

**«PROPOSED CLASS ACTION»**

**FEDERAL COURT**

BETWEEN :

**LÉOPOLD DELISLE**

Plaintiff

-and-

**THE ATTORNEY GENERAL OF CANADA**

-and-

**DEPARTMENT OF HEALTH (HEALTH CANADA)  
( SANTÉ CANADA )**

Defendants

**STATEMENT OF CLAIM  
Rule 171A of the Federal Court Rules (1998)**

**TO THE DEFENDANT:**

**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 a solicitor acting for you are required to prepare a statement of defence in Form 171B prescribed by the Federal Court Rules, 1998, serve it on the plaintiff's solicitor or, where the plaintiff

does not have a solicitor, serve it on the plaintiff, and file it, with proof of service, at a local office of this Court, WITHIN 30 DAYS after this statement of claim is served on you, if you are served within Canada.

If you are served 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 for serving and filing your statement of defence is sixty days.

Copies of the Federal Court Rules, 1998, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

**IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.**

Montreal, this 29th day of January 2004

Issued by: \_\_\_\_\_  
(Registry Officer)  
Federal Court of Canada  
30 McGill Street  
Montreal (Quebec) H2Y 3Z7

TO: Attorney General of Canada  
Complexe Guy Favreau  
200 René-Lévesque Boulevard West  
East Tower, 5th Floor  
Montreal (Quebec) H2Z 1X4

Department of Health (Health Canada)  
Complexe Guy Favreau  
200 René-Lévesque Boulevard West  
East Tower, 5th Floor  
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<b>CLAIM</b>
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1. The plaintiff's claim is the following: the plaintiff, Léopold Delisle, wishes to undertake a class action on behalf of physical persons comprised of the following group, of which, he himself is a member:
  - a) All persons who **were unable to obtain, or will be unable to obtain**, the product known as 714X or that **have suffered or will suffer undue delays** in obtaining 714X further to a request submitted by their doctor within the parameters of HealthCanada's Special Access Program; and
  - b) The spouses or dependents of the persons identified in subparagraph a); and
  - c) The heirs or successors of deceased persons that would otherwise have been included within the group;hereafter referred to as "members of the group"
2. The plaintiff, suffering from a rare and little known disease of the immune system named mastocytose, has used a product known as 714X since 1997, which can only be obtained through his attending doctor's request submitted under Health Canada's Special Access Programme (SAP) as administered by the defendant, the Department of Health (Health Canada);
3. Health Canada's SAP allows doctors treating patients affected by serious or deadly diseases to obtain medicines not otherwise available on the market when conventional therapies have revealed themselves as ineffective, not recommended or unavailable;
4. The SAP does not authorize the use or administration of a medicine, those authorizations being of the domain of the medical profession which is governed by provincial authorities;
5. The SAP does not completely evaluate the validity of the information on medicinal products and does not attest to the safety, efficacy or quality of a product;

6. Authorizations issued under the SAP do not therefore constitute an opinion nor a declaration as to the safety, efficacy or quality of a product;
7. 714X is a non toxic product, available by way of the SAP since 1989, which supports the body's natural defenses (and the immune system) when it is introduced into the lymphatic circulation and which has beneficial effects on a number of persons suffering from various diseases, for example, cancer and other degenerative diseases;
8. Between 1990 and November 2003, 20,780 injection cycles of 714X have been authorized by Health Canada, representing some 436,380 injections performed on patients and 1,341 nebulizer cycles of 714X totalling 28,161 treatments by way of inhalation;
9. However, over the last six months, even though no negative study or expertise has been completed or published dealing with 714X, the plaintiff has been approached by several sick people seeking access to 714X for treatment of their degenerative diseases to inform him of abnormal and unjustified refusals or delays on the part of Health Canada in the handling of the authorization requests for 714X submitted by their doctors;
10. On December 2nd 2003, the plaintiff's own doctor received a notice from Health Canada to the effect that his request to obtain 714X would not be dealt with, having been judged incomplete for not supplying supplemental clinical justification for its usage;
11. However, it is somewhat difficult to understand why Health Canada would now demand supplemental clinical justification from the plaintiff's own doctor for the use of 714X when the plaintiff had already received over 700 injections of 714X since 1997;
12. By requiring this added justification of Canadian doctors, Health Canada's decision was equivalent to banning the use of the product when they specifically knew that as of this day no supplemental scientific or clinical justification exists other than those having already convinced doctors to request the product for their patients for over thirteen years and further justified Health Canada's authorization of over 436,000 injections;
13. After having attended at the offices of Health Canada to demand a change of attitude in the handling of the authorization requests, the plaintiff was finally informed that he would be granted access to the product without having to produce any further clinical justifications, notwithstanding Health Canada's earlier requests for this information from his doctor;

14. However, the plaintiff's case seems quite exceptional as a review of the manufacturer's records indicates that the plaintiff's authorization is one of the only ones received from Heath Canada since December 19, 2003 and this notwithstanding the numerous pending requests for the product submitted by doctors and patients;
15. For months now, the plaintiff has witnessed the moral sufferings of patients and their families as well as their deteriorating health due to the unjustified refusals or denials of the responsible parties at the SAP at Heath Canada;
16. The plaintiff himself had to suffer through unjustified delays in the issue of his authorization to use 714X in December 2003 and can testify to the anguish and stress of a terminally ill patient having to fight to obtain a product which is unjustly and abusively refused without any reasonable motives and notwithstanding pressing requests by his or her attending physician;
17. The defendants, their agents and representatives must answer for the errors committed in the exercise of their duties, notably:
  - 17.1 Their failure to answer several authorization requests submitted by certain Canadian doctors;
  - 17.2 They allowed certain patients dealing with serious or potentially life threatening diseases to wait for authorizations to use 714X when they should have treated these cases within twenty-four hours of the requests having been submitted by their attending physician;
  - 17.3 They abused their discretion in the analysis of authorization requests submitted by doctors;
  - 17.4 They authorized the use of 714X in an arbitrary, unjustified and partial way, without any consideration for the health and welfare of the members of this group;
  - 17.5 They imposed abusive conditions in the handling of authorization requests by demanding, without any justification, from only certain doctors requesting access to the 714X, supplemental clinical or scientific justifications;
  - 17.6 They induced in error certain doctors by giving them false or baseless information as regards the safety, efficacy or quality of 714X;

18. The fact of having applied arbitrary approval criteria for a product made available under the SAP, of having created undue delays for certain members of the group, of having authorized requests in a discriminatory and arbitrary way and of having endangered the life and security of members of the group constitutes an attack on their rights guaranteed under the Canadian Charter of Rights and Freedoms thus allowing a claim in compensation and exemplary damages;
19. The defendants must also answer for the moral prejudices, troubles and inconveniences and the aggravation of medical conditions of members of this group, and in some cases the demise of certain members, that either had to await or are still awaiting authorizations duly submitted by their doctors for the use of 714X;
20. Although it is difficult to evaluate the number of members of the group due to the confidential nature of medical files, the plaintiff estimates it at approximately two hundred people, taking into account roughly three hundred and ten annual requests for the product since 1990 for a total of 4,025 users of 714X;
21. The plaintiff proposes to represent all these people and to become their representative to institute a class action suit;
22. The plaintiff, on his own behalf and that of the members of the group, asks that this Court **order the defendants to deal with all authorizations requests submitted by doctors**, without formulating any other demands or conditions, whether the concerned patient has or has not obtained such authorization in the past;
23. Furthermore, the plaintiff asks that this Court **condemn the defendants to pay damages** to compensate the moral prejudice, troubles and inconveniences, and where applicable, the aggravation of a medical condition or the death of a member of the group;
24. And also, the plaintiff asks that this Court **condemn the defendants to pay exemplary damages** for their attack on the members' rights guaranteed under the Canadian Charter of Rights and Freedoms;
25. For his part, the plaintiff seeks as compensation for moral prejudice, troubles and inconveniences and exemplary damages the sum of twenty-five thousand dollars (\$25,000.00);
26. The plaintiff proposes that the action be tried at Montreal.

Montreal, this 29th day of January 2004

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Mtre Michel Bélanger  
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