

F E D E R A L C O U R T

BETWEEN:

LÉOPOLD DELISLE

Plaintiff

-and-

THE ATTORNEY GENERAL OF CANADA

-and-

**DEPARTMENT OF HEALTH
(HEALTH CANADA)**

-and-

**DIRECTOR GENERAL
THERAPEUTIC PRODUCTS DIRECTORATE
(HEALTH CANADA)**

Defendants

PLAINTIFF'S REPLY

**THE PLAINTIFF RESPECTFULLY SUBMITS TO THE COURT AS PLAINTIFF'S
RESPONSE TO THE DEFENDANTS' REPRESENTATIONS:**

1. The plaintiff agrees with the defendants' representations that the Supreme Court of Canada's decisions rendered in *Manitoba (Attorney General) v. Metropolitan Stores Ltd.*, [1987] 1 S.C.R. 110 and *RJR-Macdonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311 establish the criteria that this court must consider when dealing with a motion for an interlocutory order under article 18.2 of the Federal Court act, to wit:
 - a) There must be a serious issue to be tried;

- b) The plaintiff must suffer irreparable harm if the interim order is refused;
- c) An appreciation of the balance of conveniences;

a) There must be a serious issue to be tried

- 2. The defendants' essentially submit under this heading, that this Court should not, within the confines of a motion for mandamus, dictate the result to be attained when the provisions enabling the Director general to authorize special access requests grant a discretionary power to the Director general.
- 3. The defendants add that the Director general is adequately exercising his discretionary power by demanding that people requesting 714X supply proof of its safety and efficacy.
- 4. At the very best, underline the defendants, this Court could send the file back to the Director general if it concludes that he misused his discretionary power;
- 5. It is important to recall that we are at an interlocutory stage and that when appreciating the existence of a serious question to be tried, the minimum threshold to be met is very low and the judge trying the issue must make a preliminary review of the substance of the file;

RJR-Macdonald Inc. v. Canada (Attorney General), [1994] 1 S.C.R. 311, 337;

- 6. It is within this context that this Court must appreciate the criteria that give rise to the interlocutory order being sought;
- 7. The defendants rest the essential part of their representations on an erroneous and restrictive qualification of the relief sought by this motion;
- 8. Let us first recall that this motion was filed within the framework of a class action suit whose damage remedies have been suspended so that the judicial review aspect of the file may be debated, such judicial review aspect to be treated as a collective recourse should the Court so approve;
- 9. As mentioned in the application, the defendants' attitude is generalized and the motives underlying the refusals or the delays of authorizations are the same in every case, thus favouring a collective approach to the present application and justifying the motion, also produced with these

pleadings, requesting that the application for judicial review be treated as a class action in accordance with articles 18.4(2) of the *Federal Court Act* and 299.11 of the *Federal Court Rules*;

10. Within this context, the plaintiff has a right to ask this Court to issue a directive in the nature of an injunction enjoining the defendants to approve special access requests for 714X within a 24 hour delay and ordering the publication of a notice to the medical profession to that effect;

Borisova et al. v. Canada (Minister of Citizenship and Immigration), [2003] F.C. 859.

11. Further, this application for judicial review rests on the defendants' decision to condition approval of authorization requests for 714X on an obligation to supply additional proof of the safety and efficacy of the product and that any provision of law that would entitle the defendants to invoke such measures affect rights guaranteed under the *Charter of rights and freedoms*;

12. More specifically, the plaintiff will argue that these decisions are contrary to the "right to life, liberty and security of the person" guaranteed under article 7 of the Charter of rights and freedoms therefore giving rise to the reparations sought on the basis of article 24 of the Charter;

Parker v. R., (2000), 146 C.C.C. (3d) 193 (Ont. C.A.)

Hitzig et al. v. R., Ontario Court of Appeal, No. C39532, C39738, C39749, October 7 2003, jj. Doherty, Goudge and Simmons

Wakeford v. R.,, Ontario Court of Appeal, No. C34280, January 17, 2002, jj. Laskin, Rosenberg and Macpherson

13. Finally, if the conclusion sought is in the form of *mandamus*, such conclusion first and foremost lies within the context of an application for judicial review and that within that context it is expressly provided for in section 18.2 of the *Federal Court Act*.

Brisset v. Canada (Minister of Citizenship and Immigration), No. IMM-3464-02, September 13, 2002, j. Blanchard, Neutral citation: [2002 CFPI 971](#)

14. If the conditions giving rise to *mandamus* must be met, as is submitted by the defendants, then it is our submission that the decision of the Federal Court of Appeal in *Apotex Inc.* (confirmed on appeal to the

Supreme Court of Canada) confirm that the plaintiff is entitled to such relief:

Apotex Inc. v. Canada (Attorney General), [1994] 1 F.C. 742 (C.A.) affirmed in *Apotex Inc. v. Canada*, [1994] 3 S.C.R. 1100;

Maple Lodge Farms Ltd. V. Government of Canada, [1982] 2 S.C.R. 2

Baker v. Canada (Minister of Citizenship and Immigration), [1999] 2 S.C.R. 817

Sharma v. Minister responsible for the Canada Customs and Revenue Agency, F.C. No. T-1485-00, June 4, 2001, Mr. Justice Pelletier, [2001 CFPI 584](#);

Dragan v. Canada (Minister of Citizenship and Immigration) (1st inst.) [2003] 4 F.C. 189

15. It is apparent from the evidence that the defendants exercised their discretionary power in a manner that can be characterized as “unjust”, that denotes “flagrant irregularities” and “bad faith”, notably in:
- Refusing to authorize access to a product without any new evidence that the product is toxic or ineffective and this after having approved over 440,000 injections over 13 years and even after having demanded additional evidence in certain cases;
 - Exercising discretion as to the safety and efficacy of the product when evaluating medical requests filed by doctors even though it is the doctors who assume entire responsibility for their prescriptions and that the defendants publicly state that they do not analyze the safety or efficacy of products accessible under the SAP;
 - Granting the product to certain patients notwithstanding an initial refusal due to the patient not having supplied additional information as requested while at the same time refusing access to the product to other patients for these very same grounds;
 - Responding to physicians’ requests for access to the product within patently unreasonable delays given that the patients concerned suffer from terminal phase serious illnesses.

16. In fact, the discretionary power afforded the defendants is not “unlimited”, “absolute” or “facultative”, being rather limited to analyzing the information in the hands of doctors dealing with the safety and efficacy of the product;
17. Even though the facts tend to confirm over the years the efficacy of the product and that no toxic side effects have been reported or put in evidence by the defendants, they decided however to demand additional evidence as to the foregoing therefore establishing the exercise of their discretion on “non-pertinent” considerations;
18. Given that the regulatory framework has not changed, that access to the product has been authorized tens of thousands of times and this even after having asked for additional proof of safety and efficacy of the product, and that no proof of toxicity or ineffectiveness has been filed and put into evidence by the defendants that could have justified a change in the evaluations of access requests to 714X, the patients have an “acquired right to the execution of the obligation” by the defendants;
19. Further, it is useful to recall that the conclusions sought by this present application are foreseen within the framework of a judicial review, subsection 18.1(3) specifically authorizes the Court to:
 - a) order the federal board in question to do any act that it has unlawfully failed or refused to do or has unreasonably delayed in doing;
 - b) declare invalid or unlawful, or quash, or set aside and refer back for determination in accordance with such directions as it considers appropriate, or prohibit or restrain a decision, order, act or proceeding of the federal board.
20. Finally, one may question, on the one hand, the legality of the delegation of power that authorizes the affiant Ian Mackay to administer the Special Access Programme (“receives, process and considers requests from physicians seeking special access”, paragraph 3 of Ian Mackay’s affidavit) in the place and stead of the Director general, and on the other hand, his competency to reevaluate the requests filed by physicians as to the efficacy of a product for their patients;

The plaintiff's interest to act

21. In concluding that the plaintiff lacks interest to act, the defendants once again ignore the nature of these proceedings that arise within the confines of a class action suit;

22. Even at this stage of the proceedings, the plaintiff has the interest to seek an order in the nature of that sought in these pleadings in the name of the putative members of the class;

Borisova et al. v. Canada (Minister of Citizenship and Immigration), [2003] F.C. 859

23. Moreover, though the change in the evaluation of access requests for 714X would have begun in the months following the introduction of new procedures in 2001, according to the defendants' statement in the letter they sent to Canadian doctors on or about January 19, 2004 (Exhibit "F" of Ian Mackay's affidavit), the plaintiff's December 2003 access request was nonetheless denied, then granted, after the plaintiff personally made representations to the defendants at a meeting at the offices of the defendants in Ottawa, without any additional information being supplied by the plaintiff's doctor, such lack of information having been the basis for the original refusal of his access request. In such a confusing and arbitrary context, nothing guarantees that the plaintiff's renewed access requests will be approved;

24. Also, given the defendants' decision to limit access to the product for a one-year period, the plaintiff has the interest to seek the requested order if only to insure access to the product until final judgment is obtained on the judicial review application, which can extend beyond the "grace period" afforded by the defendants;

25. Finally, as per the wording of article 18.1 of the Federal Court Act, this Court has the discretionary power to recognize the plaintiff's quality to act when it is convinced that the particular circumstances of the case and the plaintiff's type of interest justify this recognition;

Friends of the Island Inc. v. Canada (Min. of Public Works), [1993] 2 F.C. 229

26. In this context, by affirming that a reasonable and efficacious means to submit this question to this Court is to force people deprived of 714X to present their own applications to this Court, the defendants persist in their ignorance of the state of urgency and the suffering of those people

affected by their decision. To the contrary, it is far from reasonable and efficacious to demand that all terminal phase patients engage their own pleadings to have access to the product;

b) The irreparable harm affecting the plaintiff and the people he represents

27. By invoking the absence of irreparable harm, the defendants rely once again on the sole reason justifying their denials of access to 714X: the apparent absence of scientific proof of the non-toxicity and efficacy of the product;
28. However, the irreparable harm being suffered is first and foremost that harm being lived by the patients that find relief with 714X and a last chance at survival, the whole as appears from testimonials of certain members of the group (exhibit 12 to Léopold Delisle's affidavit), and ignored by the defendants;
29. The irreparable harm is that referred to by doctors, who deem it necessary to seek access to 714X for a patient suffering through a serious illness or whose life in danger, when in the opinion of the doctor conventional treatments have failed or are inappropriate;
30. Moreover, the level of scientific evidence suddenly being sought by the defendants as to the efficacy and the non-toxicity of 714X does not necessarily constitute the only acceptable norm, evidence based on personal experience, even qualified as anecdotal, being capable of establishing a form of control;

Hitzig et al. v. R., Ontario Court of Appeal, No. C39532, C39738, C39749, October 7, 2003, jj. Doherty, Goudge and Simmons

c) The balance of convenience

31. It appears from Ian Mackay's affidavit that the real reason underlying the access request refusals is more the desire to stop drug manufactures from circumventing the drug approval process for their products by having recourse to the Special Access Programme;
32. To the extent that the Special Access Programme is a regime of exception provided for by the Food and Drugs Regulations and that the entire responsibility as to its use rests upon the doctors deciding to have recourse to it, there is no risk of creating any precedent whatsoever;

33. In addition, at this stage of the pleadings, the risk that a precedent will be set in the manner described by the defendants can never outweigh the harm created by depriving patients of a product that may save their lives or relieve their suffering, as has been noted by doctors prescribing the product over the last 13 years (exhibit 12 to Léopold Delisle's affidavit and exhibit 19 to Gaston Naessens' affidavit);
34. If a precedent exists that may undermine the objectives of the law, is it not, to the contrary, taking hostage dying patients or gravely ill patients within a Programme adopted for them for compassionate reasons, and this as a means to pressure a manufacturer to have his product approved?
35. Finally, the argument raised that the interlocutory order may encourage eventual patients to forego traditional medical treatments reflects once more the abuse of power espoused by the defendants and the total ignorance of the Programme's objectives, to wit, a programme that, for compassionate reasons, allows doctors "to have access to non-approved drugs in Canada for the treatment of serious or life-threatening illnesses when conventional therapies have failed or are unsuitable";
36. The balance of convenience would then favour the defendants who, better than the patients or their doctors, know what is best to treat a disease for which "conventional science" can offer no solutions;
37. The defendants, contrary to their own public information document (exhibit 2 to Léopold Delisle's affidavit), are rendering judgment on the toxicity and the efficacy of the product while totally ignoring the request of the health professional who is the only competent person to speak in the name of his patients and who bears the entire responsibility of his actions;

FOR ALL OF THESE REASONS, THE PLAINTIFF RESPECTFULLY ASKS THIS COURT TO:

GRANT the request for interim relief presented by the plaintiff;

THE WHOLE with costs.

Montreal, this 27th day of April 2004

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LIST OF AUTHORITIES

- Manitoba (Attorney General) v. Metropolitan Stores Ltd.*, [1987] 1 S.C.R. 110
- RJR-Macdonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311
- Borisova et al. v. Canada (Minister of Citizenship and Immigration)*, [2003] F.C. 859
- Parker v. R.*, (2000), 146 C.C.C. (3d) 193 (Ont. C.A.)
- Hitzig et al. v. R.*, Ontario Court of Appeal, No. C39532, C39738, C39749, October 7 2003, jj. Doherty, Goudge and Simmons
- Wakeford v. R.*, Ontario Court of Appeal, No. C34280, January 17, 2002, jj. Laskin, Rosenberg and Macpherson
- Brisset v. Canada (Minister of Citizenship and Immigration)*, No. IMM-3464-02, September 13, 2002, j. Blanchard, Neutral citation: [2002 CFPI 971](#)
- Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 (C.A.) affirmed in *Apotex Inc. v. Canada*, [1994] 3 S.C.R. 1100;
- Maple Lodge Farms Ltd. V. Government of Canada*, [1982] 2 S.C.R. 2
- Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817
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- Dragan v. Canada (Minister of Citizenship and Immigration)* (1st inst.) [2003] 4 F.C. 189
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