The Evolving Landscape for Pharmaceutical Product Liability Litigation in Canada

By Gordon McKee and Robin Linley

ONLY a handful of pharmaceutical product liability cases have been tried in Canada, with the leading case being a decision from the mid-1980s involving reports of stroke in association with the use of oral contraceptives.[1] There are many reasons for this, some of general application and some unique to Canada. For example, damage awards in Canada have historically been much lower than in the U.S., and most provinces have a loser pays costs system. Accordingly, plaintiffs counsel are likely to be more careful to ensure they pursue only serious cases that they have good reason to believe have merit, and the cost of settling for defendants may often be less than the cost of defending. Further, because fewer cases are brought in Canada and plaintiff firms with inventories are rare, the benefits of a favorable trial verdict, beyond the individual case, are less compelling for both plaintiffs and defendants. However, recent developments in class actions (with a spill-over effect on individual cases) and the expanded ability (both legal and practical) of plaintiffs' counsel to solicit new cases are changing the landscape for pharmaceutical product liability litigation in Canada.

This article will (1) describe developments in mass tort litigation in Canada, with particular focus on pharmaceutical litigation, (2) describe the causes of action and remedies pursued by plaintiffs, and the defenses asserted, in such litigation; and, (3) discuss relevant aspects of Canadian procedure and trial practice.

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I. Mass Tort Treatment of Pharmaceutical Product Liability Litigation

Class actions are permitted in all provinces in Canada,[3] with most having enacted specific class action legislation.[4] In

[1] Buchan v. Ortho Pharmaceutical, (1984), 46 O.R. (2d) 113 (H.C.J.); aff'd. (1986), 54 O.R. (2d) 92 (C.A.). Other pharmaceutical product liability cases that have proceeded to trial are Rothwell v. Raes (1988), 66 O.R. (2d) 449 (H.C.J.); aff'd. (1990), 2 O.R. (3d) 332 (C.A.); leave to appeal to S.C.C. denied, 1991 S.C.C. Bulletin at 1267; Davidson v. Connaught Laboratories, [1980] O.J. No. 153 (S.C.J.) (QL).

[2] Unless noted otherwise, comments made in this paper are based on the substantive and procedural laws of Ontario.

[3] Western Canadian Shopping Centres Inc. v. Dutton, [2001] 2 S.C.R. 534. Where there is no specific legislation in a province permitting class actions, the Supreme Court of Canada has held that courts are entitled to fill the void and to set the rules of practice and procedure for class actions.

[4] Canada has ten provinces and three territories. Jurisdiction over torts and other civil wrongs rests primarily with the provincial legislature and courts. The federal government and federal courts have limited subject matter jurisdiction in areas such as aviation, admiralty and intellectual property, but do not have jurisdiction over mass torts as a general rule. In theory, a company can be faced with claims (individual or class) in all thirteen provinces

the provinces that have enacted specific legislation other than Quebec, an action can be certified as a class action if the plaintiff can establish that (a) there is a sustainable cause of action (which will be assessed based on the pleadings alone), (b) there is an identifiable class with two or more persons, (c) the claims of those persons have substantial issues of fact or law in common, (d) a class action is the preferable procedure for resolving the common issues having regard to the objectives of the legislation – access to justice, judicial economy and behavior modification, and (e) the proposed representative plaintiff can adequately represent the interests of the class.[5]

Although the Supreme Court of Canada has said that in considering whether a class action is the preferable procedure for resolution of the common issues, the court should look at preferability in the context of the action as a whole, including the individual issues,[6] the Supreme Court has also stated that predominance is not a *requirement* for class certification. Accordingly, the test for class certification is generally considered to be lower in Canada than in the U.S. As a result, a decision in the U.S. certifying a class may have persuasive significance in a Canadian class certification motion, but a decision in the U.S. denying class certification will likely carry much less weight.

The Supreme Court of Canada has held that, before certification of a class action will be granted, the plaintiff must establish "some basis in fact" for each of the certification requirements, other than the requirement that the pleadings disclose a cause of action.[7] Responding counsel are permitted to file responsive evidence in support of their position on the certification motion, including expert evidence. The Supreme Court of Canada has held, however, that the certification stage is not meant to be a test of the merits of the action.[8] Much of the argument in Ontario product liability class certification hearings will be focused on whether the plaintiff has provided some evidence that there is a way to prove class wide loss and, if not, how that renders the class definition overly broad, the alleged common issues not common and a class action not preferable.[9]

In Quebec, the threshold for certification is even lower than in the other Canadian provinces. A Quebec action will be allowed to proceed as a class action if (a) the claims of the proposed class members raise identical, similar, or related questions of law or fact, (b) the facts alleged seem to justify the conclusions sought, (c) the composition of the group makes the application of article 59 (representative actions) or 67 (joint actions) of the Quebec *Code of Civil Procedure*[10] ("CPP") difficult or impractical, and (d) the member to whom the court intends to ascribe the status of representative is in a position to represent the members adequately. As a result of recent amendments to the CPP,[11] the plaintiff need not file an affidavit in support of the motion for permission to bring the

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and territories, and no formal method like the U.S. Multidistrict Litigation ("MDL") procedure is available for coordinating discovery or trials among the provinces.

[5] *See e.g.,* the Ontario Class Proceedings Act, S.O. 1992, c. 6, s. 5.

[6] In B.C., the legislation expressly states that the Court should consider as one factor whether the common issues predominate over individual issues.

[7] Hollick v. Toronto (City of), [2001] 3 S.C.R. 158 at para. 25. *See also* Western Canadian Shopping Centres Inc., [2001] 2 S.C.R. 534; Rumley v. British Columbia, [2001] 3 S.C.R. 184.

[8] Hollick, 3 S.C.R. 158 at para. 16.

[9] Chadha v. Bayer (2003), 63 O.R. (3d) 22 at 33, 223 D.L.R. (4th) 158, 168 O.A.C. 143, 23 C.L.R. (3d) 1, 31 C.P.C. (5th) 40 (C.A.), leave to appeal refused, [2003] S.C.C.A. No. 106 (QL); Pearson v. Inco, [2005] O.J. No. 4918 at para. 76 (C.A.) (QL); application for leave to appeal to the Supreme Court of Canada filed February 14, 2006; Caputo v. Imperial Tobacco Limited, [2004] O.J. No. 299 at paras. 51, 58 (S.C.J.) (QL).

[10] R.S.Q. c. C-25.

[11] *See* Articles 1002 and 1003 of the CPP. These changes came into effect January 1, 2003.

action as a class action. Cross-examination of the representative plaintiff on that motion is not available as of right and the defendant may not be able to contest the motion for authorization in writing.[12] The net effect of these changes is that defendants in Quebec will have more difficulty challenging the veracity of the evidence upon which the plaintiff relies in support of certification than defendants in other Canadian provinces.

In those provinces that have class action legislation, the named plaintiff seeks permission from the Court to proceed by way of a class proceeding early on in the litigation. Although legislation typically requires the certification motion to be heard quickly (i.e. within ninety days of the first appearance by a defendant), it has often taken many months or even years to get to a class certification hearing. If the action is certified, notice of the certification will be given in some manner to all class members, and a limited time (typically sixty to ninety days) will be given for class members to opt out of the proceeding.[13] The certification order will have identified the common issues. Discovery will proceed on those issues, with a common issues trial to be heard thereafter. Following resolution of the common issues trial, if favorable to the plaintiffs, a procedure will be established by the court to resolve individual issues (such as specific causation and damages). The court has considerable discretion in that regard including the ability to order an aggregate assessment of damages.

Overall, the current trend in mass tort litigation in Canada continues to be towards class actions, and those involving product liability have been certified more often than not. One recent certification decision from the Ontario Court of Appeal suggests that an even "more liberal approach should be taken to certification of class proceedings" in the future, although leave to appeal that decision is being sought on the basis that it conflicts with earlier decisions of the Supreme Court of Canada.[14]

Class actions involving breast implants,[15] diet drugs,[16] pacemaker leads,[17] tainted blood,[18] TMJ implants,[19] and heart valves[20] have all been certified in Canada, either following a contested hearing or on consent for settlement approval. Although more

[12] Shortly after amendments were introduced, a group of pharmaceutical companies made a constitutional challenge on the basis that these changes to the CPP violated procedural guarantees provided for in Quebec's Charter of Rights and Freedoms, R.S.Q. c. C.12 and in s. 23 of the Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, Schedule B to the Canada Act 1982 (U.K.), 1982, c. 11 (the right to a full answer and defense). On April 29, 2005, the Quebec Court of Appeal rendered its decision in Pharmascience Inc. v. Option Consommateurs, [2005] Q.C.C.A. 437, upholding the amendments. Leave to appeal to the Supreme Court of Canada was subsequently denied: [2005] S.C.C.A. No. 252 (QL). More recent decisions from the Quebec courts suggest, however, that the amendments made to the CPP in 2003 do not have as far reaching effects on the rights of defendants as previously thought.

[13] Although most jurisdictions have an opt out regime, a number where extra-provincial classes are allowed, such as British Columbia, have "opt-in" sub-classes for non-residents. National classes certified in Ontario are "opt-out" for all class members including non-residents.

[14] Pearson, [2005] O.J. No. 4918 at para. 76.

[15] Bendall v. McGhan Medical Corp., (1993), 14 O.R. (3d) 734 (G.D.); Harrington v. Dow Corning Corp., (1996), 29 B.C.L.R. (3d) 88 (C.A.).

[16] Wilson v. Servier Canada Inc. (2000), 50 O.R. (3d) 219 (S.C.J.), leave to appeal denied (2000), 52 O.R. (3d) 20 (Div. Ct.), leave to appeal to S.C.C. denied, 2001 S.C.C. Bulletin at 1539; Knowles v. Wyeth-Ayerst Canada Inc., [2001] O.J. No. 1812 (S.C.J.) (QL) and [2001] O.J. No. 2881 (S.C.J.) (QL).

[17] Hoy v. Medtronics, Inc., [2003] B.C.J. No. 1251 (C.A.) (QL); Nantais v. Telectronics, (1995), 25 O.R. (3d) 331 (G.D.) leave to appeal denied [1995] O.J. No. 3069 (G.D.) (QL).

[18] Endean v. Canadian Red Cross Society (1997), 148 D.L.R. (4th) 158 (B.C.S.C.); *see also* Parsons v. Canadian Red Cross Society, [1999] O.J. No. 3572 (S.C.J.) (QL).

[19] Bisignano v. La Corporation Instrumentarium Inc., [1999] O.J. No. 4346 (S.C.J.) (QL).

[20] Andersen v. St. Jude Medical, Inc. (2003), 67 O.R. (3d) 136 (S.C.J.) leave to appeal denied [2005] O.J. No. 269 (S.C.J.) (QL).

recently there has been a slight increase in the frequency with which individual product liability cases are being brought, this is likely a bi-product of the frequency with which product liability class actions are being commenced and certified in Canada. Plaintiffs' firms continue to have difficulty marshalling, or are unwilling to take the steps necessary to marshal, large inventories of individual claims.[21]

In the past few years, pharmaceutical class actions[22] have been commenced in Canada with respect to a wide range of the following medications: statins such as Baycol® and Crestor® (rabdomyolysis and other soft tissue injuries); anti-depressants such as Paxil® and Serzone® (addiction and suicidal tendencies); pain medications such as Vioxx® and Celebrex® (adverse cardiovascular events); Bextra® (adverse cardiovascular events and skin reactions); Mirapex® (gambling); Zyprexa® (diabetes) and Neurontin® (suicidal behavior). Other medications are also being targeted by an increasingly entrepreneurial and aggressive plaintiffs' bar.

The first contested class certification motion in Canada involving a pharmaceutical medicine related to diet drugs.[23] In that case, an Ontario court certified a national class of all users of the diet drug and certified common issues for trial related to the adequacy of warnings, general causation, the right to recover for medical monitoring, and the equitable right to refunds of the purchase price. Recently, Canadian courts have certified pharmaceutical class actions in the Baycol litigation, following contested hearings, in the provinces of British Columbia, Newfoundland, and Manitoba.[24] At the time of writing, certification decisions involving Vioxx® and Prepulsid® are under reserve in Saskatchewan and Ontario respectively. The Vioxx case provides a good example of how a mass tort is likely to be litigated in Canada in the future. Vioxx was recalled in Canada on September 30, 2004. Within a day, a national class action was commenced in Ontario. Over the next week, class actions were also commenced in the provinces of Quebec, British Columbia, Saskatchewan, and Alberta. It has been reported that, in total, approximately thirty class-action lawsuits have been filed in Canada.[25] In January, 2005, a securities class action was commenced against Merck alleging material non disclosure of the potential for class actions relating to Vioxx®.[26] The claim pleads the fraud on the market doctrine, fraud, Securities Act violations, Canadian Business Corporations Act violations and breach of fiduciary duty for inducing retention of Merck stock. Finally, a class action was commenced against Merck on behalf of various public and private insurers, unions, and employers' drug benefit plans related to Vioxx®. The courts have not yet decided whether any of those actions can proceed as class actions.

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[21] However, there appears to be an increasing number of Canadians retaining U.S. plaintiffs' firms and suing in the U.S., presumably to access higher damage awards and settlements.

[22] With respect to medical devices, in the past two years at least two class actions have been commenced with respect to implantable cardiac defibrillators.

[23] Wilson, (2000), 50 O.R. (3d) at 219.

[24] Bouchanskaia v. Bayer Inc., [2003] B.C.J. No. 1969 (S.C.) (QL); Wheadon v. Bayer Inc. [2004] N.J. No. 147 (T.D.) (QL); aff'd. [2005] N.J. No. 122 (C.A.) (QL) application for leave to appeal to the S.C.C. dismissed with costs (without reasons) November 10, 2005; Walls v. Bayer Inc., [2005] M.J. No. 4 (Q.B.) (QL); aff'd. [2005] M.J. No. 286 (C.A.) (QL) leave to appeal to the S.C.C. filed September 19, 2005. Certification has been granted in Ontario and Quebec for the purposes of settlement approval. *See* Coleman v. Bayer Inc. [2004] O.J. No. 1974 (S.C.J.) (QL), supp. reasons at [2004] O.J. No. 2775 (S.C.J.) (QL); Dufour v. Bayer, Inc., [2004] J.Q. No. 11125 (S.C.) (QL).

[25] GLOBE AND MAIL, *The Painful Battle over the Wonder Drug* (April 15, 2005) *available at* http://www.theglobeandmail.com/servlet/story/RTGAM.2005219.VIOXX19_COPY/BNStory/.

[26] Kruger v. Merck Frosst Canada & Co. (Statement of Claim filed January 18, 2005).

Both the Vioxx and Baycol litigation illustrate that a number of issues with respect to "national classes" remain to be resolved. The ability to bring class proceedings in each province and territory of Canada has generated significant and occasionally negative competition among class counsel across the country.[27] In the Vioxx case, questions regarding which province the action should be brought and which plaintiff's firm should represent the class have been hotly contested among some plaintiffs' firms.[28]

Unlike the U.S, there is no legislation or system in place equivalent to the MDL that would allow for coordination of class actions brought in more than one province. Further, even where a national settlement is approved in one province, the courts in other provinces may not be willing to enforce or honour the settlement.[29]

Recently, class actions involving pharmaceutical medicines have been certified for settlement purposes. Key aspects of these settlements include:

1. Baycol (Ontario): Limited to all persons who ingested Baycol and contemporaneously suffered rabdomyolysis (as defined in the settlement agreement); settlement class to receive compensation in accordance with a grid; classification based on degree of injury; settlement amount not capped; screening/mediation /arbitration process put in place to deal with disputed claims; costs paid to plaintiffs' counsel as part of the settlement $2,700,000 (CDN); plus 5% of total compensatory payments to class members up to $5 million, and 10% of payments over $5 million.[30]

2. Baycol (B.C.): Agreement similar to Ontario, with class counsel to receive $400,000 (Cdn.) plus 5% of total compensatory payments to class members.[31]

3. Stadol Nasal Spray (Ontario & Quebec): Capped at $12,457,350; for those who purchased a minimum of four bottles within any thirty day period within the class period (July 1, 1984 – July 1, 2004); amount of claimant's entitlement based on point system for various events that occurred to a claimant during the period (i.e. treatment received for addiction (twenty-five points), loss of employment (twenty-five points), criminal conviction (fifty points), divorce (twenty-five points) etc.; claimants to receive benefits in proportion to points awarded to a maximum of $1500 per point; derivative claims determined based on a percentage of amount awarded to recipient; costs paid to class counsel to be approved by the court on separate motion.[32]

4. Ponderal and Redux (Ontario): Diet drug; national class excluding Quebec; settlement fund created of $25 million, with the possibility of topping up to $40 million – of that, $3 million was paid to "FDA Positive Fund" and $1 million paid to provincial health insurers. An additional million was paid by Servier for disbursements incurred by class counsel; the defendant was

[27] *See* http://www.cba.org/CBA/National/aprmay05 /feature3.aspx.

[28] *See* Setterington v. Merck Frosst Canada Ltd.,[2006] O.J. No. 376 (S.C.J.) (QL).

[29] Pardy v. Bayer Inc., [2004] N.J. No. 124 (Nfld. S.C.) (QL); HSBC Bank Canada v. Hocking, [2006] Q.C.C.S. 330 (S.C.).

[30] Coleman, [2004] O.J. No. at 1974.

[31] Bouchanskaia, [2003] B.C.J. No. 1969.

[32] Stadol Settlement, *available at* http://www. classaction.ca/pdf/Stadol_Notice_of_Hearing.pdf; *see also* http://www.classaction.ca/pdf/Stadol_ Notice_of_Settlement_Approval_EN.pdf .

also to pay costs related to settlement administrator, claims adjudicators, and notice; class counsel was also awarded $3 million in partial indemnity costs. A class counsel fee of $10 million plus $2,619,536 in disbursements to be paid by the class out of the settlement fund was subsequently approved.[33]

5. Pondimin (Ontario): Diet drug; fund of $11,240,789 (exclusive of legal fees); of that, $1.015 million was paid to provincial health insurers; entitlement of class members to payment was based on a grid with three different indices (matrix, severity of condition and age of claimant); class counsel was paid $152,250 in costs by the defendants.[34]

Settlement of a class action requires court approval in all jurisdictions and, in some, requires approval even where the settlement simply involves a dismissal or discontinuance of the action. Where there are multiple provincial class proceedings, settlement agreements have often provided that the settlement will only proceed if all courts in provinces where class actions have been commenced approve the settlement. (In these settlements, the court may be asked to grant conditional certification - conditional on the subsequent approval of the settlement by all courts.)

II. Jurisdiction & Forum Shopping

The Supreme Court of Canada has held that a provincial court may have jurisdiction over an individual claim against a foreign defendant who has not voluntarily appeared where there is a real and substantial connection between the subject matter of the litigation and the province in which the suit is brought. There has been some inconsistency in the application of that general principle by appellate courts in each of the provinces. The Ontario Court of Appeal has attempted to reconcile those decisions by identifying eight factors that the Court will consider in determining whether it has jurisdiction over a claim against a foreign defendant:[35]

1. The connection between the forum and the plaintiff's claim;
2. The connection between the forum and the defendant;
3. Any unfairness to the defendant in the court assuming jurisdiction;
4. Any unfairness to the plaintiff in the court not assuming jurisdiction;
5. Involvement of other parties to the suit (particularly other parties located within the province);
6. The court's willingness to recognize and enforce an extra-provincial judgment rendered on the same jurisdictional basis;
7. Whether the foreign defendant is in another

[33] Servier settlement, *available at* http://www.kleinlyons.com/diet/sett_agmt.pdf; *see also* Wilson v. Servier Canada Inc., [2005] O.J. No. 1039 (S.C.J.) (QL).

[34] *See* http://pondiminsettlement.com/pdf/Pondimin_Settlement_Agreement.pdf.

[35] *See* Muscutt v. Courcelles (2000), 60 O.R. (3d) 20 (C.A.); Sinclair v. Cracker Barrel Old Country Store Inc., [2002] O.J. No. 2127 (C.A.) (QL); Leufkens v. Alba Tours Int'l. Inc., [2002] O.J. No. 2129 (C.A.) (QL); Gajraj v. DeBernardo, [2002] O.J. No. 2130 (C.A.) (QL); and Lemmex v. Sunflight Holidays Inc., [2002] O.J. No. 2131 (C.A.) (QL). The Supreme Court of Canada has confirmed that the "real and substantial connection test" for assuming jurisdiction (and enforcing foreign judgments) applies not only among the provinces within Canada but to jurisdictions outside Canada; *see* Beals v. Saldanha, [2003] 3 S.C.R. 416.

province rather than another country; and

8. Comity and the standards of jurisdiction, recognition and enforcement prevailing elsewhere.

In that case, the Court of Appeal was invited to adopt a "minimum contacts" test similar to that applied in the United States but declined to do so.

In individual cases, it is clear that a provincial Court will take jurisdiction over a claim against a foreign manufacturer of pharmaceuticals medicines where they are distributed in a manner in which it was reasonably foreseeable that the medicine would be used in the province and might, if negligently manufactured or designed, cause injury to persons in the province. The question of jurisdiction becomes more difficult in the class action context where the plaintiff seeks to certify a national class and the claims of some members of the proposed class may have no connection whatsoever to the province in which the class action was commenced. Defendants have challenged the jurisdiction of Canadian provincial courts in these types of cases and have also argued that, constitutionally, national class actions are not permissible. Defendants' arguments have been largely unsuccessful in the common law provinces. Provincial courts, other than those in Quebec, continue to be willing to certify national classes that include residents of other provinces whose claims may have little or no other connection to the province of certification.[36]

The Supreme Court of Canada has yet to directly address in a judgment the complexities of proposed national class actions, and the potential difficulties and inconsistencies that can result. For example, the Newfoundland Supreme Court certified a class action related to Baycol in the face of a motion before the Ontario Court to approve settlement of a national class action that would include persons from Newfoundland.[37] Offering little comfort, in *Coleman* v. *Bayer Inc.,*[38] the Ontario Court expressed the view that, while overlapping inter-provincial class proceedings could give rise to conflicting orders and the possibility that the defendant might be exposed to double jeopardy, these problems were not insuperable provided that courts in each of the provinces had regard to the principles of comity. Most recently, however, a trial level court in Quebec refused to enforce an Ontario class settlement against a Quebec resident, and a

[36] *See e.g.,* Nantais v. Telectronics, (1995), 25 O.R. (3d) 331 (G.D.) leave to appeal denied [1995] O.J. No. 3069 (G.D.) (QL).; Wilson v. Servier Canada Inc. (2002), 59 O.R. (3d) 656 (S.C.J.)*;* Harrington v. Dow Corning Corp., (1996), 29 B.C.L.R. (3d) 88 (C.A.); Serhan v. Johnson & Johnson*,* [2004] O.J. No. 2904 (S.C.J.) (QL); leave to appeal granted [2004] O.J. No. 4580 (Div. Ct.) (QL); Hoy v. Medtronics, Inc., [2003] B.C.J. No. 1251 (C.A.) (QL); Hague v. Liberty Mutual Ins. Co.,[2004] O.J. No. 3057 (S.C.J.) (QL); Vitapharm Canada Ltd. v. F. Hoffmann LaRoche Ltd., [2005] O.J. No. 1118 (S.C.J.) (QL); Wheadon v. Bayer Inc. [2004] N.J. No. 147 (T.D.) (QL); Coleman v. Bayer Inc. [2004] O.J. No. 1974 (S.C.J.) (QL), supp. reasons at [2004] O.J. No. 2775 (S.C.J.) (QL); Andersen v. St. Jude Medical, Inc. (2003), 67 O.R. (3d) 136 (S.C.J.); For cases where jurisdiction was successfully challenged in a class action see McNaughton Automotive Ltd. v. Co-operators Gen. Ins. Co. (2003), 66 O.R. (3d) 112 and Marren v. Echo Bay Mines Ltd., [2003] B.C.J. No. 1138 (C.A.) (QL). There remains a constitutional question that has not yet been considered by the Supreme Court of Canada on the ability of a provincial court to take jurisdiction over a class that includes persons whose claims have no connection with the province in which the class action is certified. *See* McKee and Galway, *Constitutional Considerations Concerning National Class Actions*, Law Society Special Lectures 2001, Constitutional and Administrative Law, The Law Society of Upper Canada, and obiter comments in Punit v. Wawanesa Ins. Co., [2005] O.J. No. 1928 (S.C.J.) (QL). The Supreme Court of Canada has denied leave in two cases that would have given it opportunity to rule on the issues. Accordingly it is most likely to reach the Supreme Court in a case where a defendant seeks to enforce a class settlement against a non-resident.

[37] Wheadon, [2004] N.J. No. 147.

[38] *Id.*

judge in Saskatchewan rejected an argument that Ontario class action legislation allows for the creation of a "national class" that binds non-Ontario residents unless they opt out of the Ontario class action.[39]

III. Causes of Action/Remedies

A. Typical Causes of Action

Product liability in Canada for drugs and medical devices is largely based on negligence principles – alleged breach of a duty to exercise reasonable care in the design and manufacture of a product, or in the warning of risks inherent in the use of a product. Canadian courts have not imposed strict liability (outside of contract) on manufacturers and others in the distribution chain for allegedly "defective" products.[40]

In Ontario, the onus remains on the plaintiff to prove that the defendants did not exercise a reasonable standard of care in the design or manufacture of the product, or failed to adequately warn of dangers which they knew or ought to have known were inherent in the use of the product. Practically speaking, if the court finds that the product had a manufacturing defect (i.e. the product was manufactured in a manner that was inconsistent with the design specifications for the product) the court will presume negligence in the manufacturing process and will not require the plaintiff to establish how the manufacturing defect arose (whether through employee inadvertence or faulty manufacturing equipment).[41] In the context of design defect claims, Ontario courts have applied a risk utility analysis which requires plaintiffs to establish that the design of a product posed an excessive risk to the user given feasible alternatives.[42]

In a breast implant case, the Supreme Court of Canada reviewed and affirmed both the manufacturers' duty to warn consumers of dangers inherent in the use of their products, and the applicability in Canada of the "learned intermediary" principle (an exception to the duty to warn) with respect to certain types of products.[43] The Court held that there is a heavy onus on manufacturers to provide clear, complete, and current disclosure to consumers concerning the risks inherent in ordinary use of their products. The Court also held that manufacturers of medical products can rely on warnings given to physicians (a "learned intermediary") without giving a warning directly to the end consumer, provided that sufficient information was given to the physician such that the physician's knowledge "approximated" that of the manufacturer. The Court confirmed that the learned intermediary principle would apply to any product that is highly technical in nature and is intended to be used only under the supervision and advice of an expert.

B. Compensatory Damages

As in the U.S., compensatory damages for pain and suffering and economic losses (i.e. loss of past and future income and the cost of household services) are recoverable under Canadian law. However, damages for pain and suffering have been capped by the Supreme Court of Canada at $100,000 (Cdn.) in 1978 dollars, adjusted for inflation based on the current dollar equivalent as at the date of trial (presently about $310,000).

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[39] HSBC Bank Canada v. Hocking, [2006] Q.C.C.S. 330 (S.C.); Englund v. Pfizer Canada Inc., [2006] S.J. No. 9 (QL).

[40] *See* Anderson v. St. Jude Medical, Inc., [2001] O.J. No. 260 (S.C.J.) (QL).

[41] *See e.g.,* McMorran v. Dominion Stores Ltd. (1977), 14 O.R. (2d) 559 (H.C.); *see also* Hollis v. Dow Corning Corp, [1993] B.C.J. No. 1363 at paras. 36 to 48 (C.A.) (QL); aff'd. on other grounds, [1995] 4 S.C.R. 634.

[42] Rentway Canada Ltd. v. Laidlaw Transport Ltd., [1989] O.J. No. 786 (H.C.J.) (QL); aff'd. [1994] O.J. No. 50 (C.A.) (QL). Courts have assessed factors such as the utility of the product to the individual user and the individual user's ability to perceive and avoid the risk in question. *See also* Ragoonanan v. Imperial Tobacco Canada Ltd. (2000), 51 O.R. (3d) 603 (S.C.J.) at 630-31.

[43] Hollis, [1993] B.C.J. No. 1363 at paras. 36 to 48.

An award of the maximum amount for pain and suffering would only be made for the most serious of injuries (i.e. quadriplegia or permanent serious brain damage requiring full time attendant care). A person's estate cannot recover damages for the death of that person, although it can sue for losses the person suffered between the time of an accident or adverse event and the time of his or her death.

In all provinces, statutes provide some compensation for certain specified family members of the individual who has been injured or killed, although the circumstances under which there can be recovery vary from province to province. In many provinces, family members can only recover in the event of death. In Ontario, the spouse, children, grandchildren, parents, grandparents and siblings of the injured person can recover damages for loss of care, guidance, and companionship in the event of either injury or death. Such damages are unlikely to exceed an amount in the neighborhood of $85,000 to $100,000 (per claimant), and those amounts will only be recovered by a spouse or young child in a close family relationship with a person who has been seriously injured or killed. Damages are also recoverable in Ontario by family members for certain economic losses resulting from the claimant's death or injury, such as loss of contribution to family income and loss of household services.

C. Punitive Damages

Historically in Canada, punitive damage awards have rarely been made in personal injury cases and, when made, awards have generally been quite small (i.e. well below $100,000). However, the Supreme Court of Canada has upheld a $1 million punitive damage award in a case involving a claim by an insured for $287,300 for loss of his home in a fire.[44] This decision may be a signal that higher punitive damage awards are coming to Canada. Claims for punitive damages have become more common in statements of claim in this area since this decision was released. The authors are not aware of a pharmaceutical or medical device case in which punitive damages have been awarded in Canada.

With respect to class proceedings, both entitlement to punitive damages and quantum have been certified as common issues in a number of medical products class actions. However, a recent case in Ontario refused to certify punitive damages for class treatment because the aggregate of compensatory damages would not be determined in the common issues trial, making it impossible for the Court to determine either entitlement or quantum based on the "rational purpose" test for punitive damages affirmed by the Court in *Whiten v. Pilot Insurance*.[45] Some courts have certified punitive damages as a common issue but left open the possibility of a trial on that issue *after* the individual issues phase (effectively a three phase trial process).[46]

D. Psychological Injury and Medical Monitoring

Claims for fear of injury and medical monitoring have been asserted in Canada, particularly in class actions. Historically, a plaintiff in Canada was required to show that "nervous shock" or fear resulting from

[44] Whiten v. Pilot Ins. Co. (2002), 209 D.L.R. (4th) 257 (S.C.C.).

[45] *Id. See also* Cassano v. Toronto-Dominion Bank, [2005] O.J. No. 845 (S.C.J.) (QL). For cases certifying punitive damages as a common issue see Fakhri v. Alfalfa's Canada, Inc. (c.o.b. Capers Community Markets) (2004), 34 B.C.L.R. (4th) 201 (C.A.); Chace v. Crane Canada Inc. (1997), 44 B.C.L.R. (3d) 264 (C.A.); Rumley v. British Columbia, *supra* note 7; Andersen v. St. Jude Medical, Inc. (2003), 67 O.R. (3d) 136 (S.C.J.) leave to appeal denied [2005] O.J. No. 269 (S.C.J.) (QL); Wheadon v. Bayer Inc. [2004] N.J. No. 147 (T.D.) (QL); aff'd. [2005] N.J. No. 122 (C.A.) (QL).

[46] Ludwig v. 1099029 Ontario Ltd.; Horti-Pak Inc. v. Siemens Canada Ltd., [2004] O.J. No. 4573 (S.C.J.) (QL).

alleged negligent conduct of a defendant caused a diagnosable mental or physical illness before the plaintiff could recover damages for that conduct (assuming no physical injury was sustained). Fear of injury alone, and grief and sorrow, were not considered to be compensable on their own.

Although this position was recently affirmed in large part by the British Columbia Court of Appeal,[47] the Ontario Court of Appeal held, in a class action,[48] that a claim for fear of injury would not be struck on a preliminary motion but could proceed to trial so that the issue could be reconsidered by the court with a proper factual foundation. In that case, patients who had attended a medical clinical for EEG testing were later notified by local health authorities that an employee at the clinic had Hepatitis B, and that they would need to be tested to determine whether they had contracted that disease as a result of their attendance at the clinic. The class action was brought on behalf of both those who were later found to have contracted Hepatitis B as well as the larger percentage of people whose tests were negative but were worried between the time they received the notice and the time they received their test results. The case was later settled before trial, and it remains to be seen how the Court of Appeal in Ontario will deal with the issue in the future.

Based on the Court of Appeal's reasoning in its decision to revisit claims for fear of injury, as well as U.S. authorities on the issue, Canadian courts have been willing to certify as a common issue in class actions whether class members can recover medical monitoring costs. Canadian courts did not have to grapple with this issue before class actions were allowed, probably in large part because these costs were too small to be worth pursuing given the risk and expense in an individual claim. With the increasing popularity of class actions, these claims are now being pursued, and it remains unclear whether courts will allow recovery in these cases at trial. One significant difference in monitoring claims in Canada is that, in reality, the vast majority of the monitoring costs (if not all) are paid by a provincial health insurer. Health care is largely publicly funded in Canada. Legislation in most, though not all, provinces allows the public health insurer to pursue a claim for the cost of "insured" services provided to a patient, either in the name of the patient or in its own name, against a tortfeasor who caused the insured services to be needed. Further, in a number of provinces, a patient who commences an action against a tortfeasor is *required* to pursue the provincial health insurer's subrogated claim in that action and cannot settle at least that aspect of the claim without the provincial health insurer's consent. A strong argument can be made that a class action should not be certified for monitoring costs because the provincial health insurers are well able to pursue recovery of the costs in their own direct action, should they choose to do so. The additional expense, procedures, and inconvenience to proposed class members of a class action is unnecessary, particularly where the ultimate beneficiary will not be the proposed class members. However two Canadian decisions have rejected this argument.[49] It can also be argued that the specific legislation allowing the insurer to sue should require a true injury, rather than the prospect of one, before recovery in a subrogation claim or direct action is

[47] Graham v. MacMillan, [2003] B.C.J. No. 334 (C.A.) (QL). A similar result was also recently reached by an Ontario court in a now infamous case involving a complaint of nervous shock relating to the discovery of a fly in a bottle of drinking water. In permitting recovery for nervous shock in that case, the Ontario court specifically found that the plaintiff had suffered "recognized psychological illnesses" as a result of the discovery of the fly. *See* Mustapha v. Culligan of Canada Ltd., [2005] O.J. No. 1469 (S.C.J.) (QL).

[48] Anderson v. Wilson (1999), 44 O.R. (3d) 673 (C.A.) (the test was whether it was plain and obvious that the claim could not succeed.).

[49] Hoy v. Medtronics, Inc., [2003] B.C.J. No. 1251 (C.A.) (QL); Andersen, (2003), 67 O.R. (3d) at 136.

available. However, to date, this argument has not been tested.

E. New Claims – Causes of Action and Remedies

1. Waiver of Tort

One of the most potentially significant decisions in medical products litigation in the past two years is one that certified a class action claiming disgorgement of a medical device manufacturer's profits from the sale of a product, based on an allegation that the manufacturer misrepresented the quality of the product. In *Serhan*,[50] the plaintiffs sought to certify a national class action against a manufacturer of certain meters and strips used in the monitoring of diabetics' blood glucose levels. In addition to making a claim for personal injury damages based in negligence, the plaintiffs claimed that the defendants held all of the revenues generated from the sale of these products on a constructive trust basis for their benefit. The plaintiffs also sought an accounting and an order requiring "the disgorgement of such revenues."

The Court initially refused to certify the personal injury claims, but allowed certification of the common issue relating to the plaintiffs' claim for a constructive trust. The Court held that the plaintiffs' statement of claim supported a separate cause of action based on a doctrine of "waiver of tort."[51] According to the Court, "[c]laims based on waiver of tort seek 'restitution' of benefits received by the defendants, as a consequence of their tortious conduct rather than damages to compensate the plaintiffs for the loss."[52] The Court noted that waiver of tort "is said to have the advantage for a plaintiff that proof of loss as an element of the tort is not required."[53]

Leave to appeal the decision was granted by the Divisional Court on the basis that the decision of the certification judge "appeared" to conflict with existing case law that suggested that waiver of tort is not a separate cause of action but, rather, is a doctrine that allows the plaintiff to elect its remedy only after the defendant has committed a tort which gives rise to a cause of action. Since damages are an element of negligence as a cause of action, "waiver of tort" should not apply in the typical products liability case. The Canadian pharmaceutical and medical device industries are following the appeals in this case closely.

There is some encouragement from the *Serhan* decision in that the Court refused to certify as a class proceeding the personal injury claim, essentially on the basis that the cost and complexity of a class proceeding was not warranted in light of the very small damages that could be recovered, and given the individual issues of causation and damage that would have to be resolved in individual proceedings that many would not pursue in any event. This is the only recent case in Canada to refuse to certify a medical products class action for personal injuries.

2. Purchase Price Reimbursement

The Ontario Court of Appeal has ruled that plaintiffs cannot pursue a claim, either for themselves or for a proposed class, for reimbursement for the purchase price of a pharmaceutical medicine based on causes of action for breach of contract, implied warranty or unjust enrichment.[54] Claims for reimbursement of the purchase price of pharmaceuticals in negligence may be sustainable if plaintiffs can prove that negligence caused the injury and the injury in turn caused that person to need the

[50] Serhan v. Johnson & Johnson, [2004] O.J. No. 2904 (S.C.J.) (QL).
[51] Significantly, while "Waiver of Tort" had not been specifically pleaded by the plaintiffs, the Court found that the doctrine applied in the circumstances.
[52] Serhan, [2004] O.J. No. 2904 at 9.
[53] *Id.*
[54] Boulanger v. Johnson & Johnson Corp., [2003] O.J. No. 2218 (C.A.) (QL).

medication, but claims for reimbursement should not succeed for those without injury because it would be a claim for pure economic loss in the absence of any cost being incurred to avoid future damages to person or property.[55] This argument has not been ruled on in a pharmaceutical case in Canada to date, although the authors are aware of at least one pharmaceutical case, currently under reserve, where this argument is under consideration.

3. Related Securities Class Actions

As noted previously, one creative entrepreneurial plaintiffs' counsel commenced a securities class action against Merck for failure to make timely material disclosure of the potential for Vioxx class actions. Presumably, plaintiffs' lawyers would like to have the threat of a securities class action to force corporate defendants to make early disclosure of potential class proceedings, even before plaintiffs' counsel have thought of them. Many defense counsel hope that Canadian courts will not encourage this tactic.

4. Spoliation

An Ontario court has allowed the tort of spoliation of evidence to proceed to trial, although no trial has been held on the issue to date. The law in Canada as to whether spoliation constitutes an independent actionable tort is unclear. In *Spasic Estate v. Imperial Tobacco Ltd.*,[56] the Ontario Court of Appeal declined to strike out portions of a statement of claim that alleged spoliation on the basis that whether a substantive remedy was justified as a result of a defendant's destruction of evidence should be determined at trial.[57] Typically, in Canada, proof of spoliation carries a procedural as opposed to a substantive remedy. The presumption is that the evidence destroyed would have been unfavorable to the party who destroyed it, but that presumption may be rebutted. Spoliation is often used as a basis for asking the Court to draw adverse inferences or preclude evidence from being admitted.

IV. Causation

In a tort claim, the plaintiff has the burden of proving that the negligence or defect caused damage on a balance of probabilities. The test for proof of causation is usually a "but for" test, but where there are multiple causes, the court will ask whether the breach of duty "caused or materially contributed to" an injury or loss.[58]

Prior to 1990, some Canadian courts had adopted a reverse onus test for causation in situations where a defendant had, through a breach of the duty of care, created a risk of a particular injury that ultimately occurred to the plaintiff. In those cases, the Court required the defendant to show that the loss had some other cause. In *Snell* v. *Farrell*,[59] the Supreme Court of Canada rejected that view and affirmed the traditional approach to causation, whereby the plaintiff must prove on a balance of probabilities that any injury complained of was caused or materially contributed to by the defendants' negligence. However, the Court also said that where the facts lie particularly within the knowledge of the defendant, "very little

[55] *See* Winnipeg Condominium Corporation No. 36 v. Bird Construction Co., [1995] 1 S.C.R. 85; Hughes v. Sunbeam Corp. (Canada) Ltd. (2002), 61 O.R. (3d) 433 (C.A.).

[56] (2000), 49 O.R. (3d) 699 (C.A.).

[57] *See also* Nunes v. Air Transat A.T. Inc., [2002] O.J. No. 4708 (S.C.J.) (QL). *See, however,* Endean v. Canadian Red Cross Society, [1998] B.C.J. No. 724 (C.A.) (QL) (B.C. Court of Appeal held in the context of a class proceeding that an action for damages was not an appropriate response to the destruction of documents and struck a claim of spoliation).

[58] *See* Athey v. Leonati, [1986] 3 S.C.R. 458 at para. 18; Mizzi v. Hopkins (2003), 64 O.R. (3d) 365 (C.A.).

[59] Snell v. Farrell, [1990] 2 S.C.R. 311.

affirmative evidence on the part of the plaintiff will justify the drawing of an inference of causation in the absence of evidence to the contrary."

The legal or ultimate burden remains with the plaintiff, but in the absence of evidence to the contrary adduced by the defendant, an inference of causation may be drawn although positive or scientific proof of causation has not been adduced…. It is not therefore essential that the medical experts provide a firm opinion supporting the plaintiff's theory of causation. Medical experts ordinarily determine causation in terms of certainties whereas a lesser standard is demanded by the law.[60]

In medical products cases, often expert evidence (often from epidemiologists) cannot establish on a scientific basis that the plaintiff's injury was in fact caused by the defendant's conduct. Although the evidentiary burden on the plaintiffs to prove causation will, in some cases, be relatively low, they must still prove a probability, as opposed to a possibility, of causation. In *Rothwell v. Raes*[61] for example, the Ontario Court of Appeal affirmed the trial judge's decision that the plaintiff had not established, on a balance of probabilities, a causal relationship between the administration of DPTP vaccine (diphtheria, pertussis, tetanus and poliomyelitis) and certain adverse events. The Court found that the approach taken by the trial judge in applying the onus of proof to the factual circumstances was consistent with *Snell v. Farrell.* The trial judge had stated as follows:

> ...As to the degree of proof required, it is the normal civil standard of the balance of probabilities. Is it more likely than not that DPTP can cause such effects?
>
> ....While one dislikes in a case of such serious import to rely excessively upon the principle of onus, it cannot be forgotten that the onus does lie upon the plaintiffs to establish, if only by the slimmest balance of probability, that a named cause is likely. To demonstrate a possibility is not enough; probability must be established.[62]

The Supreme Court has also confirmed that causation may be established where the defendant's negligence was only one contributing cause of the plaintiff's injury, so long as it "materially contributed" to the damages alleged.[63] In *Athey* v. *Leonati*,[64] the Court found that the doctor's negligence was a 25% contributing cause of the plaintiff's injury. The Supreme Court reversed the trial judge's award of only 25% of the plaintiff's losses and held that the presence of non-tortious contributing causes will not reduce the extent of a defendant's liability; loss will not be apportioned according to the degree of causation where it is created by tortious and non-tortious causes, and the defendant was therefore liable for 100% of the loss. (Clearly, had there been multiple contributing tortious causes, liability would have been apportioned between the tortfeasors, at least between those who were parties to the action, but that was not the case in *Athey*).

The Supreme Court of Canada also dealt with another aspect of causation in the context of the manufacturer's duty to warn in *Hollis* v. *Dow Corning*.[65] Where a doctor fails to warn a patient of the risks of treatment and there is an absence of informed consent, the Court has traditionally applied an objective test of causation. The plaintiff must prove that a

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[60] *Id* at. 311.

[61] (1990), 2 O.R. (3d) 332 (C.A.), leave to appeal refused May 23, 1991 (S.C.C.).

[62] Rothwell v. Raes (1988), 66 O.R. (2d) (H.C.J.) at 474 and 506.

[63] Athey, [1986] 3 S.C.R. 458 at para. 18; Walker Estate v. York Finch General Hospital, [2001] 1 S.C.R. 647.

[64] Athey, [1986] 3 S.C.R. 458 at para. 18.

[65] Hollis v. Dow Corning Corp, [1993] B.C.J. No. 1363 at paras. 36 to 48 (C.A.) (QL).

reasonable person in his or her particular circumstances would not have consented to the surgery if he or she had received adequate warning of all of the material risks. This objective test was applied because of the inherent unreliability of a plaintiff's self-serving assertions that he or she would not personally have gone through the surgery. However, the majority of the Supreme Court in *Hollis* distinguished medical malpractice from product liability cases and held that a subjective test applied in litigation against a manufacturer for failure to warn. The plaintiff, according to the Supreme Court, need only prove that he or she personally would not have used the product if given adequate warning.

In cases with multiple manufacturers of the same product, the plaintiff must prove on a balance of probabilities which of the several possible producers manufactured the defective product, unless products of *all* of the manufacturers were defective, were used by the claimant, and increased the risk of the claimant's injury.[66] Market share product liability has not been recognized in Canada.

V. Defenses

Defenses available in a tort action may include the absence of a duty to the injured person (depending on proximity and foreseeability)[67] or the absence of negligence (no breach of the applicable standard of care). Where there are allegations of manufacturing or design defect, the absence of defect, lack of causation, and possibly voluntary assumption of risk (where the plaintiff knows of the defect and continues to use the product without justification) are additional defenses. In the context of a failure to warn allegation, defenses include the "learned intermediary" exception to the duty to warn, that the warning was adequate, and that, subjectively, a warning would not have changed the user's behavior. Concepts of voluntary assumption of risk, intervening act, and intermediate inspection in the context of a manufacturing or design defect claim will often not absolve a manufacturer of all liability because Canadian provinces typically have a "joint and several liability" regime. A manufacturer may need to plead contributory negligence against its co-defendants or bring third party proceedings for contribution and indemnity from other tortfeasors to limit its liability.

There is no "state of the art/development risk" defense in Canada, although evidence of the state of the art is admissible to assist in proving that a reasonable standard of care was used in the design or development of the product.[68] Evidence that a design deficiency in the product or a danger inherent in its use was not discoverable at the time of supply will be admitted as part of the proof that a reasonable standard of care was exercised in the design and warnings of the product. However, there is a continuing duty to warn of the danger once it is known or ought to be known. In all respects, the burden is on the plaintiff to establish negligence, including breach of a reasonable standard of care, on a balance of probabilities.

Canadian courts have held that it is not a defense to show compliance with regulatory or statutory requirements relating to the product,[69] although, if it can be established that a statute or regulation required the product to be manufactured, designed, or labeled in the specific way in which it is alleged to be faulty, then a defense of statutory compliance may be available.[70] Similarly, statutory non-compliance is not a cause of action, although, it may be evidence of one element of a negligence

[66] See Cook v. Lewis, [1951] S.C.R. 830; and Fairchild v. Glenhaven Funeral Services Ltd., [2002] 3 All E.R. 305 (H.L.).

[67] This defense is not typically available where the plaintiff is the direct user of the product.

[68] *See* Rentway Canada Ltd. v. Laidlaw Transport Ltd., [1989] O.J. No. 786 (H.C.J.) (QL); aff'd. [1994] O.J. No. 50 (C.A.) (QL).

[69] *See* R. v. Saskatchewan Wheat Pool, [1983] 1 S.C.R. 205.

[70] *See* Ryan v. Victoria (City), [1999] 1 S.C.R. 201.

claim (failure to exercise a reasonable standard of care).

VI. Regulators as Defendants

Unlike the U.S., the Canadian regulator, Health Canada, can be sued for negligence with respect to certain activities related to the approval, labeling, and recall of pharmaceutical medicines. In general, although it cannot be sued for negligence in relation to true policy decisions, it can be sued for "operational" negligence with respect to its conduct when implementing policy decisions. For example, since Health Canada has decided, as a matter of policy, to create regulations requiring a department within Health Canada to review the safety of prescription medicines, if Health Canada staff are negligent in their review of the safety of a medicine resulting in the medicine's approval and sale, and subsequent injury to a plaintiff results, there is no law precluding an action against Health Canada for such negligence.[71]

Historically, in individual product liability claims, plaintiffs' counsel have not sought to name the regulator as a defendant. Provincial legislation in most provinces provides for joint and several liability among contributing tortfeasors so that, from the plaintiff's perspective, as long as the named defendants are found contributorily negligent to any degree, the fact that Health Canada is not a defendant will not reduce the plaintiff's recovery. For obvious reasons, manufacturers have not sought to third party the regulator for contribution towards any judgment. Physicians and hospitals are often co-defendants and have also not sought to third party the regulator in the past. With the increasing use of class actions, however, plaintiffs are starting to sue the regulator, either as a co-defendant in an action against the manufacturer or in a separate action brought against the regulator after settling with the manufacturer (to top up the recovery from the manufacturer). Where Health Canada has been sued separately following a settlement with the manufacturer, Health Canada has sometimes third partied the manufacturer for contribution and indemnity.[72]

VII. Discovery

In most provinces in Canada, there is a requirement for delivery of an affidavit of documents early in the litigation. In the affidavit, a corporate representative is required to swear under oath that he or she has listed, in schedules attached, all documents in the "possession, power or control" of the company relating to any matter in issue in the litigation (as framed by the pleadings). The affidavit will include a list of each document over which privilege is claimed. In some cases, depending on opposing counsel, it is possible to avoid an exchange of sworn affidavits and simply agree that each side will produce what it considers to be the relevant documents (positive or negative), with the other party having the opportunity during the discovery process to request additional documents and cross-examine on documents that have not been produced. This strategy at least avoids (or defers to a later time) the significant effort and expense involved in preparation of the list and the concerns with swearing an oath at an early stage in the litigation when additional documents are likely to be located later no matter how diligent the initial document search has been.

As of January, 2005, the Ontario Rules of Civil Procedure were amended to expand the definition of "document" for the

[71] Klein v. American Medical Systems, Inc., [2005] O.J. No. 4910 (S.C.J.) (QL).

[72] *See e.g.,* Attis v. Canada (Minister of Health), [2003] O.J. No. 344 (S.C.J.) (QL), Logan v. Harper, [2001] O.J. No. 3744 (S.C.J.) (QL) and Logan v. Canada (Minister of Health), [2003] O.J. No. 418 (S.C.J.) (QL). Any settlement of a class action by a manufacturer needs to include provisions to ensure that either the plaintiff will not pursue the regulator in any subsequent action or, if it does, that the manufacturer will have no liability for contribution and for the costs of defending a third party claim.

purposes of discovery to include data and information "in electronic form."[73] Subsequently, in October, 2005, an "e-sub-committee" that was established as part of a broader task force into discovery-related issues in Ontario published its "Guidelines for the Discovery of Electronic Documents."[74] While these Guidelines have yet to be adopted into Ontario law in any formal way, it is anticipated that these and similar guidelines addressing the identification, location, preservation, and production of electronic documents will eventually be adopted throughout Canada.[75] The Guidelines are based on the principles that have been developed in the U.S. through the Sedona Conference Working Group and, like the Sedona principles, are intended to provide "best practices" with respect to the production of electronic documents.[76] To date, while the case law in this area is not yet well developed in Canada, one Court in Ontario has stressed the need for a cooperative approach to be taken between counsel in addressing issues associated with the production of electronic documents.[77]

With respect to depositions, in many provinces only the parties to the litigation will be deposed (discovered) orally before trial. In the case of a corporate defendant, this means that one corporate representative will be examined for discovery and, to the extent that that representative cannot answer questions about the company's conduct or information, undertakings will be given during the examination to obtain the information from others in the company who have knowledge. The information will be provided to opposing counsel later, often by way of a written answer, although opposing counsel can require a further attendance to ask questions arising from the written answers given. A few provinces allow persons who are not parties to be examined or deposed before trial for discovery purposes, either as of right or with leave of the Court if the information cannot be obtained any other way, but deposition of persons other than the parties are the exception rather than the norm in most Canadian provinces.

One other important difference between the Canadian and U.S. discovery process is that, in most Canadian provinces, there is an implied or "deemed" undertaking by all parties to keep documents and evidence provided through the discovery process confidential. The information cannot be used for any purpose other than the litigation in which it was disclosed. There are often exceptions to the confidentiality undertaking where evidence is later filed with the court (either for a motion or at trial). Further, at least in Ontario, the confidentiality undertaking does not apply to affidavits exchanged for pre-trial motions, nor to cross-examinations on those affidavits (i.e. most of the disclosure made when responding to a class certification hearing). The court has the jurisdiction to make confidentiality orders in appropriate cases, particularly where the deemed undertaking does not apply or is inadequate.

VIII. Experts

Unless an expert executes an affidavit for the purpose of an interlocutory motion (such as a class certification motion), he or she is not ordinarily examined in Canadian litigation before trial. Disclosure is made within some limited period of time prior to

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[73] RULES OF CIVIL PROCEDURE R.S.O. 1990, Reg. 194. Rule 30.01(1). This definition is consistent with the definitions contained in the ONTARIO EVIDENCE ACT R.S.O 1990, c. E. 23 s. 34.1(1) and THE CANADA EVIDENCE ACT R.S. 1985, c. C-5 s. 31.8.

[74] *See* Guidelines, *available at* http://www.oba.org/En/main/ediscovery_en/default.aspx.

[75] *See e.g.,* Quebec: An act to establish a legal framework for information technology, R.S.Q., chapter C-1.1.

[76] THE SEDONA PRINCIPLES: BEST PRACTICES RECOMMENDATIONS & PRINCIPLES FOR ADDRESSING ELECTRONIC DOCUMENT PRODUCTION, A Project of The Sedona Conference Working Group on Best practices for Electronic Document Retention & Production, (January 2004).

[77] Syncor Technology Inc. v. Kiaer, 2005 CANL11 46736 (Ont. S.C.).

trial (in Ontario, at least ninety days before trial; sixty days before for a responding report) by delivery of a report signed by the expert, disclosing his or her qualifications, findings, opinions, and conclusions. In theory at least, the expert cannot give opinions at trial if they are not disclosed in the report, although in practice judges will often allow the expert to stray beyond the confines of the report unless it prejudices the other party in a way that cannot be addressed by way of a costs order or an adjournment.[78] If an expert executes an affidavit for the purpose of a certification motion (or an expert report is attached as an exhibit to a party's affidavit), the rules of court provide opportunities to cross-examine the expert on the affidavit or report before the hearing of the motion.

The admissibility of expert opinions has historically been raised and addressed in Canadian courts at the time that the expert witness is tendered to give evidence at trial. Pre-trial motions to preclude the use of expert opinion were virtually unheard of, except where there was spoliation of physical evidence and breach of a preservation order. Often, the court will admit expert evidence even where its reliability is questionable, and leave the issue to be considered when weighing the competing evidence. Unfortunately, our courts do not have a great deal of experience dealing with scientific evidence.

However, cases from the Supreme Court on this issue[79] support an assessment of the reliability of expert opinion, particularly novel scientific theories, at the admissibility stage, applying principles akin to those advanced by U.S. courts in *Daubert*[80] and the cases that have followed it. In the most recent decision, the Supreme Court considered an expert's use of a penile plethysmograph to formulate an opinion on the lack of an accused's propensity to commit a sexual offence. The Court held that the opinion should not have been admitted at trial because there was no reliable foundation for the use of the device for that purpose.

With ever increasing use of expert evidence on class certification motions, preliminary motions to strike expert evidence based on principles similar to those applied in U.S. *Daubert* motions may become more frequent. We are aware of only one such motion being brought in Ontario to date. The Court adjourned its decision on the motion to the class certification hearing, and then dismissed the *Daubert* motion on its merits.[81] In general, Ontario courts are discouraging evidentiary challenges on class certification motions,[82] while the courts in British Columbia seem more willing to entertain them.[83]

There may also be opportunities for the court to strike expert evidence for lack of a reliable foundation in the context of a motion for summary judgment. The threshold that a plaintiff needs to meet to survive a motion for summary judgment is low (whether there is a genuine issue of fact or credibility that requires a trial). Although a somewhat novel approach, it may be possible to persuade a judge on such a motion that an expert opinion is not admissible because it is unreliable and that, once the expert evidence is struck, there is no evidence raising a genuine issue for trial.

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[78] Provincial discovery rules may allow party to obtain disclosure of expert's findings, opinions, or conclusions before receiving report by examining party if party has obtained opinions from an expert and is not prepared to call that expert as a witness at trial. Often counsel will defer obtaining an "opinion" from an expert until after discovery, but they will obtain assistance from the expert to formulate discovery questions and to obtain information that the expert requires to later formulate an opinion.

[79] *See e.g.,* R. v. Mohan, [1994] 2 S.C.R. 9 and R. v. J.L.-J., [2000] 2 S.C.R. 600.

[80] Daubert v. Merrell Dow Pharmaceuticals, Inc., 508 U.S. 579 (1993).

[81] Andersen v. St. Jude Medical, Inc., [2000] O.J. No. 4478 (S.C.J.) (QL) and [2003] O.J. No. 4314 (S.C.J.) (QL).

[82] Hague v. Liberty Mutual Ins. Co., [2004] O.J. No. 3057 (S.C.J.) (QL).

[83] Ernewein v. General Motors of Canada Ltd., [2005] B.C.J. No. 2370 (C.A.) (QL).

However, given our court's relative inexperience with complex scientific evidence and the issues surrounding its reliability, there is likely to be some judicial resistance to such a strategy. Moreover, because of the rules with respect to the recovery of legal costs, if a summary judgment motion is brought by a defendant in a complex scientific case on the basis that the plaintiff does not have reliable scientific evidence to support the claim, the defendant may simply end up funding the plaintiff's retention of experts and preparation of expert opinions. Accordingly, it will only be in the strongest of cases that defendants are likely to try this strategy.

IX. Conduct of Trials

A. Jury Versus Non-Jury

The vast majority of civil trials in Canada have been conducted as judge alone trials, although jury trials can be requested in most provinces other than Quebec.[84] Historically, juries have been selected by insurance defense counsel in motor vehicle cases, in part because Ontario juries were felt by many to be less generous than judges. However, a few of the more experienced plaintiffs' counsel will serve jury notices in appropriate cases (i.e. where there is a likeable and sympathetic plaintiff, a "faceless" corporate defendant and complexity will work against the defendant more than against the plaintiff). Although the court can strike a jury notice where the matter is so complex that a jury cannot reasonably be expected to follow the evidence or to apply the judges' charge properly, it is felt by many that judges presently tend to favor juries even in complex matters.[85]

In Ontario, a jury panel will be comprised of six jurors who are eighteen years or older, who are also Canadian citizens and Ontario residents. They cannot be lawyers or students at law.[86] Any five jurors can decide questions posed to the panel.[87]

A jury panel is assembled by the County Sheriff's Office, and both parties can obtain the name, occupation and address of the prospective jurors in advance of jury selection. Counsel for the plaintiff(s) has four preemptory challenges, and counsel for the defendants has an equal number, to be shared among the defendants if separately represented.[88] Although challenges for cause may be made in civil cases, they are rarely made. A challenge for cause must be grounded on some disqualification, such as an interest in the case. In Canada, unlike the United States, no questions are allowed of jurors.[89] Accordingly, information must be obtained about the potential jury panel members by making informal inquiries prior to trial or, if warranted, hiring a reliable and discrete private investigator to conduct an independent investigation that does not involve approaching any of the panel

[84] Juries are not permissible in actions against municipalities or the Crown or its agencies (i.e. Health Canada). *See* THE COURTS OF JUSTICE ACT, R.S.O. 1990, c. C.43, s. 108(2); PROCEEDINGS AGAINST THE CROWN ACT, R.S.O. 1990, c. P.27, s. 11; CROWN LIABILITY AND PROCEEDINGS ACT, R.S.C. 1985, c. C-50, s. 26.

[85] Historically, jury notices in medical malpractice cases were struck almost as a matter of course. *See e.g.,* Soldwisch v. Toronto Western Hospital [1988] O.J. No. 201 (H.C.) (QL). More recently, however, judges have permitted these cases to proceed to a trial before a jury. *See* Georgia Gulf Corp. v. Window City Industries Inc., 2004 WL 909113 (Ont. S.C.J.); Irish v. Vanderlinden, 2004 WL 1126156 (Ont. S.C.J.); Collette v. Cartier Partners Securities Inc., [2005] B.C.J. No. 769 (S.C.) (QL).

[86] JURIES ACT, R.S.O. 1990, c. J. 3, s. 3, as amended.

[87] COURTS OF JUSTICE ACT, *supra* note 84, s. 108(8). In British Columbia, civil juries consist of eight jurors and a verdict can be delivered by six if the eight are unable to reach a verdict after three hours. *See* JURY ACT, R.S.B.C. 242, s. 22.

[88] For the equivalent rule in British Columbia *see* JURY ACT, R.S.B.C. 242, ss. 20 & 21.

[89] JOHN SOPINKA, DONALD B. HOUSTON, AND MELANIE SOPINKA, THE TRIAL OF AN ACTION 33 (2nd ed. Toronto: Butterworths, 1998).

members. Since no questions are permitted and challenges for cause are extremely rare, the jury selection process typically takes fifteen to twenty minutes.

B. Evidentiary Objections

Objections to the admission of evidence at trial are typically made at the time in the trial when a party seeks to adduce the evidence. This includes objections to expert evidence, whether on issues of relevancy, necessity or qualifications, or the related issue of reliability.[90] Generally, counsel have advance notice of contentious evidence the opposing party intends to present, such as expert evidence or demonstrative aids, and a time will be set aside to argue admissibility during the trial, before the evidence is to be presented. In a jury trial, argument will be heard in the absence of the jury.

C. Opening Addresses

In a jury trial, opening addresses are subject to a number of judicially imposed limits on counsel's freedom to address the jury. When an opening address exceeds permissible limits, the trial judge, in his or her discretion, may caution the jury, strike the jury and conduct the trial by judge alone, or declare a mistrial.

Typically, in Ontario, an opening address is understood to be restricted to allowing counsel an opportunity to set out what he or she believes the issues are, describing the evidence to be adduced, its relationship to the issues, and the effect of that evidence on proving his or her case. Counsel are also permitted to anticipate the evidence and questions the defense may put forward. However, counsel are not permitted to assert personal opinion on the facts or the law, and are required to avoid inflammatory comments that "appeal to the emotions of jurors and invite prohibited reasoning."[91] Counsel is similarly restricted in an opening address from making reference to inadmissible and irrelevant evidence, reading law, from arguing his or her case, from explaining the importance of certain evidence, or commenting on how the evidence should be weighed or what inferences should be drawn.

In considering whether an opening address has crossed the line of appropriateness, recent case law suggests that Ontario Courts will have regard to whether counsel's words amount to "overt argument" or "persuasive narrative" (the latter being permitted).[92] Where this line is drawn by the courts is not always clear.[93]

D. Non Suit

At the conclusion of the plaintiff's case, a defendant may bring a motion for non-suit on the basis that no jury acting judicially could find in favor of the plaintiff. The decision is a question of law, not a matter of weighing evidence. The judge may, rather than ruling on the motion immediately, reserve his decision until the end of trial, forcing the defendant to elect whether or not to present evidence. The practice now is generally to require the defendant to make this election before ruling on the motion in almost all cases. Since the trial judge has discretion to allow the plaintiffs' case to be re-opened, it is generally preferable for the defendant to put in its evidence and then ask the trial judge to find that the plaintiff has not made its case.

E. Closing Addresses

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[90] In most provinces, experts are required to serve a written report of their findings, opinions, and conclusions in advance of trial, but will not be deposed before trial.

[91] Brochu v. Pond (2002), 62 O.R. (3d) 722 (C.A.) at para. 16.

[92] Hall v. Schmidt (2001), 56 O.R. (3d) 257 (S.C.J.).

[93] *Id. cf.* Creasor v. Cadillac Fariview Corp, [2000] O.J. No. 4217 (C.A.) (QL) with Khazzaka v. Commercial Union Assurance Co. (2002), 66 O.R. (3d) 390 (C.A.) and Burke v. Behan, [2004] O.J. No. 5245 (S.C.J.) (QL).

The technical rules for the order of closing addresses are as follows: the plaintiff has the right to address the trier of fact last where both parties have adduced evidence; the defendant has the right to address the trier of fact last where no defendant has adduced evidence; as amongst co-defendants, they will generally address the trier of fact in the order in which they are named in the pleadings. However, all of these rules are subject to the discretion of the Court to alter them where it is fair and just to do so. In jury cases, the order is entirely within the judge's discretion, although the plaintiff will usually be called upon to present the closing argument first, with a right of reply, whether the defendant has adduced evidence or not.

F. Jury Questions

In most modern jury trials, the decision of the jury is taken by answers to questions which will be referred to in the judge's charge to the jury. Any question may be decided by the vote of five of the six jurors.

A judge may require the jury to give a general verdict, or to answer specific questions, and judgment may be entered in accordance with the answers to the questions.[94] The questions posed to the jury are usually agreed upon by counsel, subject to the ultimate decision of the trial judge. The trial judge may decide in favor of a general verdict despite the agreement of counsel on specific questions.

X. Costs

Any discussion of pharmaceutical product liability litigation in Ontario would be remiss without a discussion of the rules with respect to costs of legal proceedings. The most disturbing recent development in this area relates to the willingness of Ontario courts in certain circumstances to order unsuccessful defendants to pay entrepreneurial plaintiffs' counsel a substantial premium above the time value of their services.

A. Loser Pays Costs Rule

The ordinary costs rule in Ontario litigation is a "loser pays" rule.[95] Subject to the discretion of the court otherwise, the normal rule is that the successful party is awarded their "partial indemnity" costs (typically 30 to 50 % of actual legal costs, although that can be reduced depending on what a court would typically award in the type of proceeding before it). In exceptional cases, a court also has the discretionary power to award a party its costs on a higher scale ("substantial indemnity"), such as where offers to settle are used by the plaintiffs,[96] there are allegations of fraud which are not proven at trial or there has been particularly outrageous and reprehensible conduct during the proceedings (i.e. destruction of evidence or a party has engaged in delaying tactics or other tactics with the intent of obstructing the court process). Substantial indemnity costs are defined as one and a half times what would otherwise be awarded on a partial indemnity scale.[97] It has been said that something less than full indemnity costs should usually be awarded so that all parties have some incentive to settle litigation before trial.

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[94] COURTS OF JUSTICE ACT, *supra* note 84, s. 108(5).

[95] The ultimate costs award is always subject to the court's discretion. Although the "loser pays" rule applies in class actions in Ontario and in individual litigation in other provinces, some provinces do not have a "loser pays" cost rule for class actions (i.e. British Columbia). "Bullock" and "Sanderson" orders and premiums discussed *infra* are not available in all provinces.

[96] ONTARIO RULES OF CIVIL PROCEDURE, Rule 49.10 (plaintiff who obtains a judgment at least as favorable as the terms of an offer to settle which was not accepted by the defendant is entitled to partial indemnity costs up to the date the offer was served and substantial indemnity costs from that date forward).

[97] R.R.O. 1990, Regulation 194, amended by O. Reg. 198/05.

In cases where a plaintiff has joined more than one defendant to the action on the basis that he or she is unsure of which defendant is liable, the plaintiff may be entitled to recover from an unsuccessful defendant the amount of the costs which he or she is obliged to pay to a successful defendant. This is known as a "Bullock Order." The threshold test is whether it was reasonable to join the defendants and to keep them in the action until judgment.[98] These orders are not normally appropriate where a plaintiff alleges an independent cause of action against two defendants or where the breaches of duty are in no way connected with each other.[99]

The "Sanderson Order"[100] has, to some extent, superseded the "Bullock Order." Pursuant to a "Sanderson Order," an unsuccessful defendant must pay costs directly to a successful co-defendant. A "Sanderson Order" is appropriate if the plaintiff has properly sued both defendants, or where the unsuccessful defendant has caused the successful defendant to be added as a party.[101] This order, however, will usually not be made if there is a real risk that the successful defendant will not recover costs against the unsuccessful defendant because of the latter's financial inability to pay.

B. Premiums

One of the more disturbing trends to emerge in Ontario law with respect to costs is the awarding of a premium to plaintiffs' counsel above and beyond an award of substantial indemnity costs. In five individual cases since 2000, the Ontario Court of Appeal has ordered an unsuccessful defendant to pay a premium to plaintiffs' counsel as part of a costs award.[102] While the Court has emphasized that a premium should be awarded in rare circumstances, such an award is felt to be justified where the joint factors of "risk" and "reward" "cry out" for an award in excess of an award of substantial indemnity costs.[103]

The rationale the courts have provided for granting such an award is that access to justice will be encouraged if a plaintiffs' firm is awarded a premium for taking on a case where the plaintiff lacked financial resources to fund the litigation, there was significant financial risk to the firm and an outstanding result was achieved in light of the complexity of the case and the importance of the case to the plaintiff.

In a recent securities class action that proceeded to trial in Ontario,[104] the Superior Court of Justice awarded partial indemnity costs to the date of an offer to settle, an estimated $1.2 million for substantial indemnity costs from the date of the offer to settle forward (because the judgment at trial

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[98] Besterman v. British Motor Cab Co., [1914] 3 K.B. 181 (C.A.). *See also* Etienne v. McKellar Gen. Hosp. (1998), 16 C.P.C. (3d) 139 (Ont. C.A.), leave to appeal to S.C.C. refused.

[99] Rooney (Litigation Guardian of) v. Graham (2001), 198 D.L.R. (4th) 1 (Ont. C.A.), the Court held that there may be times where the causes of action are independent or the actions separate, but it is nevertheless fair that the responsible defendant be called upon to pay for the inclusion of others in the trial proceedings. Each case will be considered in its context.

[100] Chippewas of Sarnia Band v. Canada (Attorney General), [2000] O.J. No. 1875 (S.C.J.) (QL).

[101] Widdis v. Hall (1995), 22 O.R. (3d) 187 (G.D.).

[102] Roberts v. Morana (2000), 49 O.R. (3d) 157 (C.A.) (trial judge awarding $1,045,538 in fees plus premium of $120,000; upheld on appeal); Jack (Litigation Guardian of) v. Kirkrude, [2002] O.J. No. 192 (C.A.) (QL) (premium of $25,500 upheld); Banihashem-Bakhtiari v. Axes Investments Inc. (2002*),* 69 O.R. (3d) 671 (C.A.) (premium of $350,000 upheld); Walker v. Ritchie, [2005] O.J. No. 1600 (C.A.) (QL); leave to appeal to the Supreme Court of Canada granted,[2005] S.C.C.A. No. 297 (QL); (at trial, plaintiff awarded substantial indemnity costs of $470,979.65 plus premium of $200,000; amount of premium upheld on appeal); Lurtz v. Duchesne, [2005] O.J. No. 354 (C.A.) (QL) (premium of $150,000 reduced to $75,000 on appeal).

[103] Walker, [2005] O.J. No. 1600 (C.A.) (QL); The appeal of this decision to the Supreme Court of Canada is being carefully watched.

[104] Kerr v. Danier Leather Inc., [2005] O.J. No. 1972 (S.C.J.) (QL).

was better than the offer) and a costs "premium" of $1 million. The Court stated that there was no reason the principles behind premium awards in individual actions would not apply to class actions. On appeal, after overturning the trial court's substantive decision, the Court of Appeal noted in *obiter* that it thought it doubtful that a costs premium can be properly awarded in a class proceeding (where there are other cost mechanisms to deal with the risk of litigation).[105]

XI. Conclusion

Expanding availability and use of class actions in Canada, new causes of action being asserted and allowed to proceed to trial, the adoption by Canadian plaintiffs' counsel of tactics and strategies used in the U.S., and greater co-operation between U.S. and Canadian plaintiffs' counsel may foreshadow an increased level of pharmaceutical litigation. As a result, the future holds more potential for pharmaceutical product liability trials. It is expected that the trend towards class actions in Canada will continue, although the economics of class actions may cause plaintiffs' counsel to re-consider soliciting inventories of plaintiffs and attempting to run multi-party actions quickly through discovery without the complexity, delay and cost of class certification. Procedural rules and trials differ from the U.S. in many respects that will impact both the manner in which the trial is prepared and presented and how any case is assessed.

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[105] Kerr v. Danier Leather Inc**.,** [2005] O.J. No. 5388 (C.A) (QL).