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Rx For The Defense

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Committee Leadership

In This Issue

Chair's Corner

By Sara Gourley

It was great seeing everyone at the DRI Annual Meeting in San Francisco! On the "main stage" we heard from Dr. Condoleeza Rice, and Valerie Jarrett! The agenda was also packed with networking opportunities, and CLE presentations in just about every area of the law. Our Drug & Medical Device Committee presented on "Current Trends and Hot Topics Emerging in Products Liability MDLs and State Coordinated Litigation." Moderated by Kelly Jones Howell (Harris Beach PLLC), attendees heard from lawyers who are involved in the biggest aggregate litigation. Speakers included Fritz Zimmer (King & Spalding LLP), Sonja Weissman (Reed Smith LLP), and Brandon Cox (Tucker Ellis LLP). The presentation was followed by a Drug & Medical Device Committee meeting.

The Drug & Medical Device Committee is also busy putting the finishing touches on our flagship seminar which will be held on May 15–17, 2019, in Washington, D.C. We have some great speakers planned, including Rebecca Wood (former Chief Counsel, U.S. Food & Drug Administration, now at Sidley Austin), a number of in-house counsel, and some great trial lawyers. As always, we will have a Young Lawyers breakout session to address topics of special interest to our up-and-coming colleagues. We listened to our members about what they would like to see more of at our seminar, and are answering the call: there will be more opportunities for networking with clients and colleagues! Firms are hosting receptions, we will offer dine-around sign-ups, there are DRI receptions, and more! As always (and one of the best networking opportunities), we will conclude our seminar on Friday afternoon with the opportunity to join clients and colleagues in a public service project to give back to the community hosting our seminar. Thank you to Jim Craven (Wiggin & Dana LLP) for leading that effort. Please join us.

Have a great fall. See you in Washington in May.

Sara Gourley is a partner in the Chicago office of Sidley Austin and a practice leader for the Firm's Product Liability and Mass Tort practice. She focuses on the national and regional defense of drug and medical device litigation. She is Chair of the Drug & Medical Device Committee of DRI.

Editors' Notes

By Kimberly Beck and Heather Howard

We enjoyed seeing everyone at the Annual Meeting. If you have an idea for an article for *Rx for the Defense*, please email Kimberly Beck at kbeck@ulmer.com and Heather Howard at hhoward@kslaw.com.

Kimberly Beck practices in the Cincinnati, Ohio office of Ulmer & Berne LLP, where she is a member of the firm's Pharmaceutical and Medical Device Defense and Mass Tort practice groups. Her practice focuses on the defense of pharmaceutical products. Kimberly currently serves as the Chair of Counsel Meetings and Newsletter Editor for the DRI Drug and Medical Device Committee.

Heather Howard is Counsel in the Atlanta office of King & Spalding LLP, where she is a member of the firm's Trial & Global Disputes practice. Ms. Howard focuses her practice on the defense of pharmaceutical and device manufacturers in product liability suits at the trial level and on appeal. Heather recently served as Young Lawyer Liaison to the DRI Drug and Medical Device Committee, and now serves as the Assistant Newsletter Editor for the DRI Drug and Medical Device Committee.

Awards

Drug and Medical Device Committee


The Drug and Medical Device Committee is honored that two of its steering committee members were recognized at Annual Meeting for their outstanding contributions to DRI. Jim Craven of Wiggin and Dana, Community Service Chair of the Drug and Medical Device Committee, received the DRI Lifetime Community Service Award, for his active and outstanding commitment to improving the social and cultural well-being of the public by initiating and participating in community service. Kelly Jones Howell of Harris Beach, Annual Meeting Chair for Drug and Medical Device contributions to the Annual Meeting, and former Chair of the Young Lawyers Committee, was awarded the Richard H. Krochock Award, which honors an individual for providing exemplary leadership, guidance, support and service to the DRI Young Lawyers Committee. Thank you Jim, Kelly, and all other award recipients, for your continued commitment and leadership.

Feature Articles

Hard Cases Can Still Make Bad Law, but Some Courts Properly Resist the Urge: Recent Developments in "Innovator Liability"

By Jeffrey A. Holmstrand

2018 continues to see efforts by the plaintiffs' bar to impose liability on manufacturers of brand-name pharmaceuticals for generic drugs made and sold by others—so-called "innovator liability." These efforts arise from a combination of the FDA's labeling requirements coupled with the preemptive force of federal law with respect to failure to warn claims against generic manufacturers. This article briefly discusses the cases—pro and con—decided in just the last months, including a favorable decision from my home state of West Virginia. Before reaching that discussion, however, it will outline briefly the labeling and preemption rules applicable.

The first component is the difference between the FDA approval process for brand versus generic prescription medicine. The process leading to the approval of a new drug is "onerous and lengthy." *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 476 (2013). The process for generic versions of an already-approved drug is more streamlined. As one court has explained:

> Normally, drug companies that wish to sell a new drug must file [a New Drug Application] with the FDA that includes certain specific data on the safety and effectiveness of the drug. However, the Drug Price Competition and Patent Term Restoration Act of 1984 (the 'Hatch-Waxman Act') [98 Stat. 1585] allows manufacturers to file Abbreviated New Drug Applications ('ANDAs') with the FDA for generic versions of already approved drugs. The generic manufacturers are not required to prove the drugs' safety and efficacy, as that has already been done by the brands. All these manufacturers need to show is that their generic copies share the same active ingredients and are bioequivalent to the brand name drug. The premise is that two drug products containing the same active pharmaceutical ingredient, in the same dose, and delivered in the same way, are equally safe and effective.

In re Emulsion, No. 18-MD-2819 (NG) (LB), 2018 U.S. Dist. LEXIS 159268, at *23–24 (E.D.N.Y. Sept. 17, 2018). Generic manufacturers must also demonstrate equivalence in labeling to the name brand product and must maintain that equivalence to maintain authorization. *Galloway v. Aurobindo Pharma Ltd. Inc.*, 2018 U.S.Dist. Lexis 90494 at *4, 2018 WL 2461986 (D.S.C. 2018) (*citing Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014). As a result, of course, the generic label and warnings must match the brand's labels and warnings.

The second component is the effect of preemption. Drug manufacturers submitting an NDA must include the proposed labeling (which includes warnings and precautions related to the drug's effects). 21 U.S.C. §355(b)(1)(F); 21 C.F.R. 314.50(c)(2)(i). The FDA reviews that labeling to determine whether it is "false or misleading." 21 U.S.C. §355(d)(7); 21 C.F.R. 314.125(b)(6). Once approved, the manufacturer must generally use the FDA-approved

labeling. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009) (holding that, generally speaking, "a manufacturer may only change a drug label after the FDA approves a supplemental application"). Because the FDA regulations permit label changes in some instances to be implemented before approval (the so-called "changes being effected" regulation, *see* 21 C.F.R. 314.70(c)), however, the Court in Wyeth concluded that some state law failure to warn claims against a brand manufacturer were not preempted.

On the other hand, it has held that such claims against generic manufacturers are preempted because such manufacturers must maintain equivalence to the brand labeling and may not unilaterally change its labeling. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (federal law demands that "generic drug labels be the same at all times as the corresponding brand-name drug labels"). The Court has held this same preemptive force applies to defective design claims against generic manufacturers on much the same reasoning. *Bartlett*, 570 U.S. at 476–77.

This combination of the generic approval process coupled with the preemptive effect of federal law has led to efforts to create "innovator liability" against brand manufacturers for prescription medicines they neither manufactured nor sold. As one Court recently explained:

> The current state of federal law makes it virtually impossible to sue generic drug manufacturers on a state-law theory for failure to warn. In response to this legal landscape, plaintiffs have advanced a new theory of liability and have sued brand-name manufacturers, who have more control over drug labels, for injuries caused by taking the generic drugs. [Plaintiff] followed this recent trend here, suing [the brand manufacturer] on the theory that it negligently failed to include warnings that paroxetine was associated with suicide in patients older than 24.

Dolin v. GlaxoSmithKline LLC, No. 17-3030, 2018 U.S. App. LEXIS 23598, at *3 (7th Cir. Aug. 22, 2018). *Dolin* was decided on the basis of preemption—because the FDA rejected the brand manufacturer's efforts to change its labeling—and therefore the court did not reach the question of innovator liability under Illinois law. These efforts have otherwise been met with varying degrees of success both historically and this year. The remainder of this article outlines several recent decisions on the subject from a number of jurisdictions.

The California Supreme Court in *T.H. v. Novartis Pharmaceuticals Corp.*, 407 P.3d 18 (Cal. 2017), held that brand manufacturers could be liable for products made and sold by others. As that Court explained the plaintiff's theory:

> The gist of plaintiffs' warning label liability claim is that [the brand manufacturer] negligently failed to warn about the drug's risk to fetal brain development. They contend that the deficient label foreseeably and proximately caused harm not only to the children of women who were prescribed [the brand name product], but also to the children of women who were prescribed its generic bioequivalent, which was legally required to — and did — bear the same deficient label. Among other things, plaintiffs rely on section 311 of the Restatement Second of Torts (section 311), which addresses negligent misrepresentation involving physical harm. Under section 311(1), '[o]ne who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results [¶] ... [¶] to such third persons as the actor should expect to be put in peril by the action taken.'

T.H. v. Novartis, 407 P.3d at 27. While recognizing that most courts have rejected this theory, the California Supreme Court discounted that fact on the basis that, "the vast majority of the out-of-state cases on which [the brand manufacturer] relies ... arose in federal court under diversity jurisdiction. Federal courts sitting in diversity are 'extremely cautious' about recognizing innovative theories under state law. *Id.* at 38. Thus, it concluded "brand-name drug manufacturers have a duty to use ordinary care in warning about the safety risks of their drugs, regardless of whether the injured party (in reliance on the brand-name manufacturer's warning) was dispensed the brand-name or generic version of the drug. *Id.* at 47.

The Massachusetts Supreme Court recognized a variation of innovator liability in a March 2018 decision, *Rafferty v. Merck & Co., Inc.*, 92 N.E.3d 1205 (Mass. 2018). There, it held that while public policy and general principles of tort law precluded failure to warn claims under common law negligence or statutory product liability law, a plaintiff could proceed under a common law "recklessness" theory where it "intentionally failed to update the label on its drug, knowing or having reason to know of an unreasonable risk of death or grave bodily injury associated with its use." *Rafferty*, 92 N.E.3d at 1209. After discussing the various benefits and burdens associated with imposing liability on brand manufacturers for products sold by others, the Court held:

> Having weighed these considerations, we conclude as a matter of public policy that allowing a generic drug consumer to bring a general negligence claim for failure to warn against a brand-name manufacturer poses too great a risk of chilling drug innovation, contrary to the public policy goals embodied in the Hatch-Waxman amendments. But we also conclude that public policy is not served if

> generic drug consumers have no remedy for the failure of a brand-name manufacturer to warn in cases where such failure exceeds ordinary negligence, and rises to the level of recklessness.

Id. at 1220. In reaching that decision, it acknowledged that most courts have not imposed innovator liability and that "We also are the only court to limit the scope of liability arising under this duty to reckless disregard of the risk of death or grave bodily injury." *Id.* It is reasonable to expect plaintiff's counsel to argue that other states should recognize this exception to the general rule if the state is unwilling to adopt the broader approach taken by California in *T.H. v. Novartis*.

More recently, the West Virginia Supreme Court, in a 3–2 vote, rejected innovator liability. *McNair v. Johnson & Johnson*, 2018 W.Va. Lexis 344, 2018 WL 2186550 (W.Va. May 11, 2018). After canvassing its prior decisions, the majority concluded that "[o]ur products liability law is abundantly clear: liability is premised upon the defendant being the manufacturer or seller of the product in question." *McNair*, 2018 W.Va. Lexis 344 at *15. Noting that the Supreme Court in *Mensing* acknowledged that the result of its decision "was that consumers of brand-name drugs could sue the manufacturers of those drugs for failure to warn, while consumers of generic drugs were generally precluded from bringing such actions against generic manufacturers," *id.* at *33, the majority agreed that the proper course to address that situation was not the "distortion" of the state's tort law but rather with action by the FDA or Congress. *Id.* at *34.

The plaintiffs in *McNair* also argued they had a claim under a common law negligent misrepresentation theory even if their product liability claim was not viable. As described by the Court, the plaintiffs' argument was straight-forward:

> Here, [plaintiffs] assert that brand manufacturers have a duty to consumers of generic drugs because brand manufacturers know that, under federal law, generic manufacturers must use brand manufacturers' warning labels. Therefore, say [plaintiffs], it is foreseeable that a defect in a warning label could cause injury to consumers of generic drugs, and, therefore, brand manufacturers have a duty to all consumers of the drug regardless of the manufacturer.

Id. at *18–*19. In rejecting that argument, the court relied on the Sixth Circuit's decision in *In re Darvocet, Darvon, and Propoxyphene Products Liability*, 756 F.3d 917 (6th Cir. 2014), which found:

> [T]he generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control. Congress made the public policy decisions to lower barriers of entry for generic drugs, as has the Illinois state legislature in enacting laws to require certain prescriptions be filled with available generics. Using these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far.

McNair, 2018 W.Va. Lexis at *20 (*quoting In re Darvocet*, 756 F.3d at 944). Stating that rejecting innovator liability was consistent with the "vast majority" of courts addressing the issue, *id.* at *22, it squarely held that "there is no cause of action in West Virginia for failure to warn and negligent misrepresentation against a brand-name drug manufacturer when the drug ingested was produced by a generic drug manufacturer." *Id.* at *34.

Less than two weeks after *McNair*, the district court overseeing the Zofran MDL considered the current status of innovator liability while addressing a brand manufacturer's motion for judgment on the pleadings against plaintiffs under the laws of Connecticut, New Jersey, and Oklahoma. *In re Zofran (Ondansetron) Products Liability Litigation*, 2018 U.S.Dist. Lexis 84816, 2018 WL 2317525 (D. Mass. May 21, 2018). There, plaintiffs contended that the brand manufacturer's alleged promotion of an off-label use of the medicine made it "foreseeable" that injuries would allegedly result from the use of generic alternatives, thereby exposing the brand manufacturer to liability under misrepresentation and negligent undertaking. *In re Zofran*, 2018 U.S.Dist. Lexis 84816, at *36–*38. The district court had previously dismissed similar claims brought by six other individuals, including one from Oklahoma.

Acknowledging that two state supreme courts had since recognized innovator liability while one had rejected it in the three cases discussed above, the district court nonetheless reaffirmed its prior decision finding that Oklahoma would not recognize innovator liability as a cause of action. *Id.* at *41. Turning to the two other states at issue (Connecticut and New Jersey), the *Zofran* court found that the highest courts of neither state had recognized the cause of action. *Id.* at *42–*44. The court found persuasive the Sixth Circuit's 2014 decision in *In re Darvocet* on the scope of Connecticut's law and concluded that it would not recognize the cause of action. *Id.* at *42–*43. As for New Jersey, it pointed out that one district court applying New Jersey law and four New Jersey trial courts had rejected the theory. *Id.* at *43. Finding no contrary authority on point, the *Zofran* court granted the motion for judgment on the pleadings as to all three plaintiffs.

Finally, in August of this year, a district court in New York declined to find that state would recognize the doctrine.

Rosser v. Sanofi-Aventis, 2018 U.S.Dist. Lexis 145318, 2018 WL 4080351 (S.D.N.Y. Aug. 26, 2018). There, the plaintiff conceded that the defendant had not manufactured the medicine he ingested. That concession, the district court concluded, was fatal to his claim:

> Although the New York Court of Appeals has not addressed whether a name-brand drug manufacturer may be held liable for injuries resulting from a generic drug manufacturer's equivalent products, the majority of courts to consider the issue, including at least two courts in this Circuit, have answered no to the question. *Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716, 721–22 (S.D.N.Y. 2017) ('[T]he New York authorities are consistent with the majority of other courts around the country in rejecting liability for a company that itself did not manufacture, sell, or distribute generic versions of its name-brand drug.'); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477 (GLS/GJD), 2006 U.S. Dist. LEXIS 49616, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006) (holding that name-brand manufacturer had 'no duty to the users of other manufacturers' products'); *see also In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 949 (6th Cir. 2014) (predicting that New York Court of Appeals would hold that name-brand manufacturers 'did not owe [p]laintiffs a duty that could give rise to liability'). I agree.

Rosser, 2018 U.S. Dist. LEXIS 145318 at *9–*10. As a result, the brand manufacturer was dismissed and the plaintiff was permitted to amend his *pro se* complaint to add the generic manufacturer of the drug he ingested.

Overall, defendants continue to fare well in defeating claims of innovator liability. Because most of the cases are pending in federal court, the bulk of the decisions come out of those tribunals. Even the *McNair* decision from the West Virginia Supreme Court arose from a certified question posed by the Fourth Circuit. Nonetheless, the stated reluctance of the California Supreme Court to give weight to decisions from the federal district court or courts of appeal in *T. H. v. Novartis* suggests that the use of certified questions might be worth considering for cases pending in federal court. A secondary advantage of that procedure would permit what amounts to an immediate appeal of a potentially adverse decision at the motion to dismiss stage. Of course, careful assessment of the likelihood of success on the certified question would be necessary.

Jeffrey A. Holmstrand, name partner with the Wheeling, West Virginia office of Grove, Holmstrand & Delk, PLLC, focuses his state-wide practice on defending product liability, mass torts/class action, and complex insurance disputes. He has both acted as lead trial counsel and worked with national counsel in cases involving a wide variety of products including tobacco, prescription medicines and devices, chemicals, and motor vehicles and their tires. He is an active member of DRI's Product Liability and Drug and Medical Device Committees, as well as a past-president of the Defense Trial Counsel of West Virginia. He has been recognized by Best Lawyers in the areas of Products Liability – Defense, Insurance Law, Commercial Litigation, Appellate Practice, and Mass Tort Litigation/Class Action – Defendants, including several "Lawyer of the Year" honors in those areas.

The Numbers Game: Nearly a Decade After EDNY Scrapped Statistical Causation in Pharma Cases, Can Plaintiffs Revive Market Share Liability?

By Molly Flynn and Rebecca Trela


With his December 2009 opinion in *In re: Zyprexa Prod. Liab. Litig.*, Judge Jack Weinstein of the United States District Court for the Eastern District of New York sounded the final gong on market share liability: a mass tort theory of establishing fraud and misrepresentation claims against pharmaceutical manufacturers by way of aggregate statistical evidence. *In re Zyprexa Prod. Liab. Litig.*, 671 F. Supp. 2d (E.D.N.Y. 2009). Traditionally, the market share theory relaxes the causation standard in a fact scenario where plaintiff cannot identify a tortfeasor amongst a group of breaching defendants. Where all defendants are presumed equally culpable, but a particular one cannot be identified, liability is assigned according to the market share each manufacturer captured. In modern iterations, it has been adapted to establish liability against a single defendant

based on probabilistic evidence and to establish damages on an aggregate basis.

Judge Weinstein rejected plaintiffs' efforts to expand the market share theory and instead adopted the reasoning of the Second Circuit, declaring, "issues of reliance, loss-causation and injury are inappropriate for aggregation, due to the need to prove these elements on an *individualized basis* for each victim or injured party." *Id.* at 434 (emphasis added). The elements of reliance and demonstrable loss transcend RICO fraud claims to govern virtually all tort causes of action against pharmaceutical companies, giving this opinion broad applicability. The *Zyprexa* decision and its progeny recognize that a doctor's decision to prescribe medicine for a patient encompasses numerous factors, including the patient's health history and the doctor's own experience—which is hardly uniform and nearly impossible to capture in broad-based statistical models.

The year following Judge Weinstein's Zyprexa decision, the Second Circuit declined to adopt a similar theory advanced by third-party payors ("TPPs") based on alleged overpromotion of Zyprexa, reasoning "[t]he nature of prescriptions, however, means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof." *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010). A handful of other courts adopted that reasoning in the immediate aftermath, confirming that pharmaceutical mass torts hew to a wholly distinct fact pattern which cannot be established by circumstantial proof.

A decade after Judge Weinstein's opinion, the question resurfaces: could plaintiffs revive the statistical causation analysis for modern mass torts? The answer may hinge on a lead paint case currently pending certiorari before the Supreme Court.

Alone in the New Pollution

This fall, the Supreme Court is poised to address a petition for certiorari in a closely watched case brought by California counties against lead paint manufacturers, in which a number of amici have already submitted briefs. *People v. ConAgra Grocery Prods. Co*, 227 Cal. Rptr. 3d 499 (Calif. Ct. App. 6th Dist. 2017), *petition for certiorari docketed* July 18, 2018, at U.S. Sup. Ct. 18-84. Santa Clara County initiated the case on behalf of 10 California jurisdictions in 2000, and following a verdict for plaintiffs, the court ordered three defendants to pay $1.15 billion into an abatement fund to remediate interior residential lead paint. The judgment was restricted in scope on appeal, but the parties continue to oppose the fundamental imposition of liability. Specifically, the defendants were found liable because their promotion of lead paint decades ago resulted in the presence of lead paint in homes today—irrespective of whether that promotion was the proximate cause of any injury resulting from the paint or their total market share.

Joint and several liability was imposed on three manufacturers, where the Court reasoned the harm was not factually separable given "these conditions are pervasive in the 10 jurisdictions, but the enormous cost of discovering each and every one of the specific locations where remediation is necessary must be borne by the wrongdoers" rather than established by the plaintiffs. *Id.* at 558. Moreover, the Court pointed out that "[n]one of the defendants claimed that it could differentiate 'its' lead paint from other lead paint at an individual location," although "even if a defendant could have proved that its paint was present in only a portion of the individual properties, the identity of the manufacturer of lead paint at a specific location was of limited relevance" given the liability based on general promotion. Id.

Unlike tort claims based on fraud and misrepresentation, public nuisance causes of action sidestep the issue of reliance. *See People v. ConAgra*, 227 Cal. Rptr 3d at 534–35 ("The critical question is whether the defendant *created or assisted in the creation of the nuisance* . . . Here, the alleged basis for defendants' liability . . . is their *affirmative promotion of lead paint for interior use*, not their mere manufacture and distribution of lead paint or their failure to warn of its hazards.") (citation omitted) (emphasis in original).

Recent cases suggest that a nuisance theory of liability predicated on statistical causation will again be tested in the pharmaceutical context. One of the *ConAgra* amici, U.S. Chamber of Commerce, argued in its Aug. 17, 2018 petition for certiorari that "[j]ust in the last twelve months, in federal courts alone, at least 80 new public nuisance cases of this sort have been filed by states and other government entities . . ." *ConAgra Grocery Products Co. v. The People of Calif., 2018 WL 4003045* at *13 (U.S. Nos. 18-84, 18-86, Aug. 17, 2018).

The tide is already rising for pharmaceutical manufacturers, currently facing numerous suits alleging liability based on public nuisance theories. *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d 1375 (U.S. Jud. Pan. Mult. Lit. 2017) (transfer order, considering claims raised by plaintiffs). In one prescription opioid case in New York, procedurally ahead of the MDL, the court refused to address the defendants' arguments opposing the use of "market share theory" to determine quantum of liability at the motion to dismiss

stage. *In re Opioid Litigation*, No. 400000/2017, 2018 WL 3115100, at *6 (N.Y. Sup. Ct. June 18, 2018).

With market share liability essentially dead as applied to traditional pharmaceutical mass tort claims, will the court permit this theory to proceed on a public nuisance theory? The outcome of that case, and many which follow it, may very well depend on the disposition of *ConAgra*.

Molly Flynn and Rebecca Trela are attorneys at Drinker, Biddle & Reath, LLP in Philadelphia, Pa. Their practice focuses on defense of pharmaceutical product liability actions.

Key Points U.S. Lawyers Need to Know About Canadian Class Actions

By Craig Lockwood and Jessica Harding


As the North American commercial markets continue to become consolidated, with U.S. entities expanding their commercial footprint beyond the traditional U.S. marketplace, it is important for foreign companies doing business in Canada (and their U.S. lawyers) to be mindful of certain key procedural aspects of Canadian class proceedings. While the Canadian class actions landscape shares many similarities with the class actions regime in the U.S., this article will highlight some fundamental differences between the jurisdictions in an effort to provide potential defendants and their advisors with a better understanding of how to effectively manage class actions "north of the border."

As a preliminary matter, class actions in Canada are typically commenced at the provincial level (as opposed to the Federal level). Canada has ten provincial and three "territorial" jurisdictions, most of which are common law regimes which have adopted specific class proceedings legislation. However, the province of Québec has adopted a civil law regime, which incorporates a unique class actions framework set out in its *Code of Civil Procedure*.

While the class proceedings statutes across the provincial jurisdictions are generally similar, it is important to be aware of certain procedural differences, particularly regarding the certification procedure and the availability of opt-in / opt-out mechanisms for putative class members.

Stages of a Canadian Class Action

The general class proceedings framework is similar across all common law provinces, and typically follows the certification procedure that exists in the U.S. federal courts. However, there are certain fundamental differences between the U.S. and Canadian procedures which are important to bear in mind. Most notably, it should be noted that most provincial statutes do not contain an equivalent to the "predominance requirement" found in Rule 23 (although certain provincial legislation includes predominance as a factor to be considered under the "preferable procedure" analysis). By virtue of this absence of a formal predominance requirement, the threshold for class certification is often considered to be lower in the Canadian context than might be the case under the U.S. regime.

At the certification stage, the court applies the certification requirements set out under the respective statute to assess whether the claims are suitable for a class proceeding. In so doing, the certification judge does not consider the merits of the case. Rather, the plaintiff typically need only demonstrate that there is "some basis in fact" that certification requirements have been met, which is a low standard. Most appellate provincial courts have confirmed that the evidentiary threshold for certification is not an onerous one. As for Québec, the authorization test (akin to certification) is even more lenient than the test for certification in other provinces. In a recent decision (*Baratto c. Merck Canada inc.*, 2018 QCCA 1240), for example, the Québec Court of Appeal stated that the authorization stage of a class proceeding in Québec amounts to a "screening process" designed to simply weed out frivolous claims.

Canadian courts have generally rejected the "rigorous analysis" required at certification in the U.S., and are reluctant to resolve any conflicts in evidence at certification. Defendants should therefore consider whether it might be beneficial in specific cases to negotiate certification on consent and proceed directly to a trial on the merits. Once certified, class actions will generally progress in a manner that is similar to standard civil proceedings.

International Service of Class Actions

Like the U.S., Canada is a party to the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters ("Hague Service Convention"). Some Canadian provinces, such as Québec and Ontario, have codified this Convention in their respective laws. Signatory states must name a central authority that is responsible for arranging for service within the member state (Articles 2–5, Hague Service Convention). The central authority may require the document to be written in or translated into the official language of the state addressed (Article 5, Hague Service Convention). Improper service of proceedings on a foreign defendant may give rise to objections to the conduct a class action in Canada.

Discovery

The Canadian discovery process in the common law provinces differs somewhat from the U.S. procedure. Generally speaking, there is a positive and ongoing obligation on parties to produce relevant documents in their possession or control, such that there is no onus on the opposing litigant to issue document requests or other interrogatories. Similarly, most provinces contemplate a single representative of each party for the purposes of oral discovery (akin to U.S. depositions), although several common law jurisdictions contemplate the possibility of multiple discovery witnesses in certain circumstances. Typically, the representatives are obliged to inform themselves as to the material facts, and their answers will bind the party for whom they are the designated representative.

In the class action context, discovery on the "merits" of the proceeding does not typically occur until after certification, although most common law provinces do contemplate some limited form of pre-certification discovery (with respect to matters relevant to certification). The class representative will be the discovery representative for the class members, absent an order from the court otherwise.

In Québec, a party cannot subject a class member other than the representative plaintiff or an intervenor to discovery, nor may a party examine a witness outside the presence of the court. However, a court can make exceptions to these rules if it deems it useful for the determination of issues of law or fact.

Damages

The amount of general damage awards in Canadian class actions is typically less than those seen in the U.S. Notably, the vast majority of civil actions in Canada (including all class actions) are not heard by a jury, but are tried in front of a judge alone. Further, Canadian judges are significantly more constrained than their U.S. counterparts in their ability to award punitive damages. Such damages are only awarded in narrow circumstances where the defendant has engaged in malicious, oppressive or high-handed conduct that offends the court's sense of decency, and the quantum of available punitive damages is usually very circumscribed.

Settlement

For a proposed class action settlement to become enforceable in Canada, it must first be approved by the Court. In order to do so, a plaintiff must demonstrate that the settlement is fair, reasonable and in the best interests of class members. Upon Court approval of the settlement, it becomes binding and the releases it contains apply to all class members.

Parallel Proceedings

Unlike the U.S. Federal Court, Canada does not have a multi-district litigation procedure to coordinate overlapping actions involving the same subject matter or parties. Rather, the relevant provincial superior courts may each continue to exercise control over the proceedings commenced in their respective jurisdictions. In an effort to curtail wasted judicial resources arising from duplicative provincial class actions, the Canadian Bar Association recently proposed a *Judicial Protocol for Multijurisdictional Class Actions* which promotes co-ordination between the parties and the judges involved in overlapping class proceedings across the country. While non-binding, the protocol has been widely endorsed by judges and practitioners in many of the common law provinces. In addition, certain provinces have amended their provincial class actions legislation to incorporate procedures for staying local proceedings in order to facilitate multijurisdictional class actions in other jurisdictions.

In most common law provinces, duplicative or overlapping class proceedings commenced by competing plaintiff groups *within* the same provincial jurisdiction are typically resolved by means of "carriage motions," whereby a court decides which claim will proceed and which will be stayed based on a number of factors (including the state of each class action and the experience of counsel, among others). The relevant factors and the weight assigned to each varies across the different provinces.

Québec proceeds differently in such cases, in that it has adopted a flexible application of the first to file rule. In

particular, the Québec Court of Appeal recently concluded that while the "first to file" rule still has priority, there is room for flexibility where the rule is not conducive to upholding the best interests of the class members. Other Québec courts have affirmed that class proceedings may be suspended in Québec if the court is convinced that the foreign cause of action is in line with the best interests of the class members in Québec.

Extra-Provincial Class Members

Most provinces allow for certification of classes which include extra-provincial residents, although some provinces require extra-provincial residents to specifically "opt-in" to the class proceeding. Other provinces, including Québec, have a blanket "opt-out" regime for class proceedings.

While Canada does not have an official mechanism to coordinate national class actions, Canadian provincial courts have consistently demonstrated a willingness to certify a "national class" which includes extra-provincial class members. The above-noted *Judicial Protocol for Multijurisdictional Class Actions* proposes various procedural mechanisms which seek to facilitate the coordination of national class actions, particularly at the settlement approval stage. In the context of a pan-national class action settlement, the Supreme Court of Canada recently held that judges sitting in different provinces may even sit outside their home jurisdictions in order to facilitate the resolution of interjurisdictional claims.

Conclusion

As the class action landscape continues to evolve, it is paramount for entities doing business in Canada to maintain a sound understanding of the characteristics of this unique procedural vehicle. As such, defendants will be better placed to develop strategies to manage complex class proceedings efficiently, should the need arise.

Craig Lockwood has extensive experience in class proceedings, product liability matters, securities regulation, commercial banking litigation and pension litigation. He also has significant experience with corporate arrangement transactions under the OBCA and the CBCA. Craig has appeared at all levels of the Ontario, Quebec and New Brunswick courts, and has appeared at the Supreme Court of Canada on multiple occasions. Craig is the Chair of the Osler Product Liability and Food Products Practice Group.

Jessica Harding is an associate in the Montréal office. She has completed her Juris Doctor and bachelor's degrees at the Faculty of Law at Université de Montréal. She obtained her bachelor's degree in biomedical sciences and her master's degree in pharmacology from the Faculty of Medicine at Université de Montréal. Jessica's practice focuses on civil and commercial litigation, including more particularly consumer class actions, product liability litigation, arbitration and international private law. Jessica has appeared before various arbitral tribunals, the Court of Québec, the Superior Court of Québec and the Québec Court of Appeal.