn't the kind of loss any of these causes of action is designed to prevent. Third party payers are by definition insurers, so they can simply raise their premiums. To be actionable, the drug itself must be either unsafe or ineffective. But safety/effectiveness claims necessarily vary from patient to patient (and thus from prescriber to prescriber), so third party payer plaintiffs must prove any claims one by one (which, of course, they have no intention of doing). ILU68 also rules that pharmaceutical companies owe no duty of disclosure to third party payers, thus this decision has to rank very high on our list. We celebrated it here.

4. Williams v. Mast Biosurgery USA, Inc., 644 F.3d 1312 (11th Cir. 2011). We absolutely hate (see 2011 bottom ten #1) decisions that relax proof standards where plaintiffs have for whatever reason disposed of the product. Such decisions only create incentives for plaintiffs to do just that – arrange for the products at issue to become unavailable. Conversely we really like decisions that reinforce the requirement that there must always be a definable defect in a purportedly defective product. We especially like decisions that reject use of *res ipsa loquitur* as an end run around the defect (and sometimes causation) requirement of product liability. Williams is just such a case, and these issues are treated at some length. An added bonus to Williams is the careful discussion of the difference between lay and expert testimony in the case of treating physicians. We blogged about it here.

5. Sorrell v. IMS Health, Inc., 131 S. Ct. 2653 (2011). Yup, the United States Supreme Court decided two cases on our top ten list on the same day. Sorrell is not a product liability case, but rather a 6-3 constitutional decision that declares, "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." 131 S. Ct. at 2259. Boom. Such speech cannot be "silence[d] . . . by censoring its content." Id. at 2264. Double boom. Our complete description of Sorrell is here. As we pointed out in that post, and as the dissent pointed stated in the decision, id. at 2678, Sorrell is of particular interest because it puts very distinct handwriting very on the wall implicating the constitutionality of the FDA's prohibition against truthful promotion of off-label use. Still, that's in the future – hopefully in a top ten list yet to come. But for its great potential (and for being a Supreme Court case), we award Sorrell the #5 spot on our list.

6. Wolicki-Gables v. Arrow International, Inc., 634 F.3d 1296 (11th Cir. 2011). Everybody knows how much we like Twlqbal. Courts of appeals follow about four different Twlqbal standards in drug/device cases. The standard articulated in W-G is the best of the bunch. Parallel violation claims must be "specifically stated." Plaintiffs must allege the "particular" statutory section/regulation supposedly violated. "Specific" facts must establish the nature of the violation. Crucial allegations must be supported by "factual detail." Seems almost self-evident, but trust us, it hasn't been. Not only that, but W-G is also good on PMA device preemption. A two-fer, and because the court enunciates the toughest Twlqbal standard, we rate it the highest. We blogged about W-G here .

7. Garza v. Merck & Co., 347 S.W.3d 256 (Tex. 2010). How often does the best Daubert decision of the year come from a state court? In Garza the Texas Supreme Court took a hard look at the epidemiological "proof" that the plaintiffs offered in support of a multi-million dollar verdict – and wiped that verdict from the face of the earth. The studies involved dissimilar populations (as is almost always the case, the plaintiff took less of the drug for less time than the studied population) and didn't show a statistically significant doubling of the relative risk. Not only that, under Texas law, there must be two qualifying studies to guard against aberrant, fluky results. Without those studies, there was no legally sufficient proof of causation in Garza. Judgment n.o.v. city. If only federal Daubert decisions stood as tall as Texans. We gave Garza the old hook-em 'Horns salute here.

8. Dobbs v. Wyeth Pharmaceuticals, 797 F. Supp.2d 1264 (W.D. Okla. 2011). A gutsy judge making a gutsy call in the post-Levine world. We've always argued that the SSRI ("selective serotonin reuptake inhibitor") suicide cases – especially the adult ones – presented the best factual basis for implied conflict preemption in the prescription drug context. The FDA record, rejecting such warnings over and over again as scientifically unsubstantiated, is just awesome, which is why the Agency intervened in these cases as *amicus curiae*. But unfortunately, the Supreme Court screwed up the law in Levine before it had a chance to review an SSRI case. After bad decisions all last year (e.g., 2010 bottom ten #3) along comes Dobbs to hold that the SSRI record constitutes the kind of "clear evidence" of FDA rejection that Levine says is needed to support preemption. Maybe there's hope yet. We blogged about Dobbs here.

9. Smith v. Wyeth, Inc., 657 F.3d. 420 (6th Cir. 2011), and Mensing v. Wyeth, Inc., 658 F.3d 867 (8th Cir. 2011). Virtually unanimous state law before Mensing absolutely required that the plaintiff have used the defendant's product for any product-related cause of action to exist. The Supreme Court's Mensing decision speaks only to preemption and has nothing to do with substantive state law. Thus, state law after Mensing absolutely requires that the plaintiff have used the defendant's product for any product-related cause of action to exist. There's not a lot of reasoning in either decision – otherwise they'd rank higher – but the bottom line message is crystal clear. We blogged about Smith here.

10. Kowalski v. Rose Drugs of Dardanelle, Inc., ___ S.W.3d ___, 2011 WL 478601 (Ark. Feb. 9, 2011) (they take a long time to publish in Arkansas). Kowalski is a ringing reaffirmation of the learned intermediary rule by the Arkansas Supreme Court, combined with extension of the rule to pharmacists and an ultimately pro-defense outcome. The court adopts the majority

position that the rule precludes any general duty to warn from being imposed on pharmacists, and affirms entry of summary judgment. Best learned intermediary case of the year. Our post on the case is here.

That's the top ten, but our Christmas tree still isn't bare. Judicial Claus has left us a bunch of smaller, but still nice, judicial presents over the past year. We like defense wins, so here are the next ten in summary form:

Honorable mentions: (11) Astra USA, Inc. v. Santa Clara County, 131 S. Ct. 1342 (2011), not a products case, but quite citable as precedent for rejecting private tort actions in the teeth of an exclusive federal enforcement provision similar to the FDCA's 21 U.S.C. §337(a) (our post here); (12) Walton v. Bayer Corp., 643 F.3d 994 (7th Cir. 2011), putting a decisive an end to fraudulently joined non-diverse pharmacists precluding removal – a commonly used dodge – that's kept cases trapped in southern Illinois hellholes (our post here); (13) Funk v. Stryker Corp., 631 F.3d 777 (5th Cir. 2011), another good appellate Twlqbal decision, just not quite as good as W-G, due in large part to the plaintiff's procedural errors (our post here); (14) Degelmann v. Advanced Medical Optics, Inc., 659 F.3d 835 (9th Cir. 2011), Preemption? In a Class-II device case? It can happen if the moon and stars align (our post here); (15) Kinetic Co. v. Medtronic, Inc., 2011 WL 1485601 (D. Minn. April 19, 2011), good on preemption, Twlqbal, parallel claims, discovery, and express warranty, all in one opinion (our post here); (16) Kapps v. Biosense Webster, Inc., ___ F. Supp.2d ___, 2011 WL 4470701 (D. Minn. Sept. 27, 2011), a trailblazing decision involving reprocessed medical devices; well-reasoned and mostly favorable to the defense (our post here); (17) In re Digitek Products Liability Litigation, ___ F. Supp.2d ___, 2011 WL 5282595 (S.D.W. Va. Nov. 3, 2011), its excellent discussion of why "adulteration" has nothing to do with product defect will be cited again and again; would rank higher but for its shooting-fish-in-a-barrel aspect (our post here); (18) Gazal v. Boehringer Ingelheim Pharmaceuticals, 647 F.3d 833 (8th Cir. 2011), we don't usually rank statute of limitations decisions, but this one stands for the general proposition that absence of scientific proof capable of surviving Daubert does not toll the statute of limitations (our post here); (19) In re Prempro Products Liability Litigation, 765 F. Supp.2d 1113 (W.D. Ark. 2011), excellent Daubert decision rejecting a type of claim – product use of less duration/amount than implicated in published studies – that recurs in multiple mass torts (our post here); (20) Hogan v. Novartis Pharmaceuticals Corp., 2011 WL 1533467 (E.D.N.Y. Apr. 24, 2011), an antidote to Y/Y (see 2011 bottom ten #3), excluding Dr. Parisian altogether on Daubert and other grounds

(our post here). A half-dozen others – literally – just missed the cut.

Breaking out the old crystal ball, we note, in looking ahead to next year, that two of 2010's bottom ten (Hamilton #4 (DTC exception to learned intermediary rule and Lance #6 (negligent design in prescription drug cases)), both from intermediate state appellate courts, have been accepted for further review by their states' respective highest courts. A third 2010 stinkeroo (Bartlett #8 (strict liability design defect without an alternative design requirement)) is in the First Circuit Court of Appeals in a much changed, and hopefully improved, post-Mensing environment. No results in any of these yet, but we're hopeful of having at least some good news to report in the coming year. In one way or another, Bexis has managed to involve himself in all three of these further appeals, so we expect prompt – if not necessarily fulsome (client concerns control, after all) – reporting. More truncated coverage is possible in Daniel (#8 of this year's bottom ten (punitive damages despite FDA compliance)), as it is also a Dechert matter accepted for further appeal.

Beyond prior listings, this U.S. Supreme Court term (at least so far) doesn't have nearly as many cases with interesting potential impact on the drug/medical device product liability arena. One that might is Kiobel v. Royal Dutch Petroleum (our post here), which could nullify a horrible Alien Tort Statute decision, Abdullahi v. Pfizer, 562 F.3d 163 (2d Cir. 2009) (#2 on our worst list for 2009). The issue before the Court in Kiobel is very broad and rather remote – whether that statute has any applicability at all to corporations – so it's not specifically drug/device related.

Other notable pending appeals we're aware of: In Weeks v. Wyeth, the Alabama Supreme Court will become the first state high court to consider Conte branded/generic issues. We blogged about that, here and here. The Second Circuit will almost surely decide the Caronia case (our posts here and here), where the constitutionality of the FDA's prohibition against truthful off-label promotion is squarely at issue. It's the same circuit that, last year, favorably decided the First Amendment Sorrell decision (see 2010 top ten best #8) that the Supreme Court turned into our #5 above. Finally, the Virginia Supreme Court has before it the question of cross-jurisdictional class action tolling, as we mentioned here. Again, we hope to have more good news to report.

Happy new year to all.