Federal Court  Cour fédérale

Date: 20100225

Docket: T-116-07

Citation: 2010 FC 213

Ottawa, Ontario, February 25, 2010

PRESENT: The Honourable Mr. Justice O'Keefe

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Applicant

and

ATTORNEY GENERAL OF CANADA
THE MINISTER OF HEALTH

Respondents

PUBLIC REASONS FOR JUDGMENT AND JUDGMENT ISSUED FEBRUARY 25, 2010

O'KEEFE J.

[1] This is an application pursuant to section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, for judicial review of the decision letter dated December 19, 2006, of the Therapeutic Products Directorate of Health Canada (or the "Board") which, on behalf of the Minister of Health, rejected a

New Drug Submission (NDS) filed by the applicant on the grounds that the NDS did not comply with the requirements of the *Food and Drug Regulations*, C.R.C. c. 870, as amended (the Regulations).

[2] The applicant requests that:

1. Its application be allowed with costs;

2. Health Canada's decision to summarily reject the applicant's NDS Control No. [omitted] be set aside;

3. A Notice of Compliance (NOC) be issued to the applicant for [omitted], upon satisfactory completion of a substantive review by Health Canada of the applicant's NDS for compliance with section C.08.002 (but excluding subsections (g) and (h)), such review to be completed within 120 days of any order made herein;

4. In the alternative to 3, Health Canada shall:

   i. Forthwith process the applicant's NDS, and

   ii. Issue an NOC with Conditions (NOC(C)) to the applicant for [omitted], upon satisfactory completion of a substantive review by Health Canada of the applicant's NDS for compliance with section C.08.002 (but excluding subsections (g) and (h));

   iii. Convene an advisory board to define the applicable conditions for the NOC(C);

   iv. Ensure that no member of the advisory board shall have had any involvement with the decision to reject that is the subject of this judicial review application; and

   v. Complete such review within 120 days of any order made herein;

5. In the further alternative to 3 and 4, that Health Canada:

i. Forthwith review the Applicant's NDS for compliance with section C.08.002;

ii. Convene an advisory board for the purpose of defining pragmatic parameters for any supplemental evidence in support of the safety and efficacy of [omitted];

iii. Allow the applicant a full opportunity to respond, and;

iv. Ensure that no member of the advisory board shall have had any involvement with the decision to reject that is the subject of this judicial review application, and;

v. Complete such review within 120 days of any order made herein.

Background

[3] A New Drug Submission (NDS) is required for the regulatory approval and issuance of a Notice of Compliance (NOC) by Health Canada. Once received, an NOC allows the manufacturer to sell the drug in Canada. The NDS contains scientific information about the product's safety, efficacy and quality. It includes the results of clinical studies, details on the production of the drug and its packaging and labelling, and information about its claimed therapeutic value, conditions for use and side effects.

[4] The drug which is the subject of the applicant's NDS is called [omitted]. [Omitted]. The respondents do not dispute that [omitted] is widely used in western countries and is now considered a "standard of care" drug for [omitted]. Even though the respondent Minister did not issue an NOC for [omitted], the drug had been available in Canada [omitted] through Health Canada's Special

Access Programme (SAP). The SAP provides for the limited use of alternative drugs when conventional drugs have failed, and involves Health Canada's approval for each usage.

[5] In 2004, the applicant consulted with Health Canada about the prospects of the applicant supplying [omitted] in Canada. In the absence of an NOC for [omitted], Health Canada took the position that a regulatory submission filed by the applicant would have to be an NDS, not an Abbreviated NDS (ANDS). It was understood early on that the usual requirement for a clinical trial for [omitted] would be hard to satisfy. The applicant viewed clinical testing of [omitted] as unnecessary, [omitted]. In February of 2005, the parties met again to discuss how the applicant might satisfy the requirement of clinical trial data for [omitted].

[6] In May 2006, the parties met again. Despite the applicant's evidence regarding the safety and effectiveness of [omitted], Health Canada advised that it would not accept an NDS for [omitted] where evidence of safety and effectiveness was confined to literature submissions. The applicant alleges that during these consultations, Health Canada undertook to define criteria and specifications it would impose on [omitted] in lieu of requiring full independent clinical testing. In other words, the applicant alleges that Health Canada undertook to define, what I will refer to as an innovative NDS for [omitted].

[7] The applicant alleges that Health Canada reneged on its commitment in a letter dated August 17, 2006 wherein Health Canada reiterated that an NDS for [omitted] must contain independent clinical trial data. In the letter, Health Canada acknowledged the "unique clinical environment of [omitted]" and contemplated the submission of an innovative NDS, but explained

that due to proposed legislative changes, [omitted] the issuance of an NOC for the applicant's [omitted].

[8] Apparently, Health Canada was referring to the *Data Protection Regulation*, SOR/2006-241 (effective October 5, 2006) and its knowledge that the original owners of [omitted] would file an NDS soon after the Regulations come into force. The new Regulations would then prevent a generic NOC for eight years.

[9] Despite the view expressed by Health Canada, the applicant filed an NDS for [omitted] on October 27, 2006 on the strength of volumes of evidence available on the safety and efficacy of [omitted]. The package of literature attempted to satisfy all of Health Canada's substantial concerns.

Health Canada's Decision

[10] In a letter dated December 19, 2006, titled "Screening Rejection Letter", Health Canada rejected the applicant's NDS for [omitted] without prejudice to the applicant's ability to refile. After screening the applicant's material submitted, Health Canada determined that the NDS did not comply with the requirements of the Regulations.

[11] The Board began by noting that NDS approval requires compliance with section C.08.002 of the Regulations. The Board then noted that no pre-clinical or clinical data had been provided with the NDS and that only literature references and reports of postmarketing experience were provided.

[12] The Board noted that in previous consultations with the applicant, Health Canada had made it clear that independent clinical trials would be necessary.

Procedural History

[13] The applicant brought a motion to require the respondent Minister to produce documents which had been identified in a Rule 317 request for production. The motion was decided by the February 1, 2008 order of Prothonotary Aronovitch, who granted the motion in part, but limited production to documents that were relevant to the December 19, 2006 decision.

[14] The Prothonotary determined that Hospira could not seek to expand the grounds of the present judicial review, in order to collaterally attack the August 17, 2006 decision of the respondent Minister not to allow or define an innovative NDS. The Prothonotary held that the jurisprudence limits and defines documents that are relevant in a judicial review to the record that was before the decision maker at the time that he or she made the decision that is the subject of the judicial review. With regard to the applicant's request, she stated:

> The allegations of breaches of procedural fairness are invoked in respect of an extraneous manner, namely, the Minister's refusal to provide criteria. To the extent that the applicant wishes to rely on the Minister's refusal to do so, it has the wherewithal to establish the fact. The history and substance of the discussions, or the Minister's conduct in that connection however, are not relevant in the sense that they are extraneous to the relief sought and will not assist the Court in determining the propriety of the decision made on December 19, 2006.

[15] The applicant sought an order reversing the Prothonotary's order.

[16] In *Hospira Healthcare Corp. v. Canada (Attorney General)*, 2008 FC 355, [2008] F.C.J. No. 505 (QL) (*Hospira I*), Mr. Justice Beaudry refused to reverse the Prothonotary's order. Mr. Justice Beaudry agreed that the decision of August 17, 2006 was a previous decision which could not be collaterally attacked in the present judicial review. The applicant chose to review Health Canada's decision of December 19, 2006 which did not include any conclusions as to the safety and efficacy of [omitted]. The submission was rejected because no pre-clinical or clinical data was provided, and as such, the NDS did not meet the requirements of the Regulations.

Issues

[17] The applicant submitted the following issues for consideration:

1. What is the standard of review?

2. Is [omitted] a "new drug" within the meaning of section C.08.001 (a) of the Regulations?

3. Does section C.08.002 of the Regulations mandate the submission of clinical trial data as part of a New Drug Submission?

4. Was Health Canada's decision reasonable?

5. Did Health Canada breach its duty of procedural fairness to the applicant?

[18] The applicant's second issue bears no relation to the decision of December 19, 2006. Furthermore, *Hospira I* above, held that the applicant's fifth issue is extraneous to this judicial review. As such, I would rephrase the issues as follows:

1. What is the appropriate standard of review?

2. Does s. C.08.002 of the Regulations mandate the submission of clinical trial data as part of a New Drug Submission?

    a. If not, did the Minister fetter his discretion by strictly adhering to a policy of requiring clinical trial data?

3. Was Health Canada's decision reasonable?

4. Is *mandamus* available as a remedy?

Applicant's Written Submissions

[19] The applicant submits that section C.08.002 does not use the words "clinical trial data" or "pre-clinical". Rather, the section allows for flexibility, giving the Minister discretion to assess and determine whether the reports and evidence tendered are sufficient to establish safety and efficacy. In addition, section C.08.003 allows the Minister to ask for supplemental information.

[20] The applicant submits that when a decision maker is granted discretion, it cannot impede that discretion and then assert immunity from judicial review on the basis that its exercise of discretion is entitled to deference (see *Delisle v. Canada (Attorney General)*, 298 F.T.R. 1, [2006] F.C.J. No. 1230 (QL)).

[21] The applicant submits that Health Canada has interpreted section C.08.002 narrowly and as a matter of policy, requires clinical trial data regardless of the surrounding circumstances. A

decision maker cannot rely on guidelines or policy to sidestep its obligations to assess, on a case by case basis, relevant facts and circumstances. If this occurs, the decision maker has fettered his discretion (see *Delisle* above). Here, the summary rejection was a blinkered adherence to policy.

[22] The applicant submits that to be reasonable, there must be justification, transparency and intelligibility within the decision making process. The decision lacks justification because it was premised on the rigid application of policy.

[23] The applicant also submits that the decision appears to have been driven by a bureaucratic motivation to avoid creation of precedent of deviating from its policy. The applicant also alleges that Health Canada preferred to receive a submission from [omitted] original owners. Such internal strategic motives constitute an improper exercise of decision making power. While decisions based on administrative convenience may be rational, they fail to meet the standard of reasonableness (see *Canadian Union of Public Employees (C.U.P.E.) v. Ontario (Minister of Labour)*, 2003 SCC 29, [2003] 1 S.C.R. 539, [2003] S.C.J. No. 28 (QL)).

[24] The applicant submits that the decision also lacks intelligibility since Health Canada was aware that conventional clinical trials for [omitted] could not be ethically repeated. Requiring such clinical trials clearly contravenes the spirit and purpose of the Regulations, which is to protect the health and safety of the Canadian public.

[25] The applicant submits that the decision does not fall within the range of acceptable outcomes. This is because it has resulted in a monopoly in [omitted] for the original owners and has caused the price to double. The legislature could not have intended the Regulations to be interpreted and applied in a manner that would yield such a result. The framework of the Regulations allow three alternative courses of action that would have avoided this outcome: (i) review the NDS on a substantive basis and issue an NOC, (ii) review the NDS on its merits and issue an NOC with conditions (an NOC(C)) whereby the applicant would supply supplemental evidence of safety and efficacy, or (iii) review the NDS and provide cogent, specific and pragmatic criteria for the additional evidence required with respect to safety and efficacy and allow the applicant an opportunity to respond.

Respondents' Written Submissions

[26] The respondents reiterate that the only decision under review is the December 19, 2006 decision by the Minister to reject the applicant's NDS because clinical and pre-clinical data required by the Regulations were absent. This Court has already confirmed the narrow scope of this application for judicial review (See *Hospira I* above)

[27] The respondents do not agree that the Minister has as much discretion as the applicant suggests. In *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742, [1993] F.C.J. No. 1098 (C.A.) (QL); affirmed [1994] 3 S.C.R. 1100 (*Apotex*), the Minister's discretion under the Regulations was described as "narrowly circumscribed". The applicant here suggests that the

Minister may or should take into account in exercising his discretion, factors such as costs and competitive conditions, which are not related to safety and effectiveness and thus should not influence the Minister in determining how to exercise his narrowly circumscribed discretion.

[28] Subsections C.08.002(2)(g) and (h) clearly state that clinical tests are required to be made in respect of a new drug, and an NDS is required to contain information about those tests that satisfy the Minister that the new drug is safe and effective. The phrase in (h) “substantial evidence of the clinical effectiveness of the new drug” can only refer to data showing the results of clinical tests designed and conducted to demonstrate the drug’s effectiveness. The applicant’s NDS did not contain such information and accordingly it was rejected.

[29] The respondents submit that even if clinical data is not explicitly required by the legislation, the Minister’s determination that it is implicitly required certainly merits deference. The Minister is permitted to make determinations that fall within a range of acceptable outcomes. Requiring clinical tests is particularly reasonable since legislators specified that the information must be sufficient to enable the Minister to assess the drug’s safety and effectiveness. The applicant appears to acknowledge the correctness of the Minister’s interpretation of the legislative requirement. In particular, the applicant seeks to have the Court order the Minister to review its submission “for compliance with section C.08.002 (but excluding subsections (g) and (h))”.

[30] The respondents submit that the applicant has failed to satisfy the conditions for the granting of *mandamus*. Namely, the applicant failed to show that it has a clear right to the performance of a

public legal duty owed to the applicant at the time of the hearing. The applicant has not drawn the Court's attention to a single case in which *mandamus* has required the Minister to issue an NOC where the Minister was not satisfied that the drug was safe and effective. Nor has the applicant shown that the Minister owes any duty to conduct any review in accordance with specified conditions. Nothing in the legislation permits the Minister to overlook sections C.08.002(2)(g) and (h) as the applicant asks. An order of *mandamus* cannot compel an officer to act in a specified manner if he or she is not under an obligation to act as of the hearing date.

[31] The respondents finally submit that *mandamus* is above all a discretionary remedy and that a judge can refuse to grant *mandamus* where potential health and safety risks outweigh an individual's right to pursue personal or economic interests (*Apotex* above, at paragraph 101).

Analysis and Decision

[32] **Issue 1**

What is the appropriate standard of review?

The parties agree that the appropriate standard of review is reasonableness. There is a presumption that reasonableness will be the appropriate standard, especially where the issue is one of fact, discretion or policy. Deference will also be shown where the decision maker is interpreting and applying its own statute or statutes closely affected to its function (see *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190, [2008] S.C.J. No. 9 (QL), *Canada (Citizenship and Immigration) v. Khosa*, 2009 SCC 12, [2009] S.C.J. No. 12 (QL), at paragraph 25).

[33] Previous jurisprudence of this Court has found that decisions of Health Canada on questions of fact and the exercise of discretion falling within Regulations (Part C) are entitled to deference (see *Canadian Pharmaceutical Technologies International (C.P.T.) Inc. v. Canada (Attorney General)*, 2006 FC 708, [2006] F.C.J. No. 906 (QL) at paragraphs 11 to 17). Indeed, the safety and effectiveness of new drugs is an issue Parliament has confided to the Minister. Thus, reasonableness is the appropriate standard for both the Minister's interpretation of the Regulations as well as the Minister's ultimate decision regarding the applicant's NDS.

[34] **Issue 2**

Does section C.08.002 of the Regulations mandate the submission of clinical trial data as part of a New Drug Submission?

The Appropriate Scope of this Review

There is some dispute as to the scope of this judicial review. While the applicant wishes to review the decision of December 2006 rejecting its NDS, it also wishes to review Health Canada's prior determination that [omitted] was a "new drug" as defined by the Regulations. The applicant also implicitly attempts to collaterally attack Health Canada's decision of August 19, 2006 not to define specific criteria for the applicant's NDS for [omitted] and instead to revert to its standard policy of requiring independent clinical trials. The respondents argue that this application should be limited to a review of the decision made in December 19, 2006.

[35] In my opinion, the scope of this judicial review is properly confined to the December 19, 2006 decision. Indeed, this Court has already ruled on this matter in *Hospira I* where Mr. Justice

Beaudry upheld the Prothonotary's determination that documentation relating to Health Canada's August 17, 2006 decision, the safety and efficacy of the drug, and the drug's eligibility for the SAP was irrelevant to the December 19, 2006 decision. The Prothonotary stated:

> … having chosen to impugn one decision the applicant, in my view, cannot rely on the grounds of review to expand the scope of the decision, to graft other decisions on to it, or use the grounds of review of an impugned decision to collaterally attack another.
>
> …
>
> The allegations of breaches of procedural fairness are invoked in respect of an extraneous matter…

Although I am not bound by the prior decisions, I am in agreement with the decisions and I accept their conclusions.

[36] I turn now to the decision of December 19, 2006 (the NDS rejection). In the NDS rejection letter, Health Canada states that the NDS was rejected at the screening stage due to a failure on the applicant's part to comply with the Regulations. It then states that no pre-clinical or clinical data were included and that only literature submissions were included. It read in relevant part:

> In accordance with the *Management of Drug Submissions* guidance, Section 5.4.2, this is to notify you that the New Drug Submission, for [omitted] is considered rejected without prejudice to a refilling.
>
> After the screening of the information and material submitted, it has been determined that the submission does not comply with the requirements of the Food and Drug Regulations. The following issues or concerns have not been resolved:
>
> 1. … no pre-clinical or clinical data was provided…

[37] I will refer to the precise enactments relevant to this application. Part C of the *Food and Drug Regulations* deals with drugs. Section C.08.002 reads as follows:

> C.08.002. (1) No person shall sell or advertise a new drug unless
>
> (a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;
>
> (b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;
>
> (c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006; and
>
> (d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.
> (2) **A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following**:
>
> …
>
> (g) **detailed reports** of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;
>
> (h) **substantial evidence** of the **clinical effectiveness** of the new drug for the purpose and under the conditions of use recommended;
>
> …
>
> (my emphasis)

[38] The NDS rejection makes it clear that in Health Canada's view the Regulations require pre-clinical and clinical data to be submitted with an NDS. The respondent Minister maintains this

position and submits that even if the Regulations do not explicitly require pre-clinical and clinical data, they do so at least implicitly.

[39] In contrast, the applicant asserts that section C.08.002 does not require data from pre-clinical and clinical trials. Rather, an NDS need only contain, under C.08.002(2)(g), “detailed reports” of the tests made to establish safety and, under C.08.002(2)(h), “substantial evidence” of clinical effectiveness. The applicant argues that the plain words of the Regulations give the Minister a considerable degree of flexibility regarding what the Minister can accept as evidence of a new drug’s safety and effectiveness. It asserts that this grant of discretionary flexibility was improperly fettered by Health Canada’s policy of requiring pre-clinical and clinical data.

[40] No judicial consideration of the above sections was referred to by either the applicant or respondents.

[41] *Dunsmuir* above, teaches that the standard of reasonableness and the concept of deference extends to a tribunal’s interpretation of its constitutive or related enactments. In *Khosa* above, Mr. Justice Binnie enunciated this principle:

> [25] … *Dunsmuir* recognized that with or without a privative clause, a measure of deference has come to be accepted as appropriate where a particular decision had been allocated to an administrative decision maker rather than to the courts. This deference extended not only to facts and policy but to a tribunal's interpretation of its constitutive statute and related enactments because "there might be multiple valid interpretations of a statutory provision or answers to a legal dispute and that courts ought not to interfere where the tribunal's decision is rationally supported" (*Dunsmuir*, at para. 41). A policy of deference "recognizes the reality that, in many instances, those working day to

> day in the implementation of frequently complex administrative schemes have or will develop a considerable degree of expertise or field sensitivity to the imperatives and nuances of the legislative regime" (*Dunsmuir*, at para. 49, quoting Professor David J. Mullan, "Establishing the Standard of Review: The Struggle for Complexity?" (2004), 17 C.J.A.L.P. 59, at p. 93). …

[42] In regard to applying the reasonableness standard to a question of statutory interpretation Mr. Justice Binnie added:

> [44]… *Dunsmuir* (at para. 54), says that if the interpretation of the home statute or a closely related statute by an expert decision maker is reasonable, there is no error of law justifying intervention….
>
> (my emphasis)

[43] In my opinion, while the applicant's interpretation of the Regulations may have merit, the respondent Minister's view that pre-clinical and clinical data is implicitly required, is certainly a reasonable interpretation of the Regulations that falls within the range acceptable outcomes**.**

[44] The Minister's view that pre-clinical and clinical data are required is strengthened when one considers that the legislators specified that the information must be sufficient to allow the Minister to assess the safety and efficacy.

[45] Indeed, the applicant appears to acknowledge the reasonableness of the Minister's interpretation of the Regulations. In its notice of application, the applicant seeks to have this Court order the Minister to review its NDS "for compliance with section C.08.002 (but excluding subsections (g) and (h))". Clearly, the applicant seeks an exemption from what can be considered

the plain requirements of section C.08.002(2)(g) and (h), likely knowing that without such exemption, its NDS could not be considered satisfactory.

[46] Therefore, the impugned decision should stand and should not be interfered with on the application of the reasonableness standard to the Minister's interpretation of its home statute and related regulations.

[47] While this appeal can be disposed of on the determination that the Minister interpreted the Regulations reasonably, I will go on to examine the merits of the applicant's further arguments. In particular, I believe that the narrative of this case requires an analysis of the applicant's procedural concerns regarding the fettering of the Minister's discretion.

[48] Even if the Minister's interpretation that pre-clinical and clinical data are required is unreasonable, the Regulations at least allow the Minister the discretion to request that clinical data be provided with an NDS. The applicant asserts that the Minister fettered this discretion by requiring clinical data in all cases as a matter of policy, and without regard to the applicant's circumstances.

[49] Nonetheless, the applicant submits that when a decision maker is granted discretion, it cannot impede that discretion with a policy it treats as binding upon itself. If this occurs, the decision maker has fettered his discretion (see *Delisle* above).

[50] To state a general administrative principle, an administrative board or tribunal may not fetter the exercise of its statutory discretion by mechanically applying an internal policy. The issue is not whether the policy was a factor in the decision, but whether the decision maker treated the policy as binding or conclusive, without the need to consider any other factors, including whether or not it should apply to the unique circumstances of the particular case (See Brown, Donald J. M. and John M. Evans, "Judicial Review of Administrative Action in Canada", Toronto: Canvasback, 1998 (loose-leaf updated July 2008 at 12:44).

[51] In *Delisle* above, several patients sought to review a decision that a director under Health Canada's SAP had made. The decision implemented a change in policy, under which SAP's access to a particular drug would become phased out. Mr. Justice Lemieux held that the Regulations gave the director considerable discretion to issue authorizations for special access on a case by case basis. The new policy unlawfully fettered that discretionary power because, even though it would allow the access to the drug in certain circumstances, it did not allow for the consideration of humanitarian concerns and it effectively barred any new patients from accessing the drug. In Mr. Justice Lemieux's opinion, the implementation of a change in SAP policy was confined within the bounds of the balance Parliament had attempted to strike with the creation of the SAP program. (see *Delisle* at paragraph 173).

[52] In *Apotex Inc. v. Canada (Minister of Health)*, 2009 FC 452, [2009] F.C.J. No. 577 (QL) (*Apotex 2009*) Mr. Justice Phelan dealt with a similar issue. Apotex's ANDS for aspirin had been rejected by the Minister because the data from two of its clinical test subjects did not meet the

Minister's standards, reflected in Health Canada's guidelines. Apotex defended its drug, asserting that the defective reference drug caused the errors. One year later, on reconsideration, Health Canada confirmed the rejection. Apotex then charged that the Minister had fettered his discretion by rigidly adhering to his guidelines. Mr. Justice Phelan disagreed and held first that the published guidelines allowed for exceptions and second, that the Minister analyzed Apotex's submissions and specifically explained its concerns. At paragraph 35 he stated:

> It is not unreasonable, nor is it intransigence, for the Minister to demand compliance with the Guidelines in the absence of a clear indication that an alternative approach is required.

[53] In the present case, the record makes it apparent that the decision to require the applicant to provide clinical data (if clinical data was not required by the Regulations) was not made on December 19, 2006, but was made prior to Health Canada's letter issued on August 17, 2006. As discussed above, the applicant cannot attack the August 17, 2006 decision in this judicial review, because as noted in *Hospira I*, the August 17, 2006 and December 19, 2006 decisions were discrete and separate decisions.

[54] Even if the August 17, 2006 decision and the December 19, 2006 are viewed as being so intertwined as to be reviewed together, the claim that the Minister fettered his discretion cannot be accepted. It is clear from the record that, like *Apotex 2009* above, the particular circumstance of the applicant was considered extensively before the Minister finally decided that it would apply its policy to require clinical data. The applicant alleges that it was in consultations with Health Canada for 22 months to determine if alternative criteria could be accepted in its NDS. In the end, Health

Canada decided it would not define or accept such alternative criteria. It is not open for the applicant to now argue its particular circumstances were not taken into account, or that the Minister was legally obliged to make an exception.

[55] Nor was there a breach in procedural fairness since requiring clinical data was Health Canada's normal procedure, and the applicant was given explicit and sufficient notice that clinical data would be required, prior to the submission of its NDS.

[56] **Issue 3**

Was the respondent Minister's decision to reject the applicant's NDS reasonable?

The applicant argues the decision was unjustified because it relied on a rigid adherence to policy. In reality, the decision was based on the applicant's failure to comply with the Regulations, and is easily justified on that basis.

[57] The applicant argues that the decision lacked transparency because it was based on internal motives. This argument however refers to the August 17, 2006 decision, which again is not part of this review. The applicant has not discussed how the December 19, 2006 decision lacked transparency.

[58] The applicant argues the decision lacks intelligibility since Health Canada knew that requiring clinical data for [omitted] would be problematic. Again, this argument seeks to attack the August 17, 2006 decision to require clinical data for [omitted].

[59] Finally, the applicant argues that the decision falls outside the range of acceptable outcomes because it has resulted in the original owners of [omitted] getting a monopoly on the drug's distribution in Canada, causing the price to double.

[60] I do not find that this outcome is beyond the range of acceptability. While some aspects of monopolies are undesirable, Parliament, with the enactment of the *Food and Drug Regulations*, must have considered and accepted the possibility that some decisions of Health Canada could result in such monopolies.

[61] Because of my findings above, I need not deal with whether *mandamus* would have been available as a remedy.

[62] The application for judicial review is therefore dismissed, with costs to the respondents.

JUDGMENT

[63] **IT IS ORDERED that** the application for judicial review is dismissed, with costs to the respondents.

"John A. O'Keefe"
Judge

ANNEX

Relevant Statutory Provisions

The relevant statutory provisions are set out in this section.

The *Food and Drug Regulations*, C.R.C. c. 870, as amended:

C.08.002. (1) No person shall sell or advertise a new drug unless	C.08.002. (1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :
(a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;	a) le fabricant de la drogue nouvelle a, relativement à celle-ci, déposé auprès du ministre une présentation de drogue nouvelle ou une présentation abrégée de drogue nouvelle que celui-ci juge acceptable;
(b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;	b) le ministre a, aux termes de l'article C.08.004, délivré au fabricant de la drogue nouvelle un avis de conformité relativement à la présentation de drogue nouvelle ou à la présentation abrégée de drogue nouvelle;
(c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006; and	c) l'avis de conformité relatif à la présentation n'a pas été suspendu aux termes de l'article C.08.006;
(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a	d) le fabricant de la drogue nouvelle a présenté au ministre, sous leur forme définitive, des échantillons des étiquettes—y compris toute notice jointe à l'emballage, tout dépliant et toute fiche sur le produit—destinées à être utilisées pour la

statement setting out the proposed date on which those labels will first be used.

drogue nouvelle, ainsi qu'une déclaration indiquant la date à laquelle il est prévu de commencer à utiliser ces étiquettes.

(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :

(a) a description of the new drug and a statement of its proper name or its common name if there is no proper name;

a) une description de la drogue nouvelle et une mention de son nom propre ou, à défaut, de son nom usuel;

(b) a statement of the brand name of the new drug or the identifying name or code proposed for the new drug;

b) une mention de la marque nominative de la drogue nouvelle ou du nom ou code d'identification projeté pour celle-ci;

(c) a list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients;

c) la liste quantitative des ingrédients de la drogue nouvelle et les spécifications relatives à chaque ingrédient;

(d) a description of the plant and equipment to be used in the manufacture, preparation and packaging of the new drug;

d) la description des installations et de l'équipement à utiliser pour la fabrication, la préparation et l'emballage de la drogue nouvelle;

(e) details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the new drug;

e) des précisions sur la méthode de fabrication et les mécanismes de contrôle à appliquer pour la fabrication, la préparation et l'emballage de la

drogue nouvelle;

(f) details of the tests to be applied to control the potency, purity, stability and safety of the new drug;

f) le détail des épreuves qui doivent être effectuées pour contrôler l'activité, la pureté, la stabilité et l'innocuité de la drogue nouvelle;

(g) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;

g) les rapports détaillés des épreuves effectuées en vue d'établir l'innocuité de la drogue nouvelle, aux fins et selon le mode d'emploi recommandés;

(h) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;

h) des preuves substantielles de l'efficacité clinique de la drogue nouvelle aux fins et selon le mode d'emploi recommandés;

(i) a statement of the names and qualifications of all the investigators to whom the new drug has been sold;

i) la déclaration des noms et titres professionnels de tous les chercheurs à qui la drogue nouvelle a été vendue;

(j) a draft of every label to be used in conjunction with the new drug;

j) une esquisse de chacune des étiquettes qui doivent être employées relativement à la drogue nouvelle;

(k) a statement of all the representations to be made for the promotion of the new drug respecting

k) la déclaration de toutes les recommandations qui doivent être faites dans la réclame pour la drogue nouvelle, au sujet

(i) the recommended route of administration of the new drug,

(i) de la voie d'administration recommandée pour la drogue nouvelle,

(ii) the proposed dosage of the new drug,

(ii) de la posologie proposée pour la drogue nouvelle,

(iii) the claims to be made for the new drug, and

(iii) des propriétés attribuées à la drogue nouvelle,

(iv) the contra-indications and side effects of the new drug;

(iv) des contre-indications et les effets secondaires de la drogue nouvelle;

(l) a description of the dosage form in which it is proposed that the new drug be sold;

l) la description de la forme posologique proposée pour la vente de la drogue nouvelle;

(m) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and

m) les éléments de preuve établissant que les lots d'essai de la drogue nouvelle ayant servi aux études menées dans le cadre de la présentation ont été fabriqués et contrôlés d'une manière représentative de la production destinée au commerce;

(n) for a drug intended for administration to food-producing animals, the withdrawal period of the new drug.

n) dans le cas d'une drogue nouvelle destinée à être administrée à des animaux producteurs de denrées alimentaires, le délai d'attente applicable.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of a new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(3) Le fabricant de la drogue nouvelle doit, à la demande du ministre, lui fournir, selon ce que celui-ci estime nécessaire pour évaluer l'innocuité et l'efficacité de la drogue dans le cadre de la présentation de drogue nouvelle, les renseignements et le matériel suivants :

(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

a) les nom et adresse des fabricants de chaque ingrédient de la drogue nouvelle et les nom et adresse des fabricants de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(b) samples of the ingredients of the new drug;

b) des échantillons des ingrédients de la drogue nouvelle;

(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

c) des échantillons de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(d) any additional information or material respecting the safety and effectiveness of the new drug.

d) tout renseignement ou matériel supplémentaire se rapportant à l'innocuité et à l'efficacité de la drogue nouvelle.

FEDERAL COURT

SOLICITORS OF RECORD

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