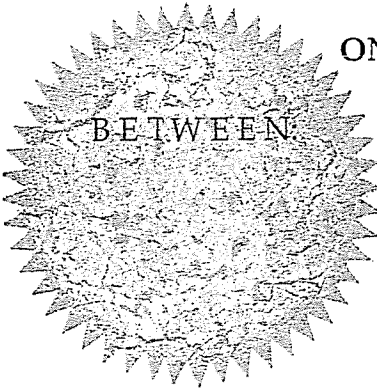


ONTARIO COURT (GENERAL DIVISION)



BETWEEN

SHEILA 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

AMENDED PLEADING  
 THE COURT  
 THE HON.  
 Mr. Justice Cunningham  
 DATED September 11, 2002  
 E  
 DATE Sept 30, 2002  
 LOCAL REGISTRAR

MODIFIÉ CONFORMÉMENT  
 L'ORDONNANCE  
 DU JUGE.

Brought under the Class Proceedings Act, 1992

FRESH AS AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Plaintiff. The Claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a Statement of Defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the Plaintiff's lawyer or, where the Plaintiff does not have a lawyer, serve it on the Plaintiff, and file it,

with proof of service, in this Court office, WITHIN TWENTY DAYS after this Statement of Claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your Statement of Defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a Statement of Defence, you may serve and file a Notice of Intent to Defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your Statement of Defence.

**IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT WILL BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.**

**IF YOU PAY THE PLAINTIFF'S CLAIM, and \$10,000.00 for costs, within the time for serving and filing your Statement of Defence, you may move to have this proceeding dismissed by the court. If you believe the amount claimed for costs is excessive, you may pay the Plaintiff's claim and \$100.00 for costs and have the costs assessed by the court.**

Date of Issue: November 17, 1998 Issued by: Y. Grant  
Local Registrar

Address of court office:  
Court House  
393 University Avenue  
Toronto, Ontario  
M5G 1W9  
Y-E

TO: Servier Canada Inc.  
235 Armand Frappier Boulevard  
Laval, Quebec  
H7V 4A7

AND TO: Biofarma S.A.

22 Rue Garnier  
92200 Neuilly Sur Seine  
France

AND TO: Les Laboratoires Servier  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: Servier Amerique  
22 rue Garnier B.P. 110  
92200 Neuilly-sur-Seine  
France

AND TO: Institut De Recherches Internationales Servier ("I.R.I.S.")  
6 Place des Pleiades  
92415 Courbevoie  
France

AND TO: Science Union et Cie  
14 rue du Val D'Or  
Suresnes  
France

AND TO: ORIL S.A.  
192 avenue Charles  
92200 Neuilly-sur-Seine  
France

AND TO: SERVIER S.A.S.  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: ARTS ET TECHNIQUES DU PROGRES  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: BIOLOGIE SERVIER  
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92200 Neuilly-sur-Seine  
France

AND TO: INSTITUT DE DEVELOPEMENT ET DE RECHERCHE SERVIER  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: ORIL INDUSTRIE  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: BIO RECHERCHE SERVIER  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: ISTITUTO DI RICERCA  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: IDUX  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: BIOPHARMA  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: ARTEM  
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92200 Neuilly-sur-Seine  
France

AND TO: SCIENCE UNION S.A.R.L.  
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92200 Neuilly-sur-Seine  
France

AND TO: LABORATOIRES SERVIER INDUSTRIE  
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92200 Neuilly-sur-Seine  
France

AND TO: I.R.I.S. ET CIE DEVELOPEMENT  
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France

AND TO: INFORMATION SERVIER  
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France

AND TO: SERVIER MONDE  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: SERVIER INTERNATIONAL  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: I.R.I.S. SERVICES S.A.R.L.  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: ADIR  
22 rue Garnier  
92200 Neuilly-sur-Seine  
France

AND TO: SERVIER R&D BENELUX  
Bd. E. Bockstael 93  
B-1020  
Brussels, Belgium

AND TO: DR. JACQUES SERVIER  
4 RUE DELEAU  
NEUILLY SUR SEINE  
FRANCE

## CLAIM

1. The Plaintiff claims:
  - (a) an Order certifying this proceeding as a class proceeding and appointing Sheila Wilson as Representative Plaintiff;
  - (b) compensatory damages, including aggravated damages or other monetary relief in the sum of \$500 million;
  - (c) damages for rescission on the purchase price of Ponderal and Redux in the sum of \$200 million;
  - (d) special damages for medical expenses in the diagnosis and treatment of diseases related to the taking of Ponderal or Redux
  - (e) punitive and exemplary damages in the sum of \$250 million;
  - (f) pre-judgment and post-judgment interest in accordance with the provisions of the Courts of Justice Act, R.S.O. 1990, c. C.43, as amended;
  - (g) the costs of this action and GST thereon on a solicitor and client basis;
  - (h) such further and other relief as this Honourable Court may deem just.

## The Parties

2. The Plaintiff, Sheila Wilson ("Wilson"), resides in the City of Toronto.

3. The Defendant, Servier Canada Inc. ("Servier Canada"), is a corporate body incorporated pursuant to the laws of Canada with its head office at 235 Boulevard Armand Frappier, Laval, Quebec. Servier Canada is the Canadian agent of Biofarma and distributor of a prescription drug known as Ponderal (Fenfluramine HCL).

4. The Defendant, Biofarma S.A. ("Biofarma"), is a corporate body incorporated pursuant to the laws of France, with its head office at 22 Rue Garnier, 92200 Neuilly Sur Seine, France. Servier Canada is a wholly owned subsidiary of Biofarma. Servier Canada and Biofarma market Ponderal as a joint venture in Canada for their mutual profit.

5. Servier Canada is one of a cluster of closely held private corporations based in France, Canada and the United States. Details with respect to this corporate cluster will be outlined below.

5.1 The Defendant, Les Laboratoires Servier ("LLS") is a corporate body incorporated pursuant to the laws of France, with its head office at 22 rue Garnier, 92200 Neuilly-sur-Seine, France.

5.2 The Defendant, Servier Amerique is a corporated body incorporated pursuant to the laws of France with its head office at 22 rue Garnier, 92200 Neuilly-sur-Seine, France.

5.3 The Defendant, Institut de Recherches Internationales Servier ("I.R.I.S.") is a corporate body incorporated pursuant to the laws of France with its head office at 6 Place des Pleiades, 92415 Courbevoie, France.

5.4 The Defendant, Science Union et Cie, is a corporate body incorporated pursuant to the laws of France with its head office at 14 rue du Val D'Or, Suresnes, France.

5.5 The Defendant, Oril S.A., is a corporate body incorporated pursuant to the laws of France with an office at 192 avenue Charles de Gaule, Neuilly-sur-Seine, France.

5.5.1 The Defendants, 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 and Servier R&D Benelux are all corporate bodies believed to be incorporated pursuant to the laws of France, and conducting business in France, however the precise location of their respective offices is not known at the time of this pleading.

5.5.2 The Defendant, Dr. Jacques Servier is an individual who resides in Neuilly-Sur-Seine, France, and was at all material times the directing mind behind all of the Defendant corporations.

5.5.3 In the alternative, Servier S.A.S. was the directing mind and will behind the activities of all the Defendant corporations.

5.6 The Defendants are all affiliated with one another, and are collectively referred to as the "Servier Defendants". They developed and marketed Ponderal (generic name: fenfluramine) and Redux (generic name: dexfenfluramine) as joint ventures for their mutual profit. The Servier Defendants are jointly and severally liable for each other's actions.

5.7 In addition, all Servier Defendants were at all material times under the complete control of a single directing corporate mind – namely that of Dr. Jacques Servier, or alternatively the corporation Servier S.A.S - such that the theory of alter ego applies and any tortious conduct on the part of any of the named Defendants may be imputed to that directing mind.

### **The Representative Plaintiff**

6. Wilson is the mother of four children and the wife of Robert Wilson. Wilson is 62 years of age and has become severely physically disabled subsequent to having taken a treatment of Ponderal. She now suffers from primary pulmonary hypertension and permanent damage to her heart valve. Due to the advanced stage of her disease, Wilson has a life expectancy of only a few years.

### **Class Definition**

7. This action is brought pursuant to the *Class Proceedings Act, 1992*. Wilson brings this action on her own behalf and on behalf of the following class:

All persons in Canada who consumed medication known as Ponderal or medication known as Redux as manufactured, developed, designed, fabricated, sold, imported, distributed,

marketed or otherwise placed into the stream of commerce in Canada by Servier Canada or Biofarma and/or the other Servier Defendants.

8. Wilson further undertakes this action on behalf of the following class:

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 treatment with Ponderal and Redux as described above.

#### **Background**

9. In 1995 Wilson was moderately over-weight and sought medical assistance to achieve reduction. Wilson attended her family doctor who recommended a course of treatment of fenfluramine as manufactured, developed, designed, fabricated, sold, imported, distributed, marketed or otherwise placed into the stream of commerce by Servier Canada and Biofarma and its affiliates referred to in paragraph 5 above (the other Servier Defendants) under the trade name Ponderal.

10. Ponderal, the subject matter of this litigation, is an appetite suppressant used to assist in weight reduction.

11. In or about August 18, 1995 Wilson's family doctor prescribed Ponderal to assist the Plaintiff with her weight reduction program. Wilson took the medication until September 1996.

12. Wilson used Ponderal in accordance with her doctor's direction and in the manner it was intended to be used.

13. In or about October 1996, Wilson developed difficulties breathing and was tiring easily. Wilson's physical condition progressively deteriorated resulting in numerous attendances on physicians, and multiple tests. In February 1998 Wilson was diagnosed with pulmonary hypertension. She was then diagnosed in March 1998 as having primary pulmonary hypertension ("PPH") with serious cardiac valvular disease attributable to her Ponderal treatments.

14. PPH is a serious progressive disease for which there is no known cure. The condition initially causes high blood pressure in the pulmonary artery which affects the lungs and eventually the heart. Cardiac valvular disease may also develop. These conditions cause symptoms including memory loss, brain damage, irregular heartbeat, heart murmur, shortness of breath, fatigue, dizziness and chest pain.

15. PPH significantly reduces life expectancy with death occurring in more serious cases within two to five years from the time symptoms first appear. The available treatments, including drug therapy, lung and heart transplant are both high-risk and extremely invasive.

#### **Regulatory Events**

16. On September 15, 1997, Servier Canada and Biofarma and the other Servier Defendants voluntarily withdrew Ponderal from the Canadian market due to concerns over the serious side effects the drug may cause to users.

17. Health Canada has recommended that every person who has used Fenfluramine should see a physician to have a complete medical history taken and a physical examination performed with emphasis on the heart and lungs. It is also recommended that such individuals have an echocardiogram and chest X-ray performed to determine whether there is any damage to the heart valves and lungs. Other, more invasive tests are required in more serious cases.

**Servier Canada and Biofarma and the other Servier Defendants**

18. Servier Canada is one of a cluster of corporations including, but not limited to, Servier S.A.S., Oril, Orsem, Servier Amerique, Science Union et Cie, Institut de Recherches Internationales Servier, Servier Research, 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, ADIR, Servier R&D Benelux, I.R.I.S. Services S.A.R.L. and Les Laboratoires Servier S.A..

19. In 1964, Biofarma registered the trademark for Ponderal in Canada in the name of Biofarma. The Canadian trademark application was granted to Biofarma June 16, 1966 in its own name for a number of years.

20. Biofarma caused Servier Canada to be incorporated on July 3, 1975. Servier Canada commenced business in Canada in September 1975.

21. Wilson states that Servier Canada was established as a shell corporation by Biofarma for the purpose of distributing, selling, marketing and

otherwise placing Ponderal into the stream of commerce within Canada on behalf of Biofarma and its affiliates.

22. On March 1, 1979 Biofarma transferred its Canadian trademark to Servier Canada.

23. Wilson states that although Servier Canada was a duly incorporated entity, it was nothing more than a vessel through which Biofarma and its affiliates placed Ponderal into the stream of commerce in Canada. Biofarma placed Ponderal into the stream of commerce within Canada with the knowledge and intention that it would be prescribed by physicians and consumed by Canadians such as Wilson.

23.1 In its daily operations the Servier Defendants did not distinguish one Servier affiliate from another, but rather, operated as if each was interchangeable with the other.

23.2 The Servier Defendants all participated in the development, testing, patenting, marketing and manufacture of Ponderal and Redux with a view towards selling these products in countries around the world, including Canada. The Servier Defendants failed to ensure that these products were safe and fit for human consumption before they were released onto the Canadian market. They failed to conduct proper animal testing of Redux and Ponderal before marketing these products to Canadian consumers, and they negligently or intentionally mischaracterized the results of the animal testing which they did conduct, failing either to recognize or to draw to the attention of public health authorities clear signs of cardiotoxicity in laboratory animals exposed to these drugs.

23.3 The Servier Defendants were all aware of increasing numbers of adverse drug reactions to Ponderal and Redux reported in Europe during the 1980s and 1990s. They failed to relay such reports to Health Canada, to class members, or to the class member's physicians.

23.4 The Servier Defendants were further aware of the public health tragedy caused by Aminorex, another anorectic drug, chemically similar to Ponderal and Redux, which was sold in Europe between 1968 and 1972. Despite such knowledge, the Servier Defendants failed to conduct adequate safety testing and drug reaction monitoring in the development and marketing of Ponderal and Redux.

23.5 The Servier Defendants further knew or ought to have known that Ponderal and Redux were ineffective in providing long term weight control, and that the limited efficacy of these drugs was far outweighed by their associated health risks. Each of the Servier Defendants therefore knew, or ought to have known, that Ponderal and Redux were drugs of dubious clinical benefit which posed a real risk to the health of Canadians.

#### **Duties and Obligations of Servier Canada and Biofarma and the other Servier Defendants**

24. Servier Canada and Biofarma and the other Servier Defendants jointly owed a duty to Wilson and to other class members to ensure that their products were fit for the purpose for which they were intended. Servier Canada and Biofarma and the other Servier Defendants breached that duty by failing to ensure that Ponderal and Redux were fit for the purpose for which they were.

25. Servier Canada and Biofarma and the other Servier Defendants continued to manufacture, develop, design, fabricate, sell, import, distribute, market or otherwise place into the stream of commerce Ponderal and Redux in Canada when they knew or ought to have known that Ponderal and Redux were potentially hazardous to the health to those who consumed Ponderal and Redux. Servier Canada and Biofarma and the other Servier Defendants jointly owed a duty to Wilson and to the other class members to adequately warn them and their physicians of the risks associated with these medications. Servier Canada and Biofarma and the other Servier Defendants breached that duty by failing to give any or any adequate warning of the risks associated with the use of Ponderal and Redux as more particularly described below.

#### **Servier Canada and Biofarma's Negligence**

26. Particulars of the negligence relating to Biofarma are as follows:

- (a) it incorporated Servier Canada and transferred its Canadian trademark to Servier Canada for the purpose of placing Ponderal into the stream of Canadian commerce, when it knew or ought to have known that to do so would expose Canadians who consumed Ponderal to potentially hazardous health effects;
- (b) it continued to place Ponderal into the stream of Canadian commerce when it knew or ought to have known that published scientific studies demonstrated that the product was unsafe;

27. Particulars of the negligence relating to Servier Canada and Biofarma and the other Servier Defendants jointly are as follows:

- (a) they failed to ensure that Ponderal and Redux were ~~was~~ not unreasonably dangerous to recipients during the course of its use;
- (b) they failed to provide Wilson, other class members and their doctors with any or any adequate warning of potentially catastrophic risks associated with the administration of Ponderal and Redux;
- (c) they failed to provide Wilson, other class members and their doctors with any or any adequate warning of the risks associated with the use of Ponderal and Redux;
- (d) they failed to provide Wilson and other class members, and their doctors with any or any adequate information and warnings respecting the correct usage of Ponderal and Redux. And in particular, failed to adequately warn Wilson and other class members with respect to the significant health risks inherent in taking Ponderal and Redux for periods longer than three months or in conjunction with other medication;
- (e) they failed to adequately test Ponderal and Redux in a manner that would fully disclose the various side effects and the

magnitude of the risks associated with its use, and in particular its use over extended periods of time;

- (f) they failed to cease the manufacture and/or distribution of Ponderal and Redux when they knew or ought to have known that Ponderal and Redux caused or could cause significant injury, particularly to those who used the medication for extended periods of time;
- (g) they failed to conduct randomized, controlled studies with long-term follow-up in order to ensure the safety and efficacy of the drugs;
- (h) they failed to provide any, or any adequate, updated and current information to Wilson or other class members and their doctors respecting the risks and efficacy of Ponderal and Redux as it became available from time to time;
- (i) they failed to establish any or adequate procedure to educate their sales representatives or prescribing physicians respecting the correct usage of Ponderal and Redux and the risks associated with Ponderal and Redux;
- (j) they failed to ensure that Ponderal and Redux was fit for its intended purposes;

- (k) they negligently misrepresented the safety of the drugs to the Health Protection Branch and failed to advise that the drugs should be immediately withdrawn after having received information as to the potential of the drugs to cause serious health effects.

### Servier Canada and Biofarma's and the other Servier Defendants' Breach of Warranty

28. Servier Canada and Biofarma and the other Servier Defendants expressly or otherwise warranted that Ponderal and Redux were reasonably fit for their intended purpose. When used in a normal manner and for its intended purpose, Ponderal and Redux caused injury to Wilson and to the other class members. The efficacy and potential benefits of Ponderal and Redux do not surpass the health risks associated with use of the drugs. Ponderal and Redux are not fit for their intended purpose. Servier Canada and Biofarma and the other Servier Defendants breached their warranty of fitness for purpose.

29. Wilson pleads and relies upon the provisions of the *Sale of Goods Act*, R.S.O. 1990, c. S.1, as amended from time to time.

30. Servier Canada and Biofarma and the other Servier Defendants placed Ponderal and Redux into the normal stream of commerce with the knowledge and expectation that it would be sold and ultimately used *without* further clinical evaluation to expose the product's latent defects. Wilson, on her own behalf and on behalf of the other class members, claims damages for breach of warranty as to merchantability and quality or fitness for a particular purpose.

31. Wilson's injuries and damages, and those of the other class members, as outlined more particularly below were caused by the negligence, misrepresentations and breach of warranties by Servier Canada and Biofarma, and the other Servier Defendants, their servants and agents.

### **Damages**

32. Wilson contracted primary pulmonary hypertension as a result of using Ponderal. She suffers many symptoms including, difficulty breathing and shortness of breath, fatigue and exercise intolerance, tightness in chest, ankle swelling, heart valve damage and high blood pressure in her lungs. These symptoms are also representative of those suffered by class members who have contracted primary pulmonary hypertension as caused by the use of Ponderal and Redux.

33. Wilson and the other class members have suffered psychological damage including mental anguish, emotional distress, and personality changes. In many cases interpersonal relationships have suffered.

34. Wilson continues to undergo medical treatment for the injuries suffered due to Ponderal and her health continues to deteriorate.

### **Damages Including Investigational Procedures**

35. Wilson and the other class members have suffered special damages, losses and expenses, included but not limited to costs associated with the medical examinations recommended by Health Canada. These include the cost of echocardiograms, transoesophageal examinations, chest X-rays and physical

examinations which would not have been necessary but for the fact of Ponderal and Redux being made available on the market.

36. Without limiting the generality of the foregoing, the Plaintiff and other class members have suffered loss of past and future income, loss of employment benefits and loss of opportunity to earn income.

### **Specialized Treatment**

37. Wilson states that many of the seriously affected class members have been required to submit to a form of treatment called Flolan. The annual cost of the treatment is approximately \$80,000 per patient. This treatment is risky, invasive and burdensome. It involves the insertion of a permanent catheter into the heart. The catheter is permanently attached to a pump affixed to the side of the patient's body. Beyond the Flolan treatments, heart and lung transplants are required.

### **Punitive Damages and Misrepresentations**

38. Wilson states that during the time she was taking Ponderal, Servier Canada and Biofarma and the other Servier Defendants were carrying out an extensive sales and marketing effort which resulted in mis-information about the product being disseminated to Wilson and other members of the class.

39. As a result of these sales and marketing efforts there was a significant increase in sales revenues and profits to Servier Canada and Biofarma and the other Servier Defendants.

40. Wilson states that a further increase of sales revenues was experienced in the months immediately ahead of the lead article in the *New England Journal of Medicine* dated August 26, 1996. That article reviewed the results of the International Primary Pulmonary Hypertension study ("IPPH study"). This study concluded that fenfluramine based anorexigens, such as Ponderal increased the risk of Primary Pulmonary Hypertension by a multiple 23 to 46 times.

41. Servier Canada and Biofarma and the other Servier Defendants were aware, or alternatively should have been aware, of the results from the IPPH study well before the time Wilson and other class members began taking Ponderal treatments and well in advance of the official publication date for the study.

42. In addition, Servier Canada and Biofarma and the other Servier Defendants were aware, alternatively, or should have been aware, of other medical and scientific data indicating that Ponderal taken alone or in combination with other fenfluramine derivatives drastically increased the risk of PPH and other serious side effects. Nevertheless, Servier Canada and Biofarma and the other Servier Defendants failed to apprise the public of these risks in a timely fashion or at all.

43. At all times, Servier Canada and Biofarma and the other Servier Defendants failed to conduct or pay heed to, the necessary tests to assure the safety and efficacy of Ponderal and Redux.

44. By failing to communicate the dangerous nature of Ponderal to the Plaintiff and to others using this medication, the Servier Defendants acted in an unacceptable manner with respect to the safety of Wilson and the other class members.

45. Servier Canada and Biofarma and the other Servier Defendants intentionally or negligently misrepresented the safety of Ponderal and Redux and concealed adverse information regarding the risks of their use. Specifically, Servier Canada and Biofarma and the other Servier Defendants concealed the actual risks of serious illness and harm in the form of primary pulmonary hypertension, heart valve damage, and other side effects such as neurotoxicity, resulting from the use of Ponderal and Redux.

46. The warnings and precautions in effect when Wilson was prescribed Ponderal were substantially and graphically wholly inadequate to alert prescribing physicians and consumer patients of the actual PPH risk associated with these drugs which was then only known to the Servier Defendants. In every meaningful sense, the warnings were false, inaccurate and inadequate regarding the PPH risk.

47. On account of Servier Canada and Biofarma's and the other Servier Defendants' failure to adequately warn doctors prescribing Ponderal and Redux, Wilson and the other class members were unaware of the importance of reporting and describing the onset of symptoms to their physicians.

48. Had Wilson and the balance of the class members been made aware of the significance of the symptoms of shortness of breath, heart palpitations and

the like, she and the others would not have continued the use of the medication through to September 1996. Indeed, had the real risks of taking Ponderal been disclosed to Wilson and the other members of the class, they would not have agreed to take Ponderal alone or in combination with any other Fenfluramine based medications.

49. Despite any inserts or additional warnings which may have been issued by Servier Canada and Biofarma and the other Servier Defendants, they continued to aggressively market and profit from the manufacture and sale of these drugs. The drug remained on the market in Canada until after studies conducted at the Mayo Clinic and others, prompted by the United States Food and Drugs Administration revealed that users of Ponderal and other related medication caused users to develop abnormalities in their heart valves.

50. Servier Canada and Biofarma and the other Servier Defendants were aware or should have been aware on or before October 9, 1995 of the results of studies on animals demonstrating a substantial loss of serotonin nerve axons in the brains of monkeys after being exposed to Fenfluramine derivative for only 4 days.

51. Wilson, on her own behalf and on behalf of the other class members, claims punitive and exemplary damages for the reckless and unlawful conduct of Servier Canada and Biofarma and the other Servier Defendants.

52. Wilson, on her own behalf and on behalf of the other class members, claims punitive and exemplary damages for the intentional misrepresentations of the Servier Defendants.

53. Wilson pleads and relies upon the provisions of the *Negligence Act*, R.S.O. 1990, c. N.1, as amended.

54. The Plaintiff pleads that this proceeding consists of claims in respect of damages sustained in Ontario arising from a tort, breach of contract or breach of fiduciary duty, wherever committed, and accordingly, the Plaintiff relies on Rule 17.02 of the *Rules of Civil Procedure* in support of service of this Statement of Claim upon the Servier Defendants outside Ontario without leave.

#### **Claims for Rescission and Special Damages**

55. The Plaintiff alleges that Ponderal and Redux are so defective that they ought never to have been marketed or sold as diet drug medication in Canada, and that these drugs provided no benefit to class members.

56. The Plaintiff therefore alleges that class members are entitled to rescission of the purchase price of the drugs on the grounds that the Defendants have been unjustly enriched by the sale of a worthless, and indeed harmful, product, for which the Defendants should never have sought approval to sell in Canada.

57. In the alternative, the Plaintiff further pleads that class members are entitled to rescission of the purchase price of Ponderal and Redux as a remedy for breach by the Defendants of an implied warranty that these drugs were safe and fit for human consumption.

58. The Plaintiff also seeks to recover special damages on behalf of the class. Such damages include the costs of medical screening and treatment incurred by or on behalf of class members to diagnose whether they had suffered any health effects from taking Ponderal or Redux, and if they had, the costs of medical treatment incurred by class members to treat such health effects.

59. The special damages referred to above may have been incurred directly by class members, or may constitute subrogated claims owed to provincial health insurers, or to private health, disability, or group benefit insurers.

60. The Plaintiff proposes that the Trial in this action take place in the City of Toronto, in the Province of Ontario.

Date Issued: *November 17, 1998*

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Solicitors for the Plaintiff

WILSON vs SERVIER CANADA et al.

Court File No.: 98-CV-158832

ONTARIO COURT  
(GENERAL DIVISION)  
PROCEEDINGS COMMENCED AT  
TORONTO

**FRESH AS AMENDED  
STATEMENT OF CLAIM**

ROCHON GENOVA  
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