CITATION: Andrea Heward v. Eli Lilly & Company, 2010 ONSC 3403
COURT FILE NO.: 05-CV-283309CP
DATE: 2010-06-11

ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:	
ANDREA HEWARD, ANDREW CHARLES HEWARD, KELLY HUTCHINS, DARLENE HUTCHINS, DANIEL WELLS and NANCY WELLS Plaintiff	*Harvin W. Pitch, Colin P. Stevenson* and *Michael Eizenga*, for the Plaintiffs
– and –	
ELI LILLY & COMPANY and ELI LILLY CANADA INC. Defendants	*David S. Morrit, Sonia L. Bsorkquist* and *Craig Lockwood*, for the Defendants *Scott C. Hutchinson*, for the Law Foundation of Ontario **HEARD:** June 8, 2010

REASONS FOR DECISION

CULLITY J.

[1] This proceeding is a consolidation of two actions commenced under the *Class Proceedings Act, 1992,* S.O. 1992, c. 6 ("CPA") in which the plaintiff sought to represent a primary class of persons who, being resident in Canada outside of British Columbia and Quebec, were prescribed and ingested the drug Zyprexa that was manufactured, marketed, sold or otherwise placed in the stream of commerce in Canada by the defendants. There is also a secondary class of family members with claims derivative of those of the primary class.

[2] In their pleading, the plaintiffs claimed damages for negligence and, in the alternative, a restitutionary remedy against the defendants in connection with the manufacture and sale of Zyprexa - an anti-psychotic medication developed by them. The drug was approved by Health Canada in 1996 as a prescription medication for the treatment of schizophrenia and related psychotic disorders. In 2003 and 2004 such approval was extended to the acute and maintenance treatment of bipolar disorders. Such approvals have not been withdrawn and Zyprexa is still marketed, distributed and prescribed across Canada.

[3] The plaintiffs did not dispute that Zyprexa is a very effective atypical anti-psychotic drug that has been, and still is, in widespread use. The substance of their claims is that, to the knowledge of the defendants, the use of the drug gives rise to a significantly increased risk of diabetes and a variety of related complaints including hyperglycemia, pancreatitis, other blood sugar disorders, weight gain and, in elderly patients, strokes. The plaintiffs allege that the defendants consistently failed to disclose to, or warn, Canadian patients and their physicians of these risks.

[4] Similar proceedings were commenced in Quebec and in British Columbia with classes restricted to residents of those jurisdictions. Plaintiffs' counsel in the three provinces co-ordinated their work and the settlement that has been reached is intended to apply to each of the cases. The proceedings in Quebec and Ontario have been certified. A motion for approval of the settlement is pending in Quebec and, in British Columbia, a motion to certify the proceeding in that province and to approve the settlement has been set down to be heard in the next two weeks. The settlement agreement is conditional on court approval in each of the three provinces.

[5] Certification in this court was strongly contested by the defendants and the hearing of the certification motion extended over four days. An appeal to the Divisional Court was subsequently dismissed and leave to appeal to the Court of Appeal was denied. The defendants then filed a statement of defence and an extensive affidavit of documents, and examinations for discovery of the defendants' representatives were conducted. The defendants have consistently denied the factual allegations on which the plaintiffs' claims are based. That is still their position.

The Settlement

[6] The settlement is intended to resolve all of the past, present and future claims of class members in the three proceedings. It is made with an express denial of any civil liability of the defendants. Conditionally on the dismissal of the three proceedings - and in return for releases of the claims - the defendants have agreed to pay a settlement amount (in US dollars) consisting of the following:

(a) $17,750,000 to eligible members of the primary class;

(b) $2,250,000 to Provincial Health Insurers;

(c) A maximum of $4,500,000 and $500,000 for Class Counsel's fees and disbursements respectively, these to be subject to the court's approval; and

(d) a maximum of $1,000,000 for notice and administration expenses.

[7] The amount of $17,750,000 is based on an estimate that there may be 1450 members of the primary class who are eligible to share in a settlement providing an average of $12,000 to each member. Eligible class members are those who make claims to a claims administrator to share in the settlement amount and who, have demonstrated that, having ingested Zyprexa for at least 90 days, were either subsequently diagnosed with diabetes or one or more other designated ailments within a specified time frame or, being previously diagnosed as diabetic, underwent a change of therapy.

[8] The estimate of 1450 claimants in the primary class was the subject of negotiation between the parties and was based, in part, on counsel's best information with respect to the number of members of that class. As the primary class extends to all persons who were prescribed and ingested the drug - and is not confined to those who suffered deleterious consequences - the number of eligible primary class members may be less than the members of the primary class.

[9] The settlement agreement provides that the payment of $17,750,000 is to be reduced, or augmented, by an amount of $6,120.69 for each eligible claimant below, or above, that number, as the case may be. In the event that there are more than 1450 eligible primary class members, the additional amount payable by the defendants is capped at $4,590,517.50.

[10] Although the amount of $17,750,000 is based on an average payment of $12,000 to each primary class member, the actual amount to be paid to each will vary according to a matrix that allocates points according to the relative seriousness of the illnesses suffered by each member. It also provides for additional payments to be allocated to those whose use of Zyprexa commenced in 2000 - 2003, the period in which class counsel is of the opinion that the case against the defendants is strongest.

[11] Members of the secondary class are to receive a specified percentage of the amount awarded to the eligible primary class member to whom they are related, with a cap of 20 per cent imposed.

[12] Important aspects of the payment schedule are, *first*, that irrespective of a shortfall in the estimate of 1450 eligible primary class members, the defendants have agreed to pay at least $8,875,000 for such members; and, *second*, that the payments to be made to claimants within the primary class in accordance with the matrix are not dependent on proof of a causal connection between the ingestion of Zyprexa and the onset or aggravation, of diabetes or other illnesses referred to in the matrix.

[13] The settlement agreement provides for a claims administrator and contains in schedule G detailed procedures for the receipt and processing of claims, and the supporting evidence required. Provision is made for the audit of claims by the administrator, and by the defendants, with any disputed claims, appeals and the administration process being subject to the supervision and appellate authority of the courts in whichever of the three provinces the claimant is resident. Interim payments are permitted in the event that a final distribution is postponed pending appeals on disputed claims.

[14] Finally, paragraphs 6 and 7 of the agreement contain provisions relating to the certification and opting out process in British Columbia; a conditional right of the defendants to terminate the settlement in respect of class members residing there if ten or more resident primary class members opt out; and rights of termination in the event that the settlement is not approved in all three jurisdictions.

Analysis

[15] The principles that should govern the court's decision to approve or refuse approval of a settlement agreement have been discussed in many cases and are now well established. The leading cases in this jurisdiction include: *Dabbs v. Sun Life Assurance Co.*, [1998] O.J. No. 1598 (G.D.), aff'd, (1998), 41 O.R. (3d) 97 (C.A.); *Parsons v. The Canadian Red Cross Society*, [1999] O.J. No. 3572 (S.C.J.); *Fraser v. Falconbridge Ltd.*, [2002] O.J. No. 2383 (S.C.J.); *Sutherland v. Boots Pharmaceutical PLC*, [2002] O.J. No. 1361 (S.C.J.) and *Fantl v. Transamerica Life Canada,* [2009] O.J. No. 3366 (S.C.J.).

[16] While the burden is on the party seeking approval - and the overriding consideration is whether it is fair and reasonable and in the best interests of the class members - a resolution of complex litigation through the compromise of claims is to be encouraged. In determining whether a settlement represents a reasonable compromise of the claims of class members, the court is to accept that there will usually be a range of reasonable alternatives.

[17] The court has no authority to amend, or attempt to renegotiate, a settlement and it has been said that there is a strong presumption of fairness when a proposed settlement is negotiated by experienced counsel acting at arm's length.

[18] The last of the factors just mentioned is, in my opinion, particularly relevant for the purposes of this motion. Throughout the case management process it has been apparent that the proceeding was conducted in accordance with high professional standards on each side. The legal and factual issues were complex and the case seemed destined to go to a long and expensive trial which - if the class was successful – might well have been followed by protracted and expensive procedures to dispose of individual issues of harm and causation

[19] I am quite satisfied that, in negotiating the terms of the settlement, class counsel approached their task at arm's length with defendant's counsel and with the right considerations in mind, and that they applied their best efforts to achieve a result that would be for the overall benefit of the class members. In short, this is a case in which I believe I am justified in attributing significant weight to class counsel's recommendation that the settlement should be accepted by their clients.

[20] In particular, I accept counsel's evaluation of the significant litigation risks for the class if the proceeding were to continue. These, and the expense and delay associated with a common issues trial and the individual proceedings that would likely have followed, will be avoided if the settlement is approved. As in other cases involving claims in respect of allegedly defective pharmaceutical products, medical devices or medical malpractice, delays can provide a significant impediment to access to justice by affected class members.

[21] The litigation risks involved in the trial of common issues related not only to the reasonableness of the defendant's conduct in dealing with Health Canada and in marketing the drug but, even more fundamentally, to the question whether a causal connection can be established between Zyprexa, diabetes and the other illnesses identified by the plaintiff.

[22] For the purpose of this motion, the defendants delivered an impressive affidavit of Dr Richard Williams who is the Dean of the schizophrenia program at the Royal Jubilee Hospital Victoria, British Columbia. As well as emphasising the benefits associated with the prescription and use of Zyprexa and the many individual factors that should affect its prescription for patients, Dr Williams was firmly of the view that:

> Based on the evidence available to date, including clinical trial data and retrospective epidemiological studies, and in view of the number of confounding factors, no conclusion can be made that Zyprexa causes hyperglycaemia or diabetes.

[23] As I have indicated, issues of general and specific causation have been avoided in determining eligibility to share in the settlement and in the distribution scheme that is proposed. This is one of the most attractive features of the settlement as it allows for a relatively simple and inexpensive administrative process when compared with claims-based procedures that have been approved in other cases.

[24] The claims administration process has been carefully designed to achieve fairness to clients in an efficient and inexpensive manner while preserving, and protecting, the interests of the defendants. The requirements for eligibility, and the appropriateness of the allocation of points in accordance with the matrix, have been reviewed and endorsed by Dr Rafael Cheung, an endocrinologist specialising in diabetes and other diabetes-related illnesses at the Windsor Regional Hospital.

[25] Class counsel's approval of the average payment of $12,000 per eligible primary class member was based largely on an approach that factored the litigation risks and the expense and delay of continuing the litigation against the range of damages awarded in this jurisdiction in personal injury cases. In my opinion, this – probably the most important aspect of the settlement in the eyes of the class members - falls well within the required zone of reasonableness. No objections were received from the class members and class counsel indicated that the reaction to the settlement of those they have been in contact with has been overwhelmingly positive.

[26] The provisions for termination appear to have been carefully considered and I do not find them to be unfair to the class members or otherwise unreasonable.

[27] In my judgment, the general features of the settlement merit approval.

[28] One of the important subsidiary aspects is the provision for giving notice to class members. The method of doing this and draft forms of notice are contained in schedules to the settlement agreement and require the approval of the court in each of the three provinces. The methods of giving notice are relatively extensive and will undoubtedly be expensive. In view of the claims-based process for making payments to class members, it is, of course, imperative for the notice program to be effective and to have as wide a reach as is practicable. I see no reason to question the adequacy of the proposed methods of providing notice. The contents of the notices could, however, benefit from some further consideration and a case conference in person or by telephone should be arranged for this purpose.

[29] In my opinion, further clarification is required with respect to the reporting obligations of the administrator and the supervision of the costs of administration. The documentation filed does not contain the terms of a proposed agreement with the administrator or any requirement for the administrator to report to class counsel or the court at the conclusion of administration. Nor is there any reference to the administrator's entitlement to be paid fees while the administration process continues.

[30] The amount of $1,000,000 to be provided by the defendants for administration costs may appear generous, but the expense of the notice program alone will be considerable. If the total costs of administration exceed $1,000,000, the excess is to reduce the amounts payable to the class members. In these circumstances, there should be some provision for a review of the claims administrator's accounts by class counsel with a requirement - or at least the possibility - of a motion to the court for directions. The selection of Crawford Class Actions Services as the claims administrator is otherwise approved.

[31] Finally, I should, and will, defer to the court in British Columbia on the approval of the provisions of paragraphs 6 and 7 of the settlement agreement that relate specifically to the application for certification in British Columbia and the procedure for, and consequences of, opting out of the action in that province if it is certified.

[32] Subject to that reservation, and to the resolution of the issues relating to the notices and the obligations of the claims administrator, there will be an order approving the settlement as requested. The order is to include the provisions requested by counsel for the Law Foundation of Ontario in respect of the levy payable to the foundation pursuant to O. Reg. 771/92.

Counsel fees

[33] Class counsel have brought a separate motion for approval of their fees. In my judgment it would be premature to deal with this motion in view of the possibility that, under the provisions of article 7 of the settlement agreement, it may be terminated in all jurisdictions if it is not approved in each of them. Accordingly, the motion with respect to legal fees will be deferred pending the outcome of the applications to approve the settlement in the courts of Quebec and British Columbia.

Cullity J.

Released: June 11, 2010