Products Liability NEWSLETTER

OSB Products Liability Section

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Notes from the Chair

by Patrick Angel

Please join the Products Liability section for its annual CLE on May 4, 2015, from noon to 3:00 p.m. at the Nines Hotel in Portland. Lunch is included in the $45 registration fee. What responsibilities do product manufacturers have after a product is in the consumer's hands? This year's CLE will answer that question and many others related to a product seller's compliance with consumer safety regulations, product warnings, and recalls. We are fortunate to have two national experts on this topic, Kenneth Ross and Sean Kane, to present a balanced view of these issues.

This month's newsletter includes a primer on Multidistrict Litigation by Maria Janoski, which we are pleased to share with permission from the Federal Bar Associations Young Lawyer Division Newsletter. Thanks are also due to OSB Product Liability Section members Todd Bradley and Kirstin Abel, and contributing author Nicholas Kampars. Todd Bradley provides an update from an earlier newsletter article by Evan Schechter on the fascinating technology known as the SawStop, a power saw which cannot cut human flesh. Nicholas Kampars discusses food labeling and the Oregon mandatory labeling initiative which failed by a very narrow margin last November. Kirstin Abel summarizes a recent Ninth Circuit case discussing federal preemption issues related to Oregon tort claims against medical device manufacturers.

Thanks to everyone who worked on a newsletter article and who helped edit and review those articles. All members of the Products Liability section are encouraged to submit articles, case summaries, or suggestions for topics they'd like to see published in the newsletter. Please contact me (patrick@angellawpc.com) or our Newsletter Editor, Derek Larwick (dlarwick@corsonjohnsonlaw.com) with any ideas or submissions.

I would like close by taking this opportunity to thank Rachel Robinson for her outstanding service as the Chair of the Product Liability Section's Executive Committee last year. Rachel's commitment and hard work were invaluable.

A Young Lawyer's Guide to Multidistrict Litigation

By Maria Janoski

(First published in 2013 in the Federal Bar Association Young Lawyers Division Newsletter.)

Eighteen months ago I had never even heard the term "multidistrict litigation." I had heard the term "mass torts" before, but I hadn't actually given any thought to what that practice area might actually involve. In short, I was only dimly aware that the world of mass tort litigation existed. That all changed when, as fate would have it, I began my career as an attorney working for a mass tort law firm. Fortunately, although it was at times akin to drinking from a fire hose, I seem to have survived my first year in the world of mass torts. This article is a brief summary of what I have learned.

For starters, mass tort attorneys use at least as many acronyms as the cast of *Jersey Shore*. Since it's always helpful to understand the language, following is a quick list of the most commonly used mass tort acronyms.

MDL = multidistrict litigation
JPML = Judicial Panel on Multidistrict Litigation
PSC = Plaintiffs' Steering Committee
DSC = Defense Steering Committee
CTO = conditional transfer order
PFS = plaintiff fact sheet
DFS = defendant fact sheet
PPO9 = Practice and Procedure Order #9

I will use these acronyms throughout the rest of this article. One other piece of preliminary information (before I begin my summary of MDLs) is that there is a bible of sorts for this practice area, entitled *Manual for Complex Litigation* by David F. Herr. If you intend to practice mass torts, you must obtain a copy of this book.

What is Multidistrict Litigation?

Multidistrict litigation (MDL) is a special federal procedure intended to more efficiently process complex litigation. The authority for creation of an MDL derives from 28 U.S.C. § 1407, which provides that "when civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). The procedure is typically used in instances where hundreds (or even thousands) of plaintiffs were injured by the same conduct of a defendant or defendants, such as in a plane crash or an oil rig blowout or by an allegedly unsafe drug or medical device. (*See, e.g., In re Air Crash over the Mid-Atl.*, MDL No. 2144; *In re Oil Spill by the Oil Rig "Deepwater Horizon" in the Gulf of Mexico, on April 20, 2010*, MDL No. 2179; *In re DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation*, MDL No. 2197.)

MDLs are created by the Judicial Panel on Multidistrict Litigation (JPML). The JPML was created in 1968 by an Act of Congress. *See* http://www.jpml.uscourts.gov/panel-info/overview-panel. It consists of seven sitting federal judges who are appointed by the Chief Justice of the United States. *Id.* Its role is to decide motions for centralization (*i.e.*, to determine whether actions pending in different district courts involve common questions of fact sufficient to establish an MDL) and to assign the created MDLs to federal district court judges. *Id.* A party seeking creation of an MDL must file a motion for centralization (also called a motion for 28 U.S.C. § 1407 transfer) with the JPML itself. The procedures for filing such a motion, as well as sample forms, are available on the JPML website. Such a motion must consist of at least two actions pending in district courts which arguably involve common questions of fact.

Once an MDL has been created, the procedure for transfer to the MDL changes slightly. The party seeking transfer files what is called a notice of "tag-along" action with the JPML. This "tag-along" notice can be filed for any case pending in a federal district court and involving the common questions of fact specific to the MDL. It does not matter whether the case was initially filed in federal court or initially filed in state court and then removed to federal court. The JPML then issues a conditional transfer order (CTO), which, as the name implies, conditionally transfers the case to the MDL. Within seven days of the issuance of the CTO, any party opposing the transfer must file a notice of opposition in the JPML. This is done using a form available on the JPML website. The opposing party must then, within fourteen days of filing its notice of opposition, file with the JPML a motion to vacate the transfer and a brief in support thereof. If the transfer is not opposed, then the MDL court will issue a "finalized CTO," transferring the case to the MDL docket.

What Happens after a Case Is Transferred to an MDL?

Once a case is transferred to an MDL, it is subject to the pretrial procedures established by the MDL

court, most notably the discovery procedures and deadlines. These differ somewhat from the discovery procedures typical in non-MDL cases. Since the purpose of creating an MDL is to avoid the proverbial reinvention of the wheel in every cause of action, the defendant or defendants produce their documents only once (and not hundreds or thousands of times), and they are then used for the benefit of all plaintiffs in the MDL.

You may now be wondering exactly how this production and sharing is accomplished, since it quite obviously involves a significant amount of coordination from both sides of the aisle. The answer to this question is steering committees. At the beginning of the litigation, an MDL court establishes a Plaintiffs' Steering Committee (PSC) and a Defense Steering Committee (DSC). Attorneys seeking appointment to these committees must submit an application to the MDL court. Once the appointments are made and the committees are formed, the PSC and the DSC then work with each other and with the MDL court to move the litigation forward. Throughout the process, there is an emphasis on streamlining discovery so that it progresses as efficiently as possible.

For instance, both sides seek to standardize the paper discovery process as much as possible by developing fact sheets, which are then completed in lieu of initial written interrogatories. The parties create a plaintiff fact sheet (PFS) and a defendant fact sheet (DFS). Each is designed to collect relevant information, and the parties often argue over the content and scope of the information sought as well as the individual questions themselves and the number of questions. When the PSC and the DSC can't agree on an issue related to one of the fact sheets, the MDL court decides the issue. All objections with respect to the fact sheets are addressed before the fact sheets are put to use. Indeed, the MDL court must approve the proposed fact sheets, and the final, approved version of each is then used in each cause of action within the MDL.

Similarly, the PSC and the DSC work together regarding the production of documents. As stated earlier, defense documents are produced to the PSC. The PSC then coordinates its review of the produced documents among the plaintiffs' attorneys involved in the MDL. This eliminates the need for defendants to repeatedly produce the same documents and for multiple plaintiffs' attorneys to review the exact same documents. Similarly, the PSC notices defendant depositions and appoints plaintiffs' attorneys from within the MDL to take them. The testimony elicited in these depositions is then available for use in every cause of action pending within the MDL.

So far (with the possible exception of the PFS), I've discussed only discovery relating to the common question(s) of fact on which formation of the MDL was based. So what happens with respect to case-specific discovery? Well, in the parlance of mass tort lawyers, they are "PPO9'ed," which means they are transferred back to the transferor federal district court for the purpose of conducting case-specific discovery. Practice and Procedure Order #9 (PPO9) establishes this procedure; hence, the term "PPO9'ed." The MDL court designates cases for PPO9 discovery in "waves," and these "waves" typically follow the completion of much of the consolidated discovery.

The MDL court, the PSC and the DSC work together throughout the litigation. If the PSC and the DSC are unable to resolve a discovery or other type of dispute, the MDL court will intervene. The MDL court addresses issues and sets scheduling deadlines at case status conferences, which are held as frequently as the MDL court deems necessary. Although it is the members of the PSC and the DSC who address the MDL court during these conferences, typically counsel for all parties in the MDL participate via telephone.

Bellwether Trials

If you've reached this point in this article, you may be wondering what all of this means for the trial of MDL cases. Consolidating cases with common questions of fact for pretrial purposes certainly saves time and resources and promotes efficiency, but what good is all that if hundreds or thousands of similar cases must still be tried?

The solution to that conundrum is bellwether trials. The immediate goal toward which the MDL court, the PSC and the DSC all work is bellwether trials. In its initial scheduling order, the MDL court sets dates for bellwether trials, which, as long as the parties have agreed to waive any venue objections, are tried before the MDL court. Other cases within the MDL are remanded to the transferor court for trial.

As their name implies, the purpose of bellwether trials is to conduct trials that will allow all parties and the MDL court to assess the strengths and weaknesses of the MDL cases as a whole and to provide a bench mark by which the cases can be valued. Bellwether cases must therefore be as representative

of the MDL cases as a whole as is possible. As with discovery and scheduling, the PSC and the DSC work together during the bellwether process. Typically, criteria are first established to create a finite universe of possible bellwether cases. Then, both sides review the cases from within that universe and select a specified number of cases to be their bellwether submissions. Each side submits its bellwether choices to the MDL court, often with a short summary of the case and the reasons why it would be an ideal bellwether. The MDL judge then selects the bellwether cases.

A Few Things to Watch Out For

If you find yourself in the world of multidistrict litigation, there are more than a few nuances specific to the practice that you should become aware of sooner rather than later. First, at least browse through the *Manual for Complex Litigation*. I know I already mentioned this book, but it would be impossible to understate its usefulness. Now that you know of its existence, read some of it. Also, exploring the JPML website is a must.

My second additional tidbit of advice also involves reading. As soon as you find yourself in an MDL court, download and read a copy of that court's local rules. Not all MDL judges are sticklers when it comes to applying the local rules to MDL proceedings, but some are, so learn them. Besides, even if your MDL judge isn't a stickler, abiding by local rules and customs garners good will. As the saying goes, "When in Rome, do as the Romans do."

Third, keep your eyes wide open for choice-of-law issues. Choice-of-law issues are, of course, inherent in complex litigation. MDLs, however, can add new wrinkles when it comes to such analysis. For instance, in multidistrict litigation, matters of federal law are governed by the law of the transferee court. *See Ricupito v. Indianapolis Life Ins. Co.*, No. 3:09-CV-2389-B, 2011 U.S. Dist. LEXIS 97334, at *5 (N.D. Tex. Aug. 31, 2011) ("As to matters of federal law, however, the Court applies the law of the transferee court."); *Bhatia v. Dischino*, No. 3:09-CV-1086-B, U.S. Dist. LEXIS 97339, at *15-16 (N.D. Tex. Aug. 29, 2011).

Conclusion

Given the staggering complexity of multidistrict litigation, and the break-neck speed at which many MDL cases proceed, I'm hopeful that the above paragraphs will provide you with at least enough guidance to determine that you are not actually in Oz. It may certainly seem that way at first. But, trust me, in hardly any time at all, you too will be peppering your speech with acronyms like "MDL," "JPML" and "PPO9."

Toward a Safer Table Saw - Update on the SawStop®

By Todd Bradley

In the Winter 2011 issue of the Products Liability Newsletter, Executive Committee member Evan Schechter wrote about a recent case involving a fascinating safety device that promised to prevent many serious injuries to users of table saws. Commonly referred to as SawStop® technology, the core of the device is a sensor that allows a spinning blade to detect any contact with human flesh, activating a brake that stops the blade in 3 to 5 milliseconds, before serious injury can occur. All of the sensors and braking parts exist underneath the table, meaning that the device does not interfere with the operation of the saw in any way.

By now, millions of people have seen the videos of an operator slowly pushing a hotdog into the spinning blade of a powerful table saw. As the hotdog reaches the blade, faster than your eye can blink, the blade disappears beneath the table, leaving a barely perceptible mark on the hotdog's skin.[1] First shown to the public at the International Woodworking Fair in 2002, SawStop® is the invention of Stephen Gass, an Oregon patent lawyer and woodworker who created his first working prototype in 1999. In 2004, after several years spent in an unsuccessful effort to persuade the major manufacturers to incorporate his device into their product lines, Mr. Gass and three friends put up the capital to enter into the table saw manufacturing business under the name SawStop®.

1 http://www.sawstop.com Not to be outdone, TV personality Roy Underhill repeated the demonstration using a piece of fried chicken, he says to prove that the technology will also work in the South. http://www.highlandwoodworking.com/blog5/roysawstop.html

A Jury Finds the Ryobi Table Saw Defective

As Mr. Schecter reported here in 2011, Carlos Osorio was injured

while using a Ryobi brand table saw on a job site in Massachusetts. He had not been well-trained in the use of table saws, and he was doing a lot of things wrong; he was not using a fence to guide the wood into the blade, and he was not using the blade guard supplied with the machine. As he was pushing the wood into the blade, his hand slipped off the board and into the spinning blade, causing very serious injuries. With the blessing of his employer's workers compensation carrier, Osorio brought suit against Ryobi, contending among other things that the saw was dangerously defective because it did not incorporate flesh-detecting technology. At the trial in 2010, Stephen Gass appeared as an expert witness, testifying that his technology was available at the time the Ryobi saw in question was manufactured, that it could have been incorporated at a reasonable cost, and that it would have prevented any serious injury to the plaintiff. The jury agreed that the Ryobi table saw was defectively designed, while also finding Osorio 35% at fault, and the verdict was upheld on appeal. *Osorio v. One World Technologies*, 2011 WL 4582425 (1st Cir 2011).

Until the Osorio verdict, the table saw was widely considered immune from defective design claims due to its obvious danger and inherent nature as a tool intended to cut wood. In addition, many injuries seemed to involve alterations or misuse, most notably the removal of blade guards. Users complained that the guards obstructed the view during use, and that they were hard to remove and replace. The position of the manufacturers was that existing guards were adequate if used correctly, and that education in proper use would keep users safe from this unavoidably dangerous, yet essential tool. If the user observed safe practices and did everything right 100% of the time, in other words, there would be no injuries. Implicit in this viewpoint was that there really was no feasible alternative design that could protect a consumer who is less than perfectly careful.

The jury in Osorio had validated the feasibility of an alternative design that would take into account the foreseeable flaws of human operators, such as fatigue, momentary lapse of vigilance, ignorance, inexperience, and even foreseeable misuses such as removing the guards. It appeared that the case may be a preview of things to come – given the estimated 30,000 or more table saw injuries involving inadvertent blade contact that occur every year,[2] many more lawsuits would be on the horizon. Perhaps we would observe an industry forced by the doctrine of strict product liability, as applied by juries, to incorporate some version of flesh detection or other active injury prevention technology in order to avoid being held responsible for injuries that previously had been considered solely the result of operator error or misconduct.

UL Standards Revised

The industry did take steps toward making table saws safer. After the SawStop® was introduced, several of the major players in the field, including Ryobi, Black & Decker, and Bosch, together with their trade group Power Tool Institute, cooperated in a project to revise the UL standards for table saws. In 2005, the UL standard was changed to require an improved, modular blade guard that would be easier to remove and replace, encouraging wider use. In 2007, the standard was revised to require a riving knife, a thin piece of metal mounted behind the blade to help prevent wood from being kicked back at the operator. For the time being, these voluntary measures deterred the Consumer Product Safety Commission from pursuing a petition filed by Gass to issue regulations that would require flesh-detecting technology in all new saws.

CPSC Proposes Action

After the Osorio verdict, the CPSC came under renewed pressure from consumer groups, such as the National Consumers League. In 2011, the CPSC voted to issue an Advance Notice of Proposed Rulemaking that would lead to new rules mandating flesh-detecting technology. https://www.cpsc.gov/PageFiles/90189/tablesaw.pdf During the ensuing comment period, the woodworking community came alive, sending a wave of protests onto the forums at FineWoodworking.com, Popularwoodworking.com, Sawmillcreek.com, and many other woodworking Internet sites, expressing scorn for Osorio, the jurors, the judge, the lawyers and, especially Stephen Gass, who many commentators believed was attempting to take away consumers' freedom of choice in order to enrich himself through the monopoly afforded by his patents. Interestingly, many of those who protested the proposed regulation praised the SawStop® itself as a wonderful invention, a high quality saw, and one they themselves would love to purchase. The outcry was such that it gained the attention of Stephen Colbert, who featured "finger hugger" Stephen Gass and the SawStop® in a segment called People Who Are

2 According to various documents filed by the Consumer Product Safety Commission under Docket No. CPSC-2011-0074, available at www.regulations.gov

Destroying America.[3] The online comments should be considered required reading for anyone preparing for a jury trial in a table saw case, though plaintiff lawyers especially will find it humbling, if not downright discouraging, as things get personal on the subject of lawyers and lawsuits.

In response to the CPSC proposed rulemaking, the Power Tool Institute objected that the Commission is required by statute to defer to voluntary standards that accomplish the goals of protecting consumers. The Power Tool Institute also noted that the Commission had not conducted any review of the efficacy of the revised UL standards concerning the new modular blade guards and that since 2007 thousands of saws meeting the new standards had been placed on the market. In May 2013, the CPSC announced it would hold off on new regulation while it conducted surveys of table saw users to determine how consumers are using the new devices and whether inadvertent blade contact injuries are being prevented. As of this date (Winter 2015), these surveys are still being conducted and analyzed.

California Takes up the Cause

While waiting for the CPSC to act, proponents in California of mandating flesh-detection technology, including California Conference of Carpenters, California Medical Association, State Building and Construction Trades Council, and Consumer Attorneys of California, were able to introduce a bill in the 2012 legislative session called the Table Saw Safety Act, which would have required all new table saws sold in California after January 1, 2015, to be "equipped with active injury mitigation technology." AB 2218 defined active injury mitigation as "technology to detect contact with, or dangerous proximity between, a hand or finger and the teeth of the blade above the table top of a table saw, and to prevent the blade from cutting the hand or finger deeper than one-eighth of an inch when the hand or finger approaches any portion of the blade above the table top at a speed of one foot per second from any direction and along any path."

Though written in the neutral language of a performance standard, it was widely understood that the SawStop® was the only table saw presently on the market that could meet the standard. Opponents of the bill, which included the Power Tool Institute, Home Depot, Lowe's, Sears, and the Chamber of Commerce, complained that it would be difficult, if not impossible, to devise an alternative to the SawStop® without violating its patents. The bill passed the Assembly by a vote of 64 to 4, and cleared the Senate Judiciary Committee 3 to 1. However, in the face of strenuous opposition and concerns that the bill would grant a *de facto* monopoly to one company, the bill died without further action. It remains to be seen whether the bill will be picked up again if the CPSC does not act.

Are Juries Ready to Blame the Saw?

The question remains: has the SawStop® changed the legal environment for lawsuits involving table saw injuries? According to Chicago lawyer John Bell, who has represented table saw manufacturers in a number of cases, at least 200 table saw lawsuits have been filed since the Osorio verdict. Many of these have been settled, but at least three cases have gone to trial. In Los Angeles, there was a hung jury, after which the case was reportedly settled. In Illinois, a jury sided with Ryobi in a case in which the plaintiff lost two fingers. Stephen Gass again appeared as an expert and repeated his testimony from the Osorio trial. Unlike the inexperienced Osorio, the Illinois plaintiff had years of experience working with table saws, and he was using the saw without the supplied guard because, he said, it was in the way. A former chief engineer from Ryobi testified that he had removed the same guard on his own table saw at home and installed his own riving knife, because he thought it was safer.

In response, Ryobi made the expected argument that its table saw complied with all applicable standards and was not unreasonably dangerous when used correctly. Ryobi's lawyer then told the jury that the case was not primarily about the injured plaintiff at all, but was instead "an intellectual property case, masquerading as a personal injury case...." He claimed that Stephen Gass and the plaintiff's lawyer were engaged in a "joint venture" to file injury lawsuits in order to force Ryobi and other manufacturers to license the SawStop® technology. In August 2013, the 7th Circuit Court of Appeals agreed that these arguments were improper and vacated the defense verdict, sending the case back for a new trial.[4] Last September, a new jury found the product defective and awarded plaintiff $1.25 million.

A month later, in October, 2014, a Minnesota federal jury sided with the manufacturer in a case where the plaintiff had removed the blade

3 http://www.colbertnation.com/the-colbert-report-videos/408216/february-13-2012/people-who-are-destroying-america--sawstop

4 *Stollings v. Ryobi Technologies et al.* 725 F3d 753, 2013 WL 3964477 (7th Cir. 2013)

guard because it interfered with the outfeed table. Reportedly, the focus in that case was the inadequate design of the blade guard assembly, although the absence of flesh-detection technology was also raised. The jury found that the product was not dangerously defective, not reaching the question of plaintiff's contributory fault.[5]

Safety Sells?

Meanwhile, SawStop® says on its website that it has sold 50,000 saws equipped with its patented technology and is now the best-selling table saw in North America. In 2015, the product line will expand to include a portable job site saw for under $1300. In a recent interview for Fine Woodworking, Stephen Gass said that he is no longer actively pushing for CPSC action.[6] He also says he is not much interested in licensing his technology to other manufacturers, now that he is well-established in the business of manufacturing high-quality saws himself.

While many woodworkers insist they want the freedom to choose, large numbers of them seem to be choosing safety when they have the means. As it was with seatbelts and airbags, it may be only a matter of time before the idea of a table saw without flesh-detection will be unthinkable.

5 *Thull v. Techtronic Industries, et al.* U.S. District Court (Minnesota) case No. 0:2011cv02368

6 http://www.finewoodworking.com/item/115195/stl72anothertablesawlawsuit (November 14, 2014)

Food Labeling in the Crosshairs of Consumer Groups and Lawyers Alike

By Nicholas A. Kampars

Last November, Oregonians narrowly defeated a food labeling initiative that was the most expensive ballot measure fight in the state's history.[1] Backed primarily by consumer groups, Measure 92 would have required all raw and packaged food produced through genetic engineering to contain a label stating as much. Although the measure failed by a slim margin, the backers have vowed to revive the effort in the next election cycle, and consumer groups in both Washington and California have indicated their intent to do the same.

These consumer groups aren't the only ones pushing for more stringent food labeling practices. Lawyers who once pursued Big Tobacco are now focusing their efforts on food companies, who they claim are using misleading labels and violating federal and state regulations in the process. That has led to an increase in class action lawsuits aimed at some of the largest food producers in the world, with new cases being filed every day in jurisdictions across the country.

The federal regulatory scheme for food labeling complicates these cases. The Food and Drug Administration and the United States Department of Agriculture's Food Safety and Inspection Service split the regulatory duties, depending on the type of food product. The FDA's jurisdictional authority for the regulation of food labeling is found in the Food, Drug and Cosmetic Act ("FDCA"), as amended by the Nutrition Labeling and Education Act of 1990 ("NLEA"). 21 U.S.C. § 343-1, *et seq*. The USDA's jurisdictional authority is found in the Federal Meat Inspection Act (21 U.S.A. § 678, *et seq*.) and the Poultry Products Inspection Act (21 U.S.C. § 451, *et seq*.). On the other hand, the Federal Trade Commission is empowered to prohibit unfair or deceptive practices and any false or misleading advertising with respect to food products. Faced with this regulatory thicket, lawyers often turn to state laws prohibiting consumer fraud or false advertising in an effort to challenge the labeling and advertising practices of food manufacturers.

The use of the phrase "all natural" provides an illustrative example of the exponential growth in food labeling litigation across the country. Hundreds of cases have been brought as putative class actions, alleging that companies misled consumers by advertising their products as "all natural," when, in fact, the products contained

1 *Willamette Week*, October 20, 2014 (http://www.wweek.com/portland/blog-32345-watch_the_gmo_ads_bought_with_record_breaking_spending_on_measure_92.html).

artificial ingredients. Because the federal agencies have refused to provide food manufacturers with definitive guidance on what "all natural" means, the federal courts have been left to grapple with the issue on a case-by-case basis.

Out of the gate, most of these cases are usually met with motions to dismiss based on arguments that the FDA (as opposed to the federal judiciary) has primary jurisdiction over "all natural" claims, or that the alleged class members didn't purchase the food product at issue, or that the ingredient list sufficiently notified the consumer that artificial ingredients were used. Such motions have met varying degrees of success. In *Gabbamonte v. The Kellogg Co.*,[2] the plaintiffs alleged that Kashi deceived customers through its use of the label "all natural" because its products contained genetically modified organisms. The defendant argued that the FDA had primary jurisdiction over "all natural" disputes and therefore, the court should dismiss the case. That motion was denied.

In *Kane v. Chobani*,[3] the plaintiffs alleged that Chobani's use of the label "all natural" was false and misleading because its yogurt contained fruit juice and used turmeric as a coloring agent. The court in that case granted the defendant's motion to dismiss, finding that the plaintiffs failed to allege reliance and economic injury, required elements under California's Unfair Competition Law.

If a food labeling case survives a motion to dismiss, then the next hurdle is class certification. The stakes for food producers at this stage are high and, as with the motions to dismiss, the results vary. In *Astiana v. Ben & Jerry's Homemade, Inc.*,[4] the plaintiffs alleged that Ben & Jerry's misled consumers by including an "all natural" label on its ice cream when, in fact, certain flavors of the ice cream contained alkalized cocoa. Alkalized cocoa, argued the plaintiffs, is processed with a man-made synthetic ingredient called potassium carbonate. The court refused to certify the class, however, because the plaintiffs could not provide any means for the court to ascertain whether a class member's ice cream contained the artificial ingredient.

In *Werdebaugh v. Blue Diamond Growers*,[5] the plaintiffs alleged that Blue Diamond's almond milk contained a synthetic ingredient, potassium citrate, rendering its "all natural" label false and misleading. The defendant argued that the question of whether the label's statements were material would vary between consumers, and that the case therefore lacked the commonality necessary to proceed as a class action. The court rejected that argument, and certified a damages class action.

Late last year, food manufacturers received a welcome decision in a case that had previously been certified as a class action. In *Brazil v. Dole Packaged Foods, LLC*,[6] the plaintiffs claimed that the "all natural" label on Dole's packaged fruit products was misleading because the products contained ascorbic and citric acids. Although the court initially certified a national class for injunctive relief and a California class for damages, it later decertified the damages class. A little over a month later, the court granted Dole's motion for summary judgment, finding that its "all natural" labels referred only to the actual fruit used, and that both ascorbic and citric acids could be reasonably expected to be used in foods that purported to contain no synthetic ingredients. This was one of the first "all natural" cases to be decided upon the merits, but it remains to be seen whether it will have any impact on the various pieces of litigation currently pending around the country.

As all of these cases show, food labeling practices will continue to be examined and challenged in the courts, and will be increasingly joined by labeling efforts in state legislatures and at the ballot box. The potential difficulties in pursuing food labeling cases under state consumer protection theories suggest that the legislative process may be the best route for any significant change to the labeling practices of America's food producers. But as new legal theories are successfully tested by lawyers representing such groups, especially with respect to consumer class action cases, there is no doubt the rapidly changing litigation landscape will shape the public discourse.

2 U.S. District Court for the Southern District of Florida, Case No. 12-21678 (September 5, 2014).

3 973 F. Supp.2d 1120 (N.D. Cal. 2014). The Northern District of California has been a hotbed for food labelling class action cases. So many cases have been filed there that it is now commonly referred to as the "Food Court."

4 20014 WL 60097 (N.D. Cal. Jan. 7, 2014).

5 2014 WL 2191901 (N.D. Cal. May 23, 2014).

6 2014 WL 2466559 (N.D. Cal. Nov. 6, 2014) (Case No. 5:12-cv-01831.

McLellan v. I-Flow Corp.: Clarification of Federal Preemption of Claims Against Medical Device Manufacturers

By Kirstin Abel

In *McClellan v. I-Flow Corp.*, No. 11-35109, 2015 WL 294292 (9th Cir. Jan 23, 2015), the Ninth Circuit held that the jury instructions requested by plaintiff on her failure to warn and strict liability claims were not preempted by federal law, and allowed plaintiff to proceed on a negligence per se theory.

Christina McClellan alleged she sustained injuries after she used the PainBuster, a continuous infusion pump device manufactured by I-Flow Corporation and sold and distributed by defendants DJO, Inc. and DJO, LLC (collectively "DJO"). Following the use of the pump after each of two surgeries, McClellan developed chondrolysis, a condition that results in the destruction of cartilage in a joint space. In McClellan's case, it led to a total loss of cartilage and caused her shoulder to fuse, resulting in zero motion of the joint and very limited movement of her shoulder.

McClellan filed suit against I-Flow and DJO for negligence and strict liability based on two theories: (1) I-Flow failed to warn that its pain pump should not be used in the shoulder joint; and (2) I-Flow was strictly liable for selling a product whose lack of adequate warnings made it unreasonably dangerous. At trial, McClellan requested the following jury instructions: negligence *per se*, Oregon *former* UCJI No. 20.03 (now 20.04); statute, rule or standard as evidence in determining reasonable care, Oregon *former* UCJI No. 20.04 (now 20.05); and nine special instructions related to federal law. The district court concluded the instructions were preempted by federal law under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 US 341, 121 S Ct 1012 (2001), and denied plaintiff's request. Plaintiff appealed, arguing that the presumption against federal preemption applied and that the district court's refusal to give the jury instructions was not harmless error.

The PainBuster product at issue is regulated by the Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetics Act (FDCA). The issue examined by the Ninth Circuit was whether the state laws set forth in plaintiff's requested jury instructions conflicted with the MDA, preempting them under the Supremacy Clause of the Constitution. Where actual conflict exists between state and federal law, and compliance with both is either impossible or the state law is an obstacle to the execution of the Congressional intent of the federal law, the state law is preempted. *Altria Grp., Inc. v. Good*, 555 US 70, 76-77, 129 S Ct 538 (2008); *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 US 707, 713, 105 S Ct 2371 (1984). The court recognized that, when Congress "has legislated in a field traditionally occupied by the states," there is a presumption against preemption. *Altria Grp.*, 555 US at 77.

At trial, the district court relied heavily on *Buckman* in determining that plaintiff's requested instructions were preempted under the MDA. There, plaintiff made what the Supreme Court referred to as "state-law fraud-on-the-FDA claims." The *Buckman* court held there was no presumption against preemption because regulating fraud against the FDA is not traditionally a state-occupied role. The *Buckman* court also noted that plaintiff's claims failed because it was clear Congress had intended the MDA to be enforced by the Federal Government, and plaintiff's fraud-on-the-FDA claims arose solely out of provisions of the FDCA. Where a plaintiff's claims do not rely on traditional state tort law but on federal enactments, they will be preempted.

The Ninth Circuit distinguished McClellan's claims from those in *Buckman*, finding that unlike *Buckman*'s claims, which arose solely out of the MDA, McClellan's failure to warn claims were based on the labeling and regulation of medical devices, an area historically within the province of the state. That distinction led the court to conclude the presumption against preemption applied, and therefore, *Buckman* was not controlling. It held McClellan's requested instructions did not conflict with the MDA, nor did her claims arise out of the MDA. Furthermore, the court found no evidence that Congress had intended to deprive the states of their traditional roles by making the "policing" of warnings and labels on drugs and medical devices exclusive to the FDA.

The Ninth Circuit rejected I-Flow and DJO's argument that plaintiff's claims were an attempt to enforce the MDA because she sought to use federal regulations to establish the standard of care. The court found the requested instructions "would not usurp the exclusive federal enforcement power over the MDA" because "the allegations

at issue occur outside the context of the regulatory process, unlike in *Buckman*."

In concluding preemption did not apply, the court held that the district court's failure to give the plaintiff's requested instructions did not result in harmless error, as argued by I-Flow and DJO. The instructions given by the court were weaker and not the equivalent to those requested by plaintiff. Having concluded that it was error for the district court to conclude that the MDA preempted plaintiff's requested instructions and that the error resulted in harm to plaintiff, the court vacated the judgment for defendants and remanded the case for a new trial.

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PROGRAM SCHEDULE

Noon	**Registration and Lunch** *Lunch is included in the registration fee*
12:15	**Welcome and Introduction**
12:20	**Regulatory Compliance: CPSC Reporting and Post-Sale Corrective Action** Kenneth Ross, *Bowman and Brooke LLP*
1:05	**Break**
1:15	**Regulatory Compliance: The Current Recall Systems** Sean Kane, *Safety Research & Strategies, Inc.*
2:00	**Regulatory Compliance: Group Discussion and Question and Answer Session** Led by David Rocker, *Davis Wright Tremaine LLP* and R. Brendan Dummigan, *Pickett Dummigan LLP*
2:30	**Final Remarks**

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