Court File No.: 98-CV-158832

### ONTARIO SUPERIOR COURT OF JUSTICE

BETWEEN:

#### SHELIA WILSON

Plaintiff

- and -

SERVIER CANADA INC., LES LABORATOIRES SERVIER, SERVIER AMERIQUE, INSTITUT DE RECHERCHES INTERNATIONALES SERVIER ("I.R.I.S"), SCIENCE UNION ET CIE, ORIL S.A., SERVIER S.A.S., ARTS ET TECHNIQUES DU PROGRES, BIOLOGIE SERVIER, INSTITUT DE DEVELOPEMENT ET DE RECHERCHE SERVIER, ORIL INDUSTRIE, BIO RECHERCHE SERVIER, INSTITUTO DI RICERCA, IDUX, BIOPHARMA ARTEM, SCIENCE UNION S.A.R.L., LABORATOIRES SERVIER INDUSTRIE, I.R.I.S. ET CIE DEVELOPEMENT, INFORMATION SERVIER, SERVIER MONDE, SERVIER INTERNATIONAL, I.R.I.S. SERVICES S.A.R.L., ADIR, SERVIER R&D BENELUX, DR. JACQUES SERVIER and BIOFARMA S.A.

Defendants

Proceeding under the Class Proceedings Act, 1992

# AFFIDAVIT OF ANNELIS K. THORSEN (Sworn September 16, 2004, in Support of a Motion for Settlement Approval)

I, ANNELIS K. THORSEN, of the City of Toronto, Province of Ontario, MAKE OATH AND SAY AS FOLLOWS:

I am an associate at the law firm of *Rochon Genova LLP*, solicitors for the representative Plaintiff herein and, as such, I have knowledge of the matters to which I hereinafter depose. Where any matters are stated to be based upon information and belief, I have

identified the source of that information and belief and I hereby confirm that I believe such facts to be true.

2. This affidavit is sworn in support of a motion for approval of a settlement reached between the Parties hereto. Attached as Exhibit "A" is a true copy of the Settlement Agreement.

#### The Proceedings and the Parties

- 3. I am advised by Joel Rochon, and believe, that he and Vincent Genova were originally retained by the representative Plaintiff, Mrs. Wilson in or about November 1998 to commence a class action on behalf of Canadians who had ingested one or both of the diet drugs Ponderal (generic name: fenfluramine) and Redux (generic name: dexfenfluramine) (collectively referred to as "the Products").
- 4. Mrs. Wilson resides in Toronto, Ontario with her husband, Robert Wilson. I am advised by Mrs. Wilson, and believe, that she was prescribed and ingested Ponderal between August 1995 and August 1996. In late 1996, she began experiencing shortness of breath, which became significantly worse by the summer of 1997. During the coming months, her condition continued to deteriorate and required numerous attendances on physicians. In February 1998, she was diagnosed with primary pulmonary hypertension ("PPH") by Dr. John Granton, a respirologist and the Director of the Pulmonary Hypertension Programme at the University Health Network in Toronto.

5. The Statement of Claim, through its various amendments, has named as Defendants a number of foreign corporations, a Canadian subsidiary and the founder of most of the corporations.

## Background: PPH, VHD and the Products

- 6. PPH is a rare, progressive, incurable and fatal respiratory disease. A more detailed discussion of the etiology, diagnosis, treatment options and prognosis for PPH will be contained in an affidavit from Dr. John Granton which will be filed in support of the within motion.
- 7. Valvular heart disease ("VHD") is a generally progressive disease involving the failure of one or more of the valves of the heart to open or close properly. A more detailed discussion about the diagnosis, treatment options and prognosis of VHD will be contained in an affidavit from Dr. Stephen Raskin which will be filed in support of the within motion.
- 8. The Products belong to a class of drugs known as anorexigens which are generally used as appetite suppressants to assist with weight loss. Suggestions of a possible association between the Products and PPH began being reported in the scientific literature in the 1980's. A more detailed review of this literature and the findings contained therein will be contained in Dr. John Granton's affidavit.
- 9. The association between the Products and VHD first appeared in the medical and scientific literature in August 1997 as a result of a case series published in the New

England Journal of Medicine. A more detailed review of the relevant literature and those scientific findings will be contained in Dr. Stephen Raskin's affidavit.

10. The Products were withdrawn from the Canadian market and other markets around the world in September 1997.

## Procedural History

- The Statement of Claim in this action was issued on November 17, 1998 and named Mrs. Wilson as the representative Plaintiff and Servier Canada Inc. ("Servier") and Biofarma S.A. ("Biofarma") as Defendants. Servier was the Canadian distributor of the Products and Biofarma is the French parent corporation of Servier. The Claim alleged that the Products increased the risk of developing PPH and VHD and, among other things, that the Defendants failed to adequately disclose these risks to Canadian physicians and Canadian consumers.
- 12. The claim was subsequently amended several times and ultimately named as Defendants several foreign corporations affiliated with Biofarma as well as the founder of most of these closely held corporations, Dr. Jacques Servier. Attached hereto at Exhibit "B" is a copy of the Fresh as Amended Statement of Claim which identifies all Parties to this litigation.
- 13. The certification motion in this matter was heard over the course of six days in May and July of 2000. In reasons released September 13, 2000, the motion was granted and the Class was defined as follows:

All persons resident in Canada (excluding Quebec) who were prescribed and ingested the diet drugs marketed under the brand name Ponderal (generic name: fenfluramine) and/or Redux (generic name: dexfenfluramine), these being diet drugs designed, developed, fabricated, manufactured, imported, distributed, marketed, sold or otherwise placed into the stream of commerce in Canada by Servier Canada Inc. and/or Biofarma S.A.

All persons including but not limited to, executors, administrators, personal representatives, spouses and relatives who on account of a relationship to those persons described in the above defined class, have a derivative claim for damages resulting from the treatment with Ponderal and/or Redux.

- 14. The following eight common issues were certified by the Court:
  - a. Whether Ponderal and/or Redux can cause primary pulmonary hypertension ("PPH"), valvular heart disease ("VHD") or valvular regurgitation;
  - b. Whether Ponderal and/or Redux are defective or unfit for the purpose for which they were 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. Whether the Defendants knowingly, recklessly, or negligently breached a duty to warn or materially misrepresented any of the risks of harm from Ponderal or Redux;
  - d. Whether Biofarma is responsible in law for the acts of Servier in respect of the sale and marketing of Ponderal and Redux in Canada;
  - e. Whether the Defendants negligently misrepresented the safety of the drugs after having received information as to the potential of the drugs to cause serious health effects;
  - f. Whether Class Members are entitled to special damages for medical costs incurred in the screening, diagnosis and treatment of diseases related to Ponderal and Redux;
  - g. Whether Class Members are entitled to equitable relief whereby they are reimbursed for the purchase price of Ponderal or Redux; and
  - h. Whether the Class Members are entitled to aggravated or punitive damages.

- 15. Prior to and following certification, voluminous documentary production was made by the various Defendant corporations. In addition, the proceeding involved at least forty-five days of discovery, conducted in Canada, France and Belgium.
- 16. This case also involved an extraordinary number of pre-trial motions and related appeals.

  Based on my review of the applicable caselaw, it is my understanding that this case has involved more reported motions than any other Canadian class proceeding to date. In addition to all the numerous formal and informal case conferences with the Honourable Mr. Justice Cumming, there were at least thirty-five motions and fifteen stay and leave applications and related appeals. A complete chronology of the various proceedings is included as an exhibit to my affidavit sworn in support of the fee approval motion.

## Mediation and Agreement in Principle

- 17. The common issues trial was scheduled to commence on February 24, 2003. Beginning on January 27, 2003, the Parties attended a court-ordered mediation under the supervision of the Honourable Mr. Justice Warren K. Winkler ("Justice Winkler").
- 18. The formal mediation took place over the course of four days in Toronto. In attendance on the Plaintiff's side were Joel Rochon and Vincent Genova of *Rochon Genova* for the National Class, our colleagues Robert Lieff and Paulina do Amaral from the American firm of *Lieff, Cabraser, Heimann, & Bernstein ("Lieff Cabraser")*, who provided valuable insights gained through their experience playing a key role in the United States' litigation involving the same medications, together with David Klein, Gary Smith and Dana Graves for the British Columbia subclass.

- 19. Following the formal mediation, the Parties agreed to enter into an agreement in principle to settle the case. As a result of the lengthy discussions, over the following weeks, the agreement in principle was reduced to writing on February 21, 2003.
- 20. The agreement in principle provided the broad framework for the settlement, however, the majority of the specific and essential terms of the settlement remained to be articulated and agreed upon. As part of the agreement in principle, it was agreed that, in the event that the Parties were unable to reach consensus, such matters would be submitted to Justice Winkler for a final determination.
- In addition to the within proceeding, two parallel class actions had been initiated in Quebec. I am advised by Joel Rochon, and believe, that he met with Class Counsel in the Quebec proceedings, and facilitated the process whereby they entered into a parallel agreement in principle with the Defendants. Thereafter, it was agreed that Class Counsel in the Quebec actions would participate in the negotiation of the specific terms of the settlement as well.
- 22. The Parties then began to draft the Settlement Agreement and related documents.

  Because there were many significant issues over which the Parties disagreed, Justice
  Winkler appointed Mr. Randy Bennett to serve as Court-Appointed Monitor, to facilitate
  the resolution of these disputes.
- 23. After numerous negotiation sessions between the summer of 2003 and September 2004, and after the exchange of a multitude of different drafts of the various settlement documents, the Parties were able to arrive at final versions of the necessary settlement documents.

#### The Settlement Agreement

24. The Settlement Agreement was executed by all Parties on June 24, 2004 and was held in escrow, pending the finalization of the exhibits to the Settlement Agreement. As a result of changes to the content of the exhibits, the Settlement Agreement was also modified.

## (a) Settlement Fund and Additional Settlement Funds

- 25. The Settlement Agreement provides initially for the payment by the Servier of a Settlement Fund of \$25 million for the payment of benefits to Claimants who satisfy the eligibility criteria under the settlement. In addition to the Settlement Fund, the Settlement Agreement requires that Servier post a letter of credit in the amount of \$15 million ("the Additional Settlement Funds"), which will be made available if required, in the event that the Settlement Fund is insufficient to satisfy the claims made by Class Members, the payment to be made to the provincial and territorial health authorities as discussed below, and Court-approved Class Counsel fees.
- 26. Payment of \$1,000,000.00 will be made from the Settlement Fund to the various provincial and territorial health authorities in satisfaction of their subrogated claims. This payment will be allocated among the provinces and territories according to an agreement reached among their representatives. In addition, if funds remain in the Settlement Fund at the end of the Administration Period and following the payment of all other possible amounts from the Settlement Fund, the public health insurers are entitled to a share of such remaining funds. The proportional division of this remainder will be calculated as provided for in section 9(c) of the Settlement Agreement.

- \$3,000,000.00 of the Settlement Fund will be notionally allocated by the Settlement Administrator and will be used to pay eligible FDA Positive Benefits, as discussed further below. The value of an individual FDA Positive Benefit is \$2,500.00, subject to a possible pro-rata reduction, in the event that the total amount required to pay all eligible FDA Positive Benefits exceeds \$3,000,000.00.
- 28. In addition to the payment of partial indemnity costs pursuant to the Settlement Agreement, of \$3,000,000.00 plus \$1,000,000.00 for disbursements, and in addition to the interim partial indemnity costs awarded and paid during the currency of the litigation, Class Counsel will seek payment of their solicitor and client fees from the Settlement Fund and Additional Settlement Funds, if necessary. The materials filed in support of the motion for fee approval specifically articulate the grounds for the application.
- 29. Class Counsel will make application for approval of their solicitor and client fees in the amount of \$10 million plus applicable taxes and disbursements based on the docketed time of *Rochon Genova*, *Lieff Cabraser* and *Klein Lyons* to date.
- 30. A further application for fees may be brought by Class Counsel at the conclusion of the Claim Period, if it appears that there will be sufficient funds remaining. In the event that such an application is brought, Class Counsel will seek no more than an additional \$5 million, plus applicable taxes.

#### (b) Notice and Administration Costs

31. Separate and apart from the Settlement Fund and the Additional Settlement Funds, the Settlement Agreement requires that the reasonable costs of the notice programmes and the costs of settlement administration will be paid by Servier. In order to secure payment

of these costs, Servier will initially be required to post a letter of credit in the amount of \$1,500,000.00. If, at the close of the Claim Period, this amount is insufficient to pay these costs, direction may be sought from Justice Winkler.

The notice programme relating to the approval hearing was designed by Jennifer Dewar of *Dewar Communications* and was approved by Mr. Justice Cumming, at a cost of approximately \$147,840,00. A further notice programme, should court approval of the settlement be granted, will also be funded by Servier at a cost of approximately \$300,000.00. Attached hereto at Exhibit "C" is a copy of Ms. Dewar's curriculum vitae. The Preliminary Approval Notice and Notice Plan are attached to the Settlement Agreement at Exhibit "A" and the draft Approval Notice and the Approval Notice Plan are attached at Exhibit "B" to the Settlement Agreement.

# (c) Appointment of Settlement Administrator

- 33. The Parties propose that Crawford Class Action Services ("Crawford") be appointed as the Settlement Administrator, given its experience and prominence in administering class action settlements in Canada. Crawford has significant staffing in both English and French and is well-suited to administering this settlement.
- 34. Every effort has been made to design a claims process which is as straightforward and efficient as possible, given the complex nature of the claims. In that regard, we endeavoured to create notices, instructions to Claimants and the Claim Package so that they can be easily understood and completed. Additional information and assistance will be made available both by Crawford and Class Counsel to any potential Claimant who requires it. All such information will be made available through websites and toll-free

telephone numbers and will be provided in both English and French. If, during the course of administering the settlement, it becomes apparent that modifications or adjustments are required, it will be possible to seek directions from Justice Winkler.

#### (d) Appointment of Roster of Claims Adjudicators

35. The Settlement Agreement also provides that a roster of Canadian physicians with the requisite medical expertise will be retained to act as Claims Adjudicators. The Claims Adjudicators will be required to determine whether Claimants are entitled to benefits under the Settlement Agreement, based on their review of the Claim Package and related medical records. The remuneration for the Claims Adjudicators will be considered an administration cost that will not be deducted from the Settlement Fund or Additional Settlement Funds.

## (e) Challenge Provisions – Justice Winkler

- 36. The Settlement Agreement and Claims Administration Procedures (Exhibit "D" to the Settlement Agreement) allow for decisions at various stages in the claims administration process to be challenged by a Claimant. The challenge provisions under the Settlement Agreement were designed to protect against the improper and unintended exclusion of legitimate claims.
- 37. The challenge process will be conducted in writing with a view to maximizing efficiency and the timely resolution of any disputed decisions. Justice Winkler has agreed to hear all such challenges. The Claims Administration Procedures set out the bases for a Challenge, the materials to be relied upon as well as the timelines for bringing Challenges and for the rendering of decisions on a Challenge. Generally speaking, a Challenge is

permitted with respect to any final determination regarding a Claimant's eligibility for benefits.

# (f) Claim Period and Administration Period

- 38. The Settlement Agreement provides that, after final court approval, Class Members will have a period of fifteen months within which to submit a claim to the Settlement Administrator pursuant to the procedures articulated in Exhibit "D" and more particularly detailed below. This Claim Period will serve as a form of registration period, and will facilitate the process of determining the timing and quantum of payments for Compensable Claims.
- After the expiry of the Claim Period, there will be a five year period during which all claims will be processed ("the Administration Period"). During the Administration Period, Product Recipients whose disease severity has worsened ("Progressed Claims") or who have new evidence on pathology ("New Pathology Evidence Claims"), may advance further claims.
- 40. In the event that the Settlement Administrator determines that a Class Member has submitted a claim after the expiry of the Claim Period but within the Administration Period, the claim will be rejected. However, such a Claimant will have the ability to challenge the rejection and have his or her claim adjudicated if Justice Winkler determines that the claim should be properly considered.

### (g) Eligibility and Diagnostic Criteria

41. Among the issues discussed in the negotiation of the Settlement Agreement were the appropriate eligibility and diagnostic criteria for VHD and PPH claims. In this regard, several medical experts, including Dr. John Granton, Dr. Stephen Raskin, Dr. Harold Rakowski and Dr. Allan Sniderman, were involved in drafting the Medical Conditions List ("MCL"). These experts participated in multiple meetings, both in person and by conference call, with Class Counsel, *Lieff Cabraser*, defence counsel and the Court-Appointed Monitor with a view to ensuring that the MCL was medically sound.

#### (i) VHD Claims

- 42. With respect to Product Recipients who suffer from VHD, the MCL and the Claims Administration Procedures stipulate specific eligibility criteria for benefits for a range of levels of disease severity.
- 43. As noted above, one level of benefit under the Settlement Agreement is for FDA Positive valvular regurgitation. This level of VHD is defined in accordance with medically appropriate diagnostic parameters.
- 44. Further, Product Recipients who qualify for an FDA Positive or greater VHD benefit and whose VHD worsens during the Administration Period can submit a Progressed Claim.

  A more detailed explanation of the diagnostic criteria for FDA Positive or higher level VHD claims will be included in the affidavit from Dr. Stephen Raskin.
- 45. In addition to benefits for FDA Positive valvular regurgitation, the settlement provides for benefits according to a matrix which identifies varying levels of VHD severity. The

specific medical conditions and the diagnostic criteria applied in the MCL for Matrix level VHD claims were the source of extensive negotiation and discussion among the experts, including Dr. Stephen Raskin, and reflect medically appropriate standards. A more complete discussion of this issue and the scientific bases for the disease levels in the matrix will be contained in the affidavit from Dr. Stephen Raskin.

46. The settlement also provides for the possibility that Claimants whose claims were rejected may submit a further claim based on new evidence of valve pathology which was not available at the time of the initial claim.

# (ii) PPH Claims

With respect to Product Recipients with PPH, the MCL articulates a diagnostic algorithm.

The approach taken to establishing the eligibility criteria for Product Recipients with PPH was based on the relevant medical literature and was also informed by Dr. John Granton's extensive clinical experience. A more detailed analysis of the diagnostic algorithm will be contained in Dr. John Granton's affidavit.

#### (h) Claim Package

48. In order to be eligible for benefits under the Settlement Agreement, Claimants are required to submit a Claim Package to the Settlement Administrator within the Claim Period. The Claim Package includes a Claim Form and Medical Diagnosis Form along with instructions.

## (i) Claim Form

49. The Claim Form will be attached to the Settlement Agreement as Exhibit "G" and will be

designed with a view towards efficiency and accessibility to Class Members. The information required in the form will also facilitate the processing of the claim by the Settlement Administrator.

The Claim Form requires the submission of "Product Identification Documentation".

Claimants are required to adduce evidence that the Product Recipient was prescribed with and ingested the Products. The specific requirements are articulated in both the form and the Claims Administration Procedures.

## (ii) Medical Diagnosis Form

- The Medical Diagnosis Form is to be completed by a qualified physician as defined in Exhibit "E". In order to avoid confusion and to streamline the process, the Form has three separate sections, depending on the injury which forms the basis of the claim.

  There is therefore an FDA Positive Form, a Matrix VHD Form and a PPH Form.
- Supporting Medical Documentation must be submitted with the Medical Diagnosis Form.

  The specific nature of the documentation required varies with the injury which forms the basis of the claim.
- 53. The first \$500.00 in costs incurred by a Claimant in obtaining this documentation will be borne by the Claimant. Amounts between \$500.00 and \$2,500.00 will be paid as costs of the administration of the settlement for successful claims. Amounts in excess of \$2,500.00 will also be paid as costs of the administration of the settlement, in cases where such costs are determined by the Settlement Administrator to be reasonably necessary for the Claimant to be able to advance his or her claim. These administration costs will not be drawn from the Settlement Fund or the Additional Settlement Funds.

### (i) Compensation Levels

- 54. With respect to the quantification of benefit levels under the settlement agreement, a number of factors were considered, including prior settlement values, relevant and applicable case law, the estimated take-up rate under this settlement and the litigation risks. In consideration of all of these factors, the benefit levels provided for under this settlement are reasonable, and will provide meaningful compensation to Product Recipients who have sustained varying levels of injury.
- The compensation values for Matrix level benefits are incorporated into the Matrix Grid (attached as Exhibit "F" to the Settlement Agreement) and vary based on the level of disease severity and the Product Recipient's age at diagnosis. The Matrix Grid provides for supplementary benefits for PPH claims and for VHD claims approved at Matrix Level V in certain circumstances.

# (j) Derivative Claims

- With respect to those Class Members asserting claims which are derivative to the claims of Product Recipients, the approach taken was based on an effort to provide fair and appropriate benefits to the derivative Claimants and to recognize that this type of claim in most jurisdictions is based on the loss of care, guidance and companionship of the Product Recipient.
- 57. In this regard, no derivative claims will be compensated in relation to FDA Positive or Matrix Level I claims. The rationale for this exclusion is based on the fact that Product Recipients with these levels of injury are generally asymptomatic and therefore there is no corresponding compensable loss of care, guidance or companionship.

- 58. Where an injured Class Member is entitled to a Matrix benefit at level II, Eligible Derivative Claimants will be entitled to a maximum benefit of \$1,000.00, and where an injured Class Member is entitled to a benefit for PPH or at Matrix level III or higher, Eligible Derivative Claimants will be entitled to a maximum benefit of \$10,000.00, subject to the potential for a *pro rata* reduction dependent on the total value of approved Derivative claims.
- 59. Based on a review of other Canadian class action settlements as they relate to the compensation of derivative claims, I believe that this approach is fair and in line with the current jurisprudence on the subject.

# (k) Class Size – Estimated Payout

- I am advised by Joel Rochon, and believe, that based on a review of the IMS data previously disclosed by the Defendants during the course of the litigation, the total size of the Class as defined in the certification order is estimated to be approximately 160,000 members. This number includes all individuals in Canada who consumed the Products, regardless of whether any injury was sustained.
- 61. Since the inception of this lawsuit, my firm has maintained a database of Class Members.

  I am advised by Allison Phillips, a law clerk at *Rochon Genova*, and believe, that the total number of such Class Members who have contacted our firm is 886. Of that number, 126 have provided my firm with information regarding injuries they believe they have sustained as a result of their ingestion of the Products.
- With a view to estimating the number of known Class Members who will receive benefits under the Settlement Agreement, the database was reviewed in detail. According to the

information known to National Class Counsel relating to the 126 Class Members and the applicable provisions of the MCL and the Matrix Grid, we estimate that, based on our initial review, 69 of these Class Members have provided medical information which has allowed us to estimate the level at which each might qualify for benefits. Of those 69 Class Members, the information we have indicates that 27 might qualify for FDA Positive benefits and the remaining 42 may qualify for Matrix-level benefits (either VHD or PPH). The information provided by the other 57 Class Members is insufficient to determine whether or not they will be eligible for benefits under the settlement.

- 63. There are several factors which could change the number of the claims entitled to benefits, including the possibility that more of the 760 Class Members will supply information after the settlement is approved which will substantiate a claim. Further, among those who are believed to have Compensable Claims, it is possible that their disease severity will have increased, giving rise to a higher benefit level.
- 64. Finally, it is anticipated that there will be Class Members who are not currently known to Class Counsel but who have a Compensable Claim and who will come forward following approval of the settlement and publication of the Approval Notice.
- On the other hand, it is also possible that some of the 69 claims will be denied based the presence of additional medical factors which, pursuant to the Settlement Agreement, would preclude recovery.

# (I) Payment Schedule

The Settlement Administrator will seek directions from Justice Winkler at the end of the Claim Period with respect to the distribution of the FDA Positive Fund.

- 67. With respect to the payment of Matrix Benefits, the Claims Administration Procedures requires that the Settlement Administrator forward 20% of the maximum approved benefit amount within thirty days of a Claimant's acceptance of the approved claim.
- 68. The Claims Administration Procedures also provide that Class Counsel may bring a motion no earlier than three months following the Approval Notice Date with respect to whether and in what amounts additional advance payments may be made on approved Matrix claims. All advance payments are to be deducted from the total benefit amount payable to a given Claimant.
- 69. Further, the Claims Administration Procedures require that Class Counsel bring a motion within thirty days after the expiry of the Claim Period for directions relating to the payment of remaining entitlements for approved claims.

# Recommendation of Settlement Agreement

#### (a) Class Counsel

Rochon Genova LLP is a nine-lawyer firm which focuses on class action litigation and is lead counsel on several class action proceedings including Coleman et al. v. Bayer Inc. et al., a product liability action involving the cholesterol-lowering drug Baycol. Rochon Genova LLP has successfully prosecuted that case to settlement and the settlement agreement has been recently approved by Mr. Justice Cullity of the Ontario Superior Court of Justice. I am advised by Joel Rochon, and believe, that the two principals of the firm have collectively some 31 years of experience in prosecuting personal injury cases and class action litigation.

- 71. Our firm is also class counsel in litigation involving other defective pharmaceutical products, securities litigation and institutional abuse.
- 72. Rochon Genova LLP has developed a close association with the American firm of Lieff Cabraser which has extensive experience prosecuting class action litigation and is very familiar with the within litigation and medical issues relating to the Products, through their involvement in the U.S. settlement with American Home Products, as noted above. Elizabeth J. Cabraser served on the Plaintiff Management Committee for the National Class in the United States and Donald Arbitblit played a central role on the Science Committee. To date, Lieff Cabraser has settled scores of claims stemming from the use of these medications for tens of millions of dollars.
- 73. Through this association, we were able to obtain valuable insights into the relevant medical and scientific issues, including the process of identifying and retaining leading experts in the field of VHD, PPH and pharmacovigilence.
- 74. In addition, as noted above, our colleagues from *Lieff Cabraser* particularly Robert Lieff, Elizabeth Cabraser, Paulina do Amaral, Donald Arbitblit and Fabrice Vincent were directly involved in the settlement discussions. In addition, Paulina do Amaral was in attendance either in person or by conference call for most negotiation sessions and virtually all Class Counsel caucus session.
- 75. Class Counsel and the team which was formed for the purpose of representing Class Members in this litigation as described above, together with Class Counsel for the British Columbia subclass, were in a position to properly represent the interests of Class Members through the litigation and negotiation phases of this matter.

# (b) Arm's Length Negotiations – Recommendation of Neutral Parties

- 76. As noted above, all terms of this settlement were negotiated at arm's length, in an adversarial context and under the supervision of Justice Winkler, a neutral party in the process with significant experience in negotiating class action settlements.
- 77. The negotiations subsequent to the agreement in principle were also of a highly adversarial nature and required the assistance of the medical experts and the Court-Appointed Monitor, Randy Bennett, without which, the final settlement may not have been achieved.
- 78. In my view, the positions taken by the Parties and the time and effort required to arrive at a settlement amply demonstrate the arm's length nature of the negotiations as well as a complete absence of collusion between the Parties in arriving at the terms of the settlement.

# (c) Duration of Litigation Without Settlement – Related Delay and Expense

- 79. It is further my view that given the history of this litigation, which is more particularly detailed in the affidavit I have sworn in support of the fee approval hearing, if the Parties had not succeeded in reaching this settlement and the matter was required to proceed to trial, the delay and expense occasioned by the trial and appeals process could have been extraordinary.
- 80. If the settlement is not approved, Class Counsel will have to conduct a further round of examinations for discovery of Defendants added in the last amendment to the Statement

- of Claim, including Dr. Jacques Servier. Additional documentary productions will likely be made, necessitating further review by Class Counsel.
- The common issues trial has not been rescheduled, but if the settlement is not approved, the trial would not likely be heard before the Spring of 2005 at the earliest. It has been estimated that such a trial would take six months at a minimum. In contemplating such a trial, we expected that the Defendants would raise, *inter alia*, the following substantive and procedural defences, arguing that:
  - the limitation periods for many Class Members have expired;
  - there is no causal link between the ingestion of the Products and the development of VHD and/or PPH;
  - Class Members would have ingested the Products even if they had received adequate warnings about the potential health risks;
  - Class Members did receive adequate warnings of the potential health risks associated with the Products;
  - any risks of ingesting the Products were outweighed by the benefits of taking the Products;
  - Class Members' injuries pre-dated their use of the Products and/or their injuries resulted from other causes/medical conditions;
  - the Defendants complied with all applicable regulatory standards;
  - prescribing physicians were responsible for warning their patients about any potential risks associated with the Products (learned intermediary defences);
  - the Ontario Court lacks jurisdiction to hear the case.
- 82. In the event of a successful ruling for the representative Plaintiff on the common issues trial, it is highly likely that the Defendants would have sought to appeal, resulting in further delay and expense.

83. Further, upon resolution of the common issues trial and any related appeals, assuming success to the representative Plaintiff, the process of adjudicating individual Class Members' damages would have required a mini-trial process for each claim, causing yet further delay and expense for all Parties.

# (d) Mrs. Wilson's Approval of the Settlement

- Mrs. and Mr. Wilson have been actively involved in this litigation from the beginning.

  With respect to the process of arriving at the settlement, Mrs. and Mr. Wilson attended a portion of the mediation conducted in January 2003 and have remained in regular contact with my firm in relation to the progress of the negotiations.
- 85. I am advised by Joel Rochon, and believe, that Mrs. Wilson has been advised of the terms and conditions of the Settlement Agreement and has provided her instructions to enter into the settlement on her own behalf and on behalf of the Class. An affidavit sworn by Mrs. Wilson in support of the settlement has been filed in the within motion.

#### Conclusion

- 86. There is tremendous value to the Class in terms of the certainty that a settlement can provide. This certainty is particularly valuable when contrasted with the litigation risks noted above, as well as the significant time and financial expenditures which would be inevitable in a case such as this.
- 87. In summary, I believe that this Settlement Agreement is reasonable and provides fair and valuable compensation to Class Members. The process by which the settlement was achieved was at all times arms-length and adversarial in nature. At various times, the

Parties took conflicting views which, had they not been resolved, would have resulted in termination of the negotiations or a lengthy arbitration. The settlement fulfils the objectives of the *Class Proceedings Act* and I am advised by all Class Counsel, and believe, that they have no hesitation in recommending its approval by this Honourable Court.

88. I make this affidavit in support of a motion for approval of the Settlement Agreement, and for no other or improper purpose.

of Toronto, in the Province of Ontario, this 6 day of September, 2004.

A Commissioner for Taking Affidavits

Annelis K. Thorsen