COURT FILE NO.: 181/07
DATE: 20080702

ONTARIO
SUPERIOR COURT OF JUSTICE

DIVISIONAL COURT

FERRIER, CUMMING AND ARCHIBALD JJ.

B E T W E E N:	
ANDREA HEWARD, ANDREW CHARLES HEWARD, KELLY HUTCHINS, DARLENE HUTCHINS, DANIEL WELLS AND NANCY WELLS	***Michael A. Eizenga*** and ***Harvin Pitch*** --for the Plaintiffs
Plaintiffs (Respondents)	
- and -	
ELI LILLY & COMPANY AND ELI LILLY CANADA INC	***David S. Morritt*** and ***Craig T. Lockwood*** -- for the Defendants
Defendants (Appellants)	
	HEARD at Toronto: February 22, 2008

CUMMING J.

Background

Introduction

[1] The representative plaintiffs in this class action allege that the prescription antipsychotic drug Zyprexa, manufactured and distributed by the defendants, has the risk of significant negative side effects.

[2] Health Canada has approved the drug for the treatment of schizophrenia, bipolar disorder and other mood disorders. The drug is widely sold around the world and the record indicates the drug is beneficial and efficacious for its stated purposes. An update to the product monograph concerning diabetes and related risks was approved by Health Canada in March, 2003. Physicians throughout Canada continue to prescribe the drug for thousands of patients notwithstanding the explicit information approved by Health Canada regarding possible associations between Zyprexa and diabetes.

[3] The national class (excluding British Columbia and Quebec) certified by Cullity, J. embraces an estimated 575,000 individuals in Canada as having ingested Zyprexa since 1996, as well as an indeterminate number of derivative claimants.

[4] The plaintiffs say the defendants have been negligent in manufacturing and distributing Zyprexa because of the increased risk of diabetes and related disorders including hyperglycemia; pancreatitis and other blood sugar disorders; weight gain; and, in elderly patients, strokes. Moreover, they claim the defendants were negligent in not having given an adequate and timely warning of such risks.

[5] The plaintiffs claim, in the alternative that, because of the defendants' alleged wrongful conduct, they are entitled on a so-called "waiver of tort" basis to an accounting for disgorgement and/or constructive trust of the proceeds of the defendants' sale of the drug.

The decision of the motion judge in respect of the motion for certification

[6] Justice Cullity granted the motion to certify the action as a class proceeding based on causes of action in negligence and waiver of tort pursuant to s. 5 (1) of the *Class Proceedings Act, 1992*, S.O. 1992 ("*CPA*") on February 2, 2007: *Heward v. Eli Lilly & Co.*, [2007] O.J. No. 404 (S.C.J.). In certifying the cause of action based in waiver of tort, Justice Cullity took into account this Court's conclusion in *Serhan v. Johnson & Johnson* (2006), 269 D.L.R. (4th) 279 (Ont. Div. Ct), leave to appeal to S.C.C. ref'd, [2006] S.C.C.A. No. 494 ("Serhan") that waiver of tort is an unsettled area of law, which involves significant matters of policy that should be decided on a full factual record.

[7] In his Order, dated June 6, 2007, Cullity J. set forth eight common issues:

a) Can Zyprexa cause diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom?

b) If the answer to (a) is yes, is Zyprexa thereby defective or unfit for the purpose for which it was intended... as designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or both of the defendants?

c) Did the defendants breach a duty of care owed to the Class by marketing and distributing Zyprexa in Canada?

d) Did the defendants knowingly, recklessly or negligently breach a duty to warn or materially misrepresent any of the risks of harm from Zyprexa?

e) If one or more of common issues (a) through (d) are answered affirmatively, are class members ... entitled to special damages for medical costs incurred in the screening, diagnosis and treatment of diseases related to Zyprexa?

f) Should the defendants be required to implement a medical monitoring regime and, if so, what should that regime comprise and how should it be established?

g) Should the defendants pay exemplary or punitive damages?

h) By virtue of waiver of tort, are the defendants liable on a restitutionary basis:
   i. To account to any of the Class ... for any part of the proceeds of the sale of Zyprexa? If so, in what amount and for whose benefit is such accounting to be made? Or, in the alternative,
   ii. Such that a constructive trust is to be imposed on any part of the proceeds of sale of Zyprexa for the benefit of the Class...and, if so, in what amount, and for whom are such proceeds held?

Leave to appeal the motion judge's decision to the Divisional Court

[8] The defendants have been given leave to appeal two discrete issues arising from the decision granting certification. As framed by Lederman J., the two issues are:

> (1) Did the certification motion judge err in concluding that proof of the amount of the alleged wrongful gain subject to an accounting and disgorgement and/or a constructive trust is a common issue?
>
> (2) Did the certification motion judge err in concluding that a class proceeding is the preferable procedure to resolve the plaintiffs' claim in waiver of tort?

[9] For the purpose of the appeal at hand, it is the quantum of a possible remedy under common issue (h), above, which is seen as problematic from the perspective of the defendants. The defendants also claim that a class proceeding is not the preferable procedure for the related cause of action in waiver of tort.

[10] In his consideration of common issue (h), as it was then proposed, Cullity J. remarked that the finding of a cause of action on the basis of waiver of tort was insufficient in itself to qualify the related restitutionary relief as an issue common to the class as a whole. He concluded, instead at para. 101 that:

> ...the court must be satisfied that it is possible to determine on a class-wide basis whether a sufficient causal connection existed between the wrongful conduct and the amount for which the defendants could be ordered to account.

[11] Justice Cullity then concluded that a sufficient causal connection between the wrongful conduct and the amount of the wrongful gain could be established if the plaintiffs could prove that the defendants were negligent with respect to the manufacture and distribution of Zyprexa and/or the failure to warn of its alleged risks, namely common issues (b)-(d) above. This, he explained, would satisfy a "but for" test of causation as the defendants would not have derived proceeds but for the breach of the duty. Consequently, Justice Cullity found that the remedies of constructive trust and an accounting for disgorgement based in waiver of tort were common issues. In this regard he stated, at para. 101:

> ...a necessary causal link between the wrong and the amount claimed by way of "restitution" or disgorgement would be established if the plaintiffs can prove their claim that the defendants were negligent in placing Zyprexa on the market, or in continuing to market it after November, 2001, without a sufficient warning of its side-effects. In the event of a finding to this effect, the defendants would not have derived any proceeds but for their breach of duty and, in this sense, the proceeds would have resulted from the wrong. In consequence, I believe the question of causation could - as in *Serhan* - be dealt with in respect of the class as a whole.

[12] In granting leave to appeal, Lederman J. questioned whether proof of the amount of the wrongful gain to be recovered by class members is a common issue. Justice Lederman did not take issue with the entirety of common issue (h), stating, at para. 25, "whether the remedies of an accounting and disgorgement and constructive trust are available in a waiver of tort claim is clearly a common legal issue." Moreover, he agreed with Cullity J. that there must be a causal connection on a class-wide basis between the amount subject to disgorgement or constructive trust and the wrongful conduct. However, Lederman J. respectfully disagreed, at para. 32, "that the pleadings or the evidence support the assumption made by Cullity J. that Eli Lilly's gain was caused by its wrongful conduct."

[13] Justice Lederman based his decision upon his finding that neither the pleadings nor the evidence support two inferences:

> (1) All class members would not have taken Zyprexa if properly warned of the associated risks; or
> (2) Health Canada would not have approved Zyprexa for sale if properly warned of the associated risks.

Without these two inferences, Lederman J. asserted that the only way to determine the amount of the wrongful gain would be to conduct individual investigations of each class member. He noted that having to resort to individual investigations in such circumstances "is the antithesis of a common issue." (para. 29)

[14] Justice Lederman reasoned that since Zyprexa continued to be used some three years after Health Canada ordered the defendants to add a warning regarding the risk of developing diabetes, class members may have taken the drug even if the warning had been improved earlier. Moreover, because Health Canada did not order Zyprexa off the market once the regulator was warned of its health issues, it could be inferred that the drug would have been approved for sale in the 1990's even if Health Canada had been properly warned at that time of its associated risks.

[15] In the proceeding before us, the defendants assert that proof of the amount to be disgorged or held in a constructive trust cannot possibly be a common issue. They assert that it is an individual issue whether different warnings would have made a difference to a physician's decision to prescribe Zyprexa or to any particular patient's decision to take the drug in view of her or his unique circumstances. Health Canada has continued to expand the approved uses of the drug despite knowledge of possible risks associated with its use. The defendants say that there is an absence of evidence that class members would have been unwilling to take Zyprexa had they been warned of the alleged risks. The defendants ask as to how a court could determine the portion of profits to be disgorged from the defendants, if any, or how those profits would be apportioned among class members, in light of the different circumstances facing the plaintiffs.

Standard of Review

[16] The Supreme Court of Canada addressed the standard of review of an appeal from a judge's decision in *Housen v. Nikolaisen* (2002), 211 D.L.R. (4th) 577 (S.C.C.), [2002] S.C.J. No. 31 [Cited to QL]. In summary:

> On a pure question of law, the basic rule with respect to the review of a trial judge's findings is that an appellate court is free to replace the opinion of the trial judge with its own. Thus the standard of review on a question of law is that of correctness. (at para. 8)
>
> The standard of review for findings of fact is that such findings are not to be reversed unless it can be established that the trial judge made a "palpable and overriding error": *Stein* v. *The Ship "Kathy K"*. (at para. 10)
>
> Where the trier of fact has considered all the evidence that the law requires him or her to consider and still comes to the wrong conclusion, then this amounts to an error of mixed law and fact and is subject to a more stringent standard of review [than for findings of fact]. (at para. 28)

[17] With respect to appeal of a certification of a class proceeding, in *Anderson v. Wilson* (1999), 44 O.R. (3d) 673, application for leave to appeal dismissed, [1999] S.C.C.A. No. 476, the Court of Appeal for Ontario said, at 677:

> I am mindful of the deference which is due to the Superior Court judges who have developed expertise in this very sophisticated area of practice. The Act provides for flexibility and adjustment at all stages of the proceeding and any intervention by this court at the certification level should be restricted to matters of general principle.

[18] MacPherson J.A., writing for the Ontario Court of Appeal in *Carom v. Bre-X Minerals Ltd.* (2000), 51 O.R. (3d) 236 at 247-248, reiterated this principle when he noted that judges assigned to hear certification motions "develop an expertise which should be recognized and respected by appellate courts." See also: *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.).

[19] More recently, in *Cassano v. The Toronto Dominion Bank*, [2007] O.J. No. 4406 (C.A.), Chief Justice Winkler, writing for the majority held, at para. 23, that

> The motion judge is an experienced class action judge. His decision is entitled to substantial deference: see *Markson v. MBNA Canada Bank* (2007), 85 O.R. (3d) 321 at para. 33 (C.A.), leave to appeal to S.C.C. requested, [2007] S.C.C.A. No. 346. The intervention of this court should be limited to matters of general principle: see *Cloud v. Canada (A.G.)* (2004), 73 O.R. (3d) 401 at para. 39 (C.A.), leave to appeal to S.C.C. refused, [2005] S.C.C.A. No. 50. However, legal errors by the motion judge on matters central to a proper application of s. 5 of the *CPA* displace the deference usually owed to the certification motion decision: see *Hickey-Button v. Loyalist College of Applied Arts & Technology* (2006), 267 D.L.R. (4th) 601 at para. 6 (Ont. C.A.).

Analysis

[20] The nomenclature "waiver of tort" is somewhat confusing. A plaintiff is not waiving the right to sue in tort but rather, electing to base his/her claim in restitution. The plaintiff thereby seeks to recoup the benefits that the defendant has derived from the tortious conduct. For example, if the tortfeasor's gain exceeds the quantum of damages that the plaintiff might recover in an action in tort, the plaintiff might well choose to concurrently pursue the alternative (so-called 'waiver of tort') remedy founded in restitution.

[21] Professor John D. McCamus and Peter D. Maddaugh in their chapter on "Waiver of Tort" in *The Law of Restitution*, looseleaf (Aurora: Canada Law Book Inc., August 2007) at 24-19 assert that the doctrine constitutes an independent cause of action and is not simply parasitic to the tort claim. The modern theory of restitution is based squarely upon the principle of preventing unjust enrichment. It is not necessary to prove a loss, but rather, simply that there has

been unjust enrichment. *Strand Electric & Engineering Co. Ltd. v. Brisford Entertainments Ltd.*, [1952] 2 Q.B. 246 (C.A.) at 253 per Denning L.J. Arguably, waiver of tort is available whenever tortuous conduct has produced a profit. There seems to be no principled reason to exclude waiver of tort from negligence actions.

[22] Issues concerning the doctrine of waiver of tort and its related remedies of constructive trust and/or accounting for disgorgement have recently been presented to this Court in two other class proceedings, namely *Serhan, supra,* and *Peter v. Medtronic Inc.*, [2008] O.J. No. 1916 (Ont. Div. Ct.) ("Medtronic").

[23] In *Serhan*, the Divisional Court conducted a thorough review of the doctrine of waiver of tort in the context of a medical products liability case. The majority of the Court upheld the decision of Cullity J. granting the motion to certify the class action. The majority concluded that the doctrine of waiver of tort is an uncertain area of law and, accordingly, there were matters of policy that should not be decided at the pleadings stage. Rather, policy issues regarding the nature and scope of waiver of tort, including whether it is an independent cause of action or a remedy for certain torts, are to be resolved in the context of a complete record after a trial.

[24] In *Medtronic*, Carnwath J. denied an application for leave to appeal the decision of Hoy J. certifying a class action in a medical products liability claim. In his Reasons, Carnwath J. relied on the majority of the Divisional Court in *Serhan* for the principle that

> Given the uncertain state of law concerning both waiver of tort and the potential of disgorgement liability and the circumstances under which the remedy of a constructive trust may be recognized, it is not appropriate that the court should embark upon an analysis of the nature and significance at this early stage without a complete factual foundation. This is particularly so given the policy implications of the issues raised in this proceeding, implications for which the class proceedings regime in this province is specifically designed in that it is intended to provide a mechanism for correcting the behaviour of wrongdoers who would, absent its specialized procedures, be immune from legal consequences for their behaviour. (*Serhan* at para. 157)

[25] This appeal concerns the discrete issue of whether proof of the amount of the remedies relating to waiver of tort is a common issue. The amount of relief was certified as a common issue in both *Serhan* and *Medtronic*. In *Medtronic*, as noted above, Carnwath J. relied on the uncertainty of the state of the law as regards waiver of tort in considering whether the certification judge erred with respect to the common issues. In *Serhan*, while the question of whether the amount of relief relating to waiver of tort is an appropriate common issue was not directly addressed by the Court, Epstein J. for the majority commented at para. 124 that

> Not only these policy concerns, but also the essential nature of the remedy of disgorgement, require clarification in our jurisprudence. In fact, in stating the common issue of whether or not the defendants might be liable to account to the class members on a restitutionary basis, Cullity J. implicitly anticipated these

concerns by posing the additional question of "if so, in what amount and for whose benefit is such an accounting to be made?"(at para. 73) Questions of the circumstances under which manufacturers and distributors of health care products might have to disgorge their profits and to whom or to what entities the assets in issue may be directed need to be developed on the basis of a full factual record.

[26] A certification motion is procedural in nature. There has as yet not been discovery of documents or witnesses. As well, the application of the doctrine of waiver of tort is a relatively recent theory of recovery under principles of restitution and is particularly new to the sphere of class proceedings. The requisite nature of proof of the amount of the remedy relating to a claim based on waiver of tort is likewise an uncertain area of law. Significant matters of legal theory and policy issues must be considered which are best left to a full evidentiary record.

[27] Shortly after the parties in this proceeding appeared before the Divisional Court on February 22, 2008, the Honourable Justice Masuhara of the British Columbia Supreme Court released a decision, on May 6, 2008, concerning the doctrine of waiver of tort in the context of a class action: *Pro-Sys Consultants Ltd. v. Infineon Technologies AG et al.*, 2008 B.C.S.C. 575 ("Pro-Sys Consultants"). The defendants cite that decision to the effect that the doctrine of waiver of tort cannot be relied on to circumvent the requirement to demonstrate that the alleged wrongful conduct has given rise to harm on a class-wide basis.

[28] *Pro-Sys Consultants* is distinguishable from the case before us based on several factors. The specific facts of that case are not analogous to those involved in the present appeal. *Pro-Sys Consultants* involves an anti-competition claim on behalf of a class predominantly made up of indirect purchasers. Evidence was tendered in that case that the supply chain from the manufacturer of the product in question to the ultimate purchaser was long and multifaceted involving a complex series of relationships. The courts have taken a hard look at class actions involving anti-competition claims where the class includes indirect purchasers: *Chadha v. Bayer Inc.* (2001), 54 O.R. (3d) 520 (Div. Ct.), aff'd (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. refused (2003), 65 O.R. (3d) xvii; *Price v. Panasonic Canada Inc.* (2002), 22 C.P.C. (5th) 379 (Ont. S.C.J.); *Harmegnies c. Toyota*, 2007 QCCS 539, aff'd 2008 QCCA 380.

[29] More importantly, the Court in *Pro-Sys Consultants* rejected the plaintiffs' proposed common issues relating to waiver of tort in their entirety based on that Court's legal determination that "liability to a class....requires that the wrongful conduct actually impacted the class" (para. 149). Justice Masuhara held that proof of harm is a requisite element of liability in a claim based on waiver of tort. Moreover, he found that the plaintiffs failed to put forward a sufficient means of proving the issue of liability on a class-wide basis.

[30] The approach of Justice Masuhara can be contrasted with that adopted by this Court in *Serhan, supra*. As stated previously, in *Serhan*, in dismissing the appeal of the certification judge, Epstein J. emphasized that waiver of tort is an uncertain area of law, the requisite elements of which have yet to be determined in Ontario. She took particular account of the debate surrounding whether proof of loss is necessary for liability, without adopting a definitive position. Moreover, when the defendants in *Serhan* similarly relied on the British Columbia

Supreme Court judgment in *Reid v. Ford Motor Co.*, [2006] B.C.J. No. 993, wherein Gerow J. expressed concern about a cause of action that eliminates the requirement to prove loss, Epstein J. stated:

> I share this concern, but am of the view that it should be considered and resolved on the basis of a full record. (para. 67)

[31] Arguably, nothing the plaintiffs did or would have done mitigates the defendants' alleged wrongful conduct. If it were established that the defendants inadequately warned of the risks of the side effects of the drug so as to increase sales, there would be a live issue before the trial judge as to whether the defendants should disgorge all or part of the their profits, as well as whether the circumstances of individual class members requires consideration.

[32] In our view, the defendants' assertion in the proceeding before this Court mischaracterizes the embryonic nature of the waiver of tort doctrine. In certifying the pertinent common issue, above all, Cullity J. recognized the uncertain state of the law and the need for a full evidentiary record in order to make a proper determination. Indeed, Cullity J. stated at para. 101:

> I believe the question of causation **could** – as in *Serhan* – be dealt with in respect of the class as a whole. On this basis, and **in view of my findings with respect to the present state of the law governing waiver of tort**- and in particular the uncertainty relating to its application to the tort of negligence **as well as on the question of whether proof of loss is required**- I will include common issue [h] in any certification order. [emphasis added]

[33] The *CPA* provides a flexible mechanism for the common issues judge to modify the claim based on the evidence before him or her. In *Medtronic*, Hoy J. noted on this particular issue, as we do here that "it is open to the common issues judge to create a "waiver of tort" subclass, or even subclasses, crafted with regard to his or her findings as to the boundaries of the doctrine of waiver of tort and remedy of disgorgement, including the requisite causal link." It is also open to the common issues judge to decertify common issues where he or she sees fit.

[34] Finally, it is noted that Lederman J's observations as regards proof of the amount of wrongful gain relate uniquely to common issue (d), above, pertaining to the duty to warn. However, common issues (b)-(c) relate to the allegation of the drug's lack of fitness for the purpose for which it was manufactured and distributed. The asserted misconduct in this analysis is the defectiveness of the drug rather than the failure to warn. Leave to appeal common issues (b)-(c) was not granted. A common issues trial will have to determine whether the defendants negligently manufactured and distributed Zyprexa.

[35] Compliance with the regulations of Health Canada does not insulate drug manufacturers from claims based on a breach of common law. *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1984), 8 D.L.R. (4th) 373, 1984 CarswellOnt 95 (WL) (Ont. H.C.J.) at para. 73. It is to be noted

also that Health Canada makes its decisions as to approval of drugs and warnings in considerable part upon the basis of the information provided by the manufacturer.

[36] If the drug is found to be unfit for the purpose for which it was manufactured and distributed, there may not be any need to investigate the circumstances pursuant to which individual class members received the drug. The determination of this issue may not require any evidence from individual class members. The wrongful conduct of placing an unfit product on to the market may arguably sustain a restitutionary remedy based upon waiver of tort.

[37] We observe that the answer to the second issue (is a class proceeding the preferable procedure) as framed by Lederman J. is dependent upon how the first issue is answered. As stated above, the only necessary evidence with respect to waiver of tort may well be simply the wrongful conduct of the defendants. If such is the case, then a class action is evidently the preferable procedure for the determination of the defendants' liability with respect to waiver of tort.

[38] Nevertheless, a common issue may be answered differently after the evidence is given for one component of the class and differently for another component. For example, after a common issues trial a court could conclude that a warning after a specific year was appropriate but not before. In the event there are individual issues that factor into the determination of the quantum of the restitutionary disgorgement or constructive trust, such individual issues would not undermine the issue of the applicability of waiver of tort on a class wide basis.

[39] Justice Cullity recognized this in certifying the common issue related to waiver of tort, at para. 102:

> ...depending on the method of computation approved by the trial judge, a final decision on the amount of any liability to account might have to be deferred until individual issues have been decided, or at least, until the size of the class, or the number of claimants, has been determined.

[40] Restitutionary relief may be available in class proceedings even in the case where only a portion of the class are victims of the wrongful conduct. See *Markson v. M.B.N.A. Canada Bank*, 2007 ONCA 344 (CanLII). Subsections 24 (2) and (3) of the *CPA* afford the Court a flexible mechanism for receiving and resolving individual claims in order to give effect to an aggregate damages award. This mechanism could be utilized in dealing with individual claims where an aggregate award is based upon restitution rather than damages.

[41] If on a full evidentiary record, the trial judge were to find that proof of the amount of relief based in waiver of tort cannot be assessed in aggregate, a class action remains the preferable procedure. An aggregate award of damages is not a prerequisite for certification. If the other, unchallenged common issues related to the waiver of tort claim are resolved favourably, the proceeding will still have advanced the claims of the class as a whole. This is so particularly in consideration of s.25 of the *CPA* which confers broad jurisdiction on the common issues trial judge to develop procedures for individual participation in determining the allotment of relief. It

is not just the common issues trial which is to be considered in determining whether a class action is the preferable procedure. As stated succinctly by Winkler C.J. in *Cassano, supra*

> Therefore, what is called for in addressing the preferable procedure requirement is to look not just at the common issues trial, but at the other procedural options for conducting the class action litigation pursuant to the *CPA*. (at para. 64)

[42] An experienced class proceedings judge has found that there are plausible common issues in this proceeding and that a class action is the preferable procedure. Even if this Court were to apply the more stringent standard of review as enunciated by Chief Justice Winkler in *Cassano, supra*, it could not be said that the motion judge committed a legal error on a matter of central importance to a proper application of s.5 of the *CPA*. Justice Cullity's decision is both reflective of the state of the law on the doctrine of waiver of tort as well as the remedial purpose of the *CPA*.

Disposition

[43] For the reasons given, the appeal is dismissed. The certification of Cullity J. and all eight of the common issues as determined thereby remain intact.

[44] Given the relative novelty of the issues pertaining to waiver of tort in the context of class proceedings, it is our view that the costs of this appeal should be left to the discretion of the judge hearing the common issues trial. The parties in their submissions agreed that such disposition of the matter of costs would not be inappropriate irrespective of who might be successful in the appeal at hand.

FERRIER J.

CUMMING J.

ARCHIBALD J.

Released: July 2, 2008

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Plaintiffs

- and -

ELI LILLY & COMPANY AND ELI LILLY AND CANADA INC

Defendants

REASONS FOR DECISION

CUMMING J.

Released: July 2, 2008