Date: 20080703

Docket: A-486-07

Citation: 2008 FCA 227

CORAM: **LINDEN J.A.**
NADON J.A.
SEXTON J.A.

BETWEEN:

NU-PHARM INC.

Appellant

and

HER MAJESTY THE QUEEN IN RIGHT OF CANADA,
THE ATTORNEY GENERAL OF CANADA, and THE DIRECTOR
GENERAL, THERAPEUTIC PRODUCTS DIRECTORATE OFHEALTH CANADA

Respondents

Heard at Toronto, Ontario, on May 26, 2008.

Judgment delivered at Ottawa, Ontario, on July 3, 2008.

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: LINDEN J.A.
SEXTON J.A.

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REASONS FOR JUDGMENT

NADON J.A.

[1] This is an appeal from a decision of Hugessen J. of the Federal Court in *Nu-Pharm Inc. v. Canada*, 2007 FC 977, who, on a motion for summary judgment, dismissed the appellant's (the "appellant" or "Nu-Pharm") action for damages on the ground that the action did not raise a genuine issue for trial.

[2] More particularly, relying on this Court's decision in *Grenier v. Canada*, 2005 FCA 348, [2006] 2 F.C. 287 (CA), Hugessen J. concluded that since the relief sought by the appellant in its action was contingent upon a determination by the Federal Court that decisions made by the Director General of the Therapeutic Products Directorate of Health Canada (the "Director General") were unlawful and that such a determination could only be made if the decisions were challenged by way of a judicial review application, it necessarily followed that the appellant's action could not possibly succeed without such a prior determination. This led the learned Judge to make the following Order:

> THIS COURT ORDERS that
>
> 1. The motion is allowed and the action is dismissed.
>
> 2. Paragraph 1 of the present Order is stayed for a period of 30 days to allow the plaintiff to seek an extension of time to file an application for judicial review and if such extension is granted for a further period of time until such application is finally determined in the plaintiff's favour at which time either party may move to have the present judgment vacated. If the plaintiff fails to move timely for an extension, or if such extension is denied, or if the application is finally dismissed, the present stay shall end and the action shall stand dismissed.
>
> 3. The defendant is entitled to its costs which are hereby fixed and determined in the amount of $5,000 payable forthwith and in any event of the cause.

[3] As the appellant did not move for an extension of time to commence a judicial review application, its action was dismissed.

THE FACTS

[4] A brief review of the salient facts will be useful to a proper understanding of the appeal.

[5] On September 11, 1997, Nu-Pharm filed an Abbreviated New Drug Submission ("ANDS") with Health Canada seeking authorization to sell the drug NU-ENALAPRIL. As part of its submission, Nu-Pharm relied on a comparison with APO-ENALAPRIL, itself a generic version of a drug called VASOTEC produced by Merck and Co. ("Merck"). Health Canada refused to review Nu-Pharm's ANDS on the basis that it did not make reference to a valid Canadian Reference Product. This decision was overturned by Cullen J. of the Federal Court on November 19, 1998 (*Nu-Pharm v. Canada*, [1999] 1 F.C. 620).

[6] As a result of the Federal Court's decision, Health Canada reviewed Nu-Pharm's ANDS and, on February 25, 1999, issued a Notice of Compliance ("NOC") for NU-ENALAPRIL. This prompted Merck to apply for an Order quashing the NOC. On November 23, 1999, McGillis J. of the Federal Court concluded that the Minister of Health (the "Minister") had erred when he issued a NOC to Nu-Pharm for NU-ENALAPRIL. Accordingly, the Judge allowed Merck's application and prohibited the Minister from issuing a NOC to Nu-Pharm (*Merck v. Canada* (1999), 176 F.T.R. 21).

[7] Nu-Pharm appealed McGillis J.'s decision to this Court which, on March 13, 2000, dismissed the appeal (*Merck & Co. v. Nu-Pharm*, 2000 FCJ No 380 (CA)(QL)).

[8] On March 22, 2000, Nu-Pharm wrote to the Director General to advise him that it would be seeking a stay of this Court's decision and would also be seeking leave to appeal to the Supreme Court of Canada. On June 22, 2000, the Supreme Court dismissed Nu-Pharm's leave application ([2000] S.C.C.A. No. 185 (QL)).

[9] On March 31, 2000, the Director General replied to Nu-Pharm's letter advising it that, in his view, the NOC for NU-ENALAPRIL was invalid from the date of the Judgment of the Federal Court of Appeal and that

> Continued sale or advertisement of NU-ENALAPRIL by anyone is contrary to section C.08.002 of the "Food and Drug Regulations". This includes the distribution or dispensing of existing stock of the drug purchased from Nu-Pharm prior to the Judgment.

[10] On March 31, 2000, the Director General also wrote to the provincial drug benefit managers and Registers of Pharmacists, which letter was a follow-up to his letter to the provincial drug benefit managers of March 22, 2000. These letters read as follows:

> **1. Letter of March 22, 2000:**
>
> A recent judgment from the Federal Court of Appeal has affected the status of the Notice of Compliance (NOC) for Nu-Enalapril 2.5, 5, 10 and 20 mg tablets, issued on February 25, 1999.
>
> On March 13th, 2000, in Court File No. A-804-99, a decision was delivered by the Court which dismissed the appeal sought by Nu-Pharm of the trial division's decision in Court File No. T-398-99.
>
> Pursuant to the decision, the NOC for Nu-Enalapril is no longer valid. Consequently, the Nu-Enalapril products may no longer be sold or advertised pursuant to the NOC issued on February 25, 1999, subject to any further judicial consideration of the decision.

> **2. Letter of March 31, 2000:**
>
> …
>
> Unless a further judicial order is made to the contrary, the NOC for Nu-Enalapril is invalid from the date of issuance of the Judgment of the Court of Appeal, March 13, 2000. Continued sale or advertisement of Nu-Enalapril by anyone is contrary to section C.08.002 of the *Food & Drug Regulations*. This includes the distributing or dispensing of existing stock of the drug purchased from Nu-Pharm prior to the Judgment.
>
> The TPP has clarified the above interpretation with Nu-Pharm.
>
> [Emphasis added]

[11] Nu-Pharm again wrote to the Director General on April 3, 2000, to advise him that it was in total disagreement with the position which he had taken in his letters of March 22 and 31, 2000. More particularly, Nu-Pharm argued that since NU-ENALAPRIL was not a new drug, as defined in section C.08.001 of the *Food and Drug Regulations*, C.R.C c. 870 (the "Regulations"), a NOC was not required for the lawful sale thereof. Accordingly, Nu-Pharm's letter requested the Director General to signify his agreement with Nu-Pharm's position.

[12] Nu-Pharm further wrote to the Director General on April 10, 2000, pointing out that the Therapeutic Products Directorate's official Policy, enacted August 21, 1991, was to the effect that following the lapse of seven years after the initial date of marketing of a medicinal substance in Canada, a drug product containing that substance would no longer be regarded as a new drug and that "manufacturers were to determine for themselves what particular drug products were no longer New Drugs in accordance with the Policy". On that basis, Nu-Pharm submitted that it had determined that NU-ENALAPRIL was no longer a new drug and, accordingly, requested the

Director General to confirm his agreement with Nu-Pharm's view of the matter and that he would no longer seek to prohibit the sale of NU-ENALAPRIL.

[13] The Director General responded to Nu-Pharm's letters of April 3 and 10, 2000, by way of a letter dated April 14, 2000, in which he made it clear that he did not subscribe to Nu-Pharm's view with regard to the necessity of obtaining a NOC in order to sell NU-ENALAPRIL.

[14] By letter dated May 1, 2000, Nu-Pharm responded to the Director General's letter of April 14, 2000, outlining in some detail why, in its view, the position taken by him was incorrect.

[15] By letter dated June 28, 2000, Nu-Pharm wrote directly to the Minister, indicating that NU-ENALAPRIL was not a new drug and that if the Minister so treated it, such treatment would be discriminatory and unfair in view of the Department's prior practice under the Policy and the Regulations.

[16] On July 17, 2000, the Minister wrote to Nu-Pharm rejecting its view that NU-ENALAPRIL was not a new drug. Notwithstanding further letters from Nu-Pharm to the Minister, he refused to change his view regarding the treatment of NU-ENALAPRIL.

[17] As a result, Nu-Pharm commenced an application for judicial review on February 22, 2001, seeking the following orders:

(1) declaring that the Minister of Health had no authority to state that the sale of NU-ENALAPRIL contravenes the Regulations;

(2) declaring that the Minister of Health acted unlawfully in treating NU-ENALAPRIL as a "new drug"; and

(3) requiring the Minister of Health to retract all statements made to the effect that the sale of NU-ENALAPRIL was unlawful

[18] This application was followed, on February 12, 2002, by the filing of a Statement of Claim (subsequently amended on July 17, 2002) against a number of defendants, namely, Her Majesty the Queen, the Attorney-General of Canada and the Director General, seeking the following relief:

> (1) an Order enjoining the Director-General… from publishing any statements which expressly or impliedly advise that the sale of Nu-Enalapril tablets is unlawful;
>
> (2) a mandatory Order requiring the Director-General… to retract any and all statements made to provincial regulatory authorities… which advise that the sale of NU-ENALAPRIL tablets is unlawful; and
>
> (3) damages from the Defendant, Her Majesty the Queen in Right of Canada on behalf of the Government of Canada, for:
>
> i. the misfeasance, abuse of authority, and illegal interference with Nu-Pharm's economic interests in unlawfully advising provincial regulatory authorities, third party pharmacists, distributors of pharmaceutical products, public and private insurers and others persons that the sale of Nu-Enalapril tablets is unlawful;
>
> ii. gross negligence, or in the alternative, negligence, and blatant disregard for the *Food and Drug Regulations* ("*Regulations*") and the limits of the delegated statutory authority the Director-General is permitted to exercise in (i) purporting to make a legal determination regarding the marketability of Nu-Pharm tablets that the Director-General had no authority to make, (ii) unlawfully acting on that invalid "determination" by advising provincial regulatory authorities,

> third party pharmacists, distributors of pharmaceutical products, public and private insurers and other persons that the sale of Nu-Enalapril tablets is unlawful; (iii) refusing to review or consider the objective evidence which demonstrated that the sale of Nu-Enalapril tablets was and is not unlawful, and (iv) assuming the Director-General had the legal authority to determine the marketability of Nu-Enalapril tablets, arbitrarily purporting to do so without giving any *bona fide* consideration to the evidence, and discriminatorily denying natural justice and procedural fairness to Nu-Pharm by purporting to make that determination, and advising provincial regulatory authorities, third party pharmacists, distributors of pharmaceutical products, public and private insurers and other persons that the sale of Nu-Enalapril tablets is unlawful, without first affording Nu-Pharm the process and the opportunity to present evidence demonstrating that the sale of Nu-Enalapril tablets was and is not unlawful;
>
> (see paragraph 1 of the Amended Statement of Claim)

[19] On June 24, 2002, Nu-Pharm filed a Notice of Discontinuance of its judicial review application.

[20] As appears from the relief sought by Nu-Pharm in paragraph 1 of its Amended Statement of Claim, the essence of its action is that the Minister, through his delegate, the Director General, has acted unlawfully and without authority in declaring the sale of NU-ENALAPRIL to be unlawful and in refusing to withdraw that statement. Further, Nu-Pharm says that the Minister has refused to acknowledge that NU-ENALAPRIL is not a new drug and that he has published statements declaring that the sale of NU-ENALAPRIL tablets would contravene the Regulations. At paragraphs 24 to 26 of its Amended Statement of Claim, Nu-Pharm makes the following arguments::

> 24. These statements [contained in the Director-General's letters of March 22 and 31, 2000] were published wilfully and recklessly, knowing that the Minister had no authority to issue them, and were made with the intention of causing consequential damage to Nu-Pharm. The Director-General failed to even advert to whether Nu-Enalapril was a New Drug before issuing these statements, and afforded Nu-Pharm no opportunity to advise him that it was in fact an old drug. Even if the Director-General had the authority to make a determination regarding the status of Nu-Enalapril, which is denied, and to issue a public declaration based on any such determination, which is denied, he was grossly negligent in doing so in these circumstances, since he would not have purported to make any such determination and would not have issued the statements had he objectively and *bona fide* considered the status of Nu-Enalapril before doing so.
>
> 25. The Director-General intended these statements to damage Nu-Pharm because he knew that, as a consequence of publishing the statements, the provincial regulatory bodies responsible for administering their respective interchangeability programs would proceed to de-list Nu-Enalapril tablets, and that, as a result, pharmacists would no longer dispense Nu-Enalapril tablets in substitution for any other drug product containing the active medicinal substance enalapril. Similarly, as a consequence of these statements, public and private insurers would no longer reimburse patients for any purchase of Nu-Enalapril.
>
> 26. The Director-General knew and intended that, as a consequence of all of the foregoing, not only would Nu-Pharm fail to receive any new orders for its Nu-Enalapril tablets, but pharmaceutical distributors, wholesalers and individual pharmacists would return any existing stock of the drug held in their respective inventories. The Director-General knew that Nu-Pharm would suffer severe consequential damage as a result of such lost sales and the return of trade inventories and because much of its own inventory of Nu-Enalapril tablets would soon become stale-dated and hence unsaleable.

[21] Thus, Nu-Pharm takes the position that the Director General did not have lawful authority to decide that the marketing of NU-ENALAPRIL was unlawful in the absence of a NOC and to make his view of the matter known to others, i.e. the provincial drug benefit managers and registers of pharmacists. On that premise, Nu-Pharm submits that it is entitled to damages as compensation for the profits it would have otherwise made by marketing NU-ENALAPRIL.

[22] On April 13, 2007, the respondents filed a Notice of Motion for summary judgment seeking the dismissal of Nu-Pharm's action on the ground that since the decisions of the Director General, namely, by way of his letters dated March 22 and March 31, 2000, were decisions of "a federal board, commission or other tribunal" ("federal board"), the orders sought by Nu-Pharm, i.e. enjoining the Director General from making further statements regarding the sale of NU-ENALAPRIL and requiring him to retract earlier statements regarding the sale of NU-ENALAPRIL, were remedies which could only be obtained by way of an application for judicial review under sections 18 and 18.1 of the *Federal Courts Act*.

[23] Hence, in the respondents' view, Nu-Pharm was prevented from seeking damages in its action without a prior order invalidating the Director General's decisions. Accordingly, since Nu-Pharm had not obtained such an order, the Federal Court was without jurisdiction to grant the relief in damages sought by Nu-Pharm.

[24] As I indicated earlier, Hugessen J., on September 28, 2007, allowed the motion for summary judgment and dismissed Nu-Pharm's action. Of relevance to this appeal is paragraph 16 of the learned Judge's Reasons where, after reviewing both the relief sought by Nu-Pharm in its Amended Statement of Claim and the relief which it had sought in its judicial review proceedings, he opined that the relief for damages sought by Nu-Pharm in its action was "entirely dependant upon the plaintiff showing the unlawful character of the Director General's decisions". For the sake of completeness, I reproduce paragraph 16 in its entirety:

> 16. In my view the obtaining of the damages claimed in paragraph 1(c) of the amended statement of claim above is entirely dependant upon the plaintiff showing the unlawful

> character of the Director-General's decisions which are the subject of the reliefs claimed in the two preceding paragraphs. There is no difference other than one of form in the claims for declaratory relief in the judicial review application and the claim for injunctive relief in the action. The addition of an allegation of negligence, gross or not, in the action cannot be divorced from the allegation that the Director-General acted unlawfully. Unless and until the Director-General's actions are found to be unlawful the plaintiff has no claim in either proceeding. The holding in *Grenier* makes it plain that the plaintiff must proceed by way of judicial review. It is simply not open to this Court, as plaintiff seems to suggest, that the scope and reach of *Grenier* should be restricted to a far narrower field than what was very clearly stated by the Court of Appeal.
>
> [Emphasis added]

ISSUES

[25] The appellant submits that the appeal raises the following issues (see para. 34 of the Appellant's Memorandum):

(a) **Issue One**: Does the *Grenier* decision stand for the proposition that *all* civil causes of action against the *Crown*, regardless of the relief sought, must be preceded by a predicate application of judicial review, to determine the "unlawful" character of those government actions?

(b) **Issue Two**: If the answer to the first question is "no", does the reasoning in *Grenier* warrant the dismissal of this proceeding?

(c) **Issue Three**: If the answer to the first question is "yes", was *Grenier* wrongly decided?

[26] The respondents submit that the appellant has not correctly stated the issues. With respect to the first issue, the respondents say: "Stated as such, this issue is far more broad than any issue raised here. This case obviously does not require consideration of '*all* civil causes of action against the *Crown*, regardless of the relief sought …'". With respect to the second issue, they make the following comment: "As noted, the 'first question' need not be answered as formulated. In any

event, the reasoning in *Grenier* does warrant the dismissal of this proceeding". Finally, with respect to the third issue, they say: "As noted, the 'first question' need not be answered as formulated. Further, as will be discussed below, this Court will not overrule a prior decision of this Court merely because it considers it 'wrongly decided'; more must be shown" (see para. 20 of the Respondents' Memorandum).

[27] I agree with the respondents that the first issue has been stated too broadly by the appellant. In my view, the true issue which arises in this appeal is whether the learned Motions Judge was correct in his determination that the remedy of damages sought by the appellant in its action was contingent upon a determination that the Director General's "decisions" were unlawful and that such determination could only be made by way of a judicial review. Underlying that issue is whether the Director General's letters of March 22 and 31, 2000 constitute decisions of a federal board and whether the Judge properly understood and applied this Court's decision in *Grenier, supra*.

ANALYSIS

[28] Before addressing these issues, I must point out that the appellant did not before us attempt to persuade us that *Grenier, supra,* had been wrongly decided. Rather, the appellant argued that the Motions Judge has misconstrued *Grenier, supra,* "giving it a legal scope and impact that it does not have" (see the Appellant's Memorandum, para. 50).

[29] I begin my analysis with this Court's decision in *Grenier, supra*. On June 13, 2008, in *The Minister of Citizenship & Immigration v. Alan Hinton and Irina Hinton*, 2008 FCA 215, this Court had occasion to take a close look at *Grenier, supra*. At paragraphs 40 to 42 of his Reasons for the Court, Sexton J.A., under the heading "A Review of *Grenier*: What it Does and Does Not Stand For", wrote the following:

> [40] The case of *Grenier* concerned an action brought by an inmate seeking damages for administrative and disciplinary segregations he faced while serving time in a maximum security penitentiary. The inmate had not sought a judicial review of the Institutional Head's decision, even though he knew or ought to have known of the effect of the decision upon him personally and knew or ought to have known that judicial review was available to him if he wished to challenge the decision. Following this Court's decision in *Tremblay v. Canada* (2004) 244 D.L.R. (4th) 422 (F.C.A.), leave to appeal to S.C.C. refused (file: 30424**),** Justice Létourneau concluded that a litigant who seeks to impugn a federal agency's decision is not free to choose between a judicial review proceeding and an action in damages but must rather proceed by judicial review in order to have the decision invalidated. According to Grenier, to assert such a claim as an action as opposed to an application for judicial review would constitute a collateral attack on the original decision in light of section 18 of the *Federal Courts Act*.
>
> [41] Justice Létourneau explained the rationales and importance of the exclusive jurisdiction outlined in section 18 of the Federal Courts Act at paragraphs 24-6:
>
> > In creating the Federal Court and in enacting section 18, Parliament sought to put an end to the existing division in the review of the lawfulness of the decisions made by federal agencies. At the time, this review was performed by the courts of the provinces: see Patrice Garant, *Droit administratif*, 4th ed., vol. 2 (Les Éditions Yvon Blais Inc., 1996), at pages 11 to 15. Harmonization of disparities in judicial decisions had to be achieved at the level of the Supreme Court of Canada. In the interests of justice, equity and efficiency, subject to the exceptions in section 28, Parliament assigned the exercise of reviewing the lawfulness of the decisions of federal agencies to a single court, the Federal Court. This review must be exercised under section 18, and only by filing an application for judicial review. The Federal Court of Appeal is the court assigned to ensure harmonization in the case of conflicting decisions, thereby relieving the Supreme Court of Canada of a substantial volume of work, while reserving it the option to intervene in those cases that it considers of national interest.
> >
> > To accept that the lawfulness of the decisions of federal agencies can be reviewed through an action in damages is to allow a remedy under section 17. Allowing, for that purpose, a remedy under section 17 would, in the

> first place, disregard or deny the intention clearly expressed by Parliament in subsection 18(3) that the remedy must be exercised only by way of an application for judicial review. The English version of subsection 18(3) emphasizes on the latter point by the use of the word "only" in the expression "may be obtained only on an application for judicial review".
>
> It would also judicially reintroduce the division of jurisdictions between the Federal Court and the provincial courts. It would revive in fact an old problem that Parliament remedied through the enactment of section 18 and the granting of exclusive jurisdiction to the Federal Court and, in the section 28 cases, the Federal Court of Appeal. It is precisely this legislative intention that the Quebec Court of Appeal recognized in the *Capobianco* case, *supra*, in order to preclude the action in damages filed in the Superior Court of Québec attacking the lawfulness of the decisions of federal boards, commissions or other tribunals from leading, in fact and in law, to a dysfunctional dismemberment of federal administrative law.

The respondents emphasize – and I agree – that one of the primary concerns of this Court in *Grenier* was also that an action should not be used as a way to circumvent the procedural requirements and limitation periods outlined in section 18 of the *Federal Courts Act*. Such concerns are of no relevance in this proceeding as the respondents – after the Federal Court's decision of *Momi* – correctly commenced this proceeding by way of an application for judicial review.

[42] *Grenier* simply stands for the proposition that certain civil actions against the Crown must be preceded by an application of judicial review where the basis for the claim is a challenge to the lawfulness, *vires* or legality of the federal board or tribunal's decision.

[Emphasis added]

[30] Thus, *Grenier, supra*, is to the effect that because decisions of a federal board can only be challenged by way of a judicial review application commenced pursuant to sections 18 and 18.1 of the *Federal Courts Act*, any action which seeks a relief in damages on the premise that such decisions are unlawful will not be allowed to proceed unless the decisions have been challenged by way of a judicial review application. Conversely, if the action does not seek to challenge the validity

or lawfulness of a decision of a federal board, the action will be allowed to proceed and to run its course.

[31] That, in my view, is what *Grenier, supra*, stands for and the question which must be asked and answered in order to dispose of the appeal is whether the appellant, by its action, seeks to challenge the lawfulness of a decision rendered by a federal board. The determination of that question requires that we answer two other questions, namely, whether the decisions of the Director General constitute decisions of a federal board and whether Nu-Pharm's action constitutes a collateral attack on or an indirect challenge to the decisions of a federal board.

[32] I therefore turn to the question of whether the Director General's letters of March 22 and 31, 2000 are decisions of a federal board. Section 2(1)*(h)* of the *Federal Courts Act* defines the expression "federal board, commission or other tribunal" as follows:

> "federal board, commission or other tribunal" means any body, person or persons having, exercising or purporting to exercise jurisdiction or powers conferred by or under an Act of Parliament or by or under an order made pursuant to a prerogative of the Crown, other than the Tax Court of Canada or any of its judges, any such body constituted or established by or under a law of a province or any such person or persons appointed under or in accordance with a law of a province or under section 96 of the *Constitution Act, 1867*.
>
> « office fédéral » - Conseil, bureau, commission ou autre organisme, ou personne ou groupe de personnes, ayant, exerçant ou censé exercer une compétence ou des pouvoirs prévus par une loi fédérale ou par une ordonnance prise en vertu d'une prérogative royale, à l'exclusion de la Cour canadienne de l'impôt et ses juges, d'un organisme constitué sous le régime d'une loi provinciale ou d'une personne ou d'un groupe de personnes nommées aux termes d'une loi provinciale ou de l'article 96 de la *Loi constitutionnelle de 1867*.
>
> [Emphasis added] [Non souligné dans l'original]

[33] As the summary of the facts and Nu-Pharm's pleadings clearly reveal, Nu-Pharm argues that because the Minister's delegate, the Director General, did not have lawful authority to determine that the marketing of NU-ENALAPRIL was unlawful in the absence of a NOC, nor did he have lawful authority to make known his decision to others, it is entitled to damages as compensation for the profits which it has been deprived of due to its inability to market NU-ENALAPRIL.

[34] Subsection C.08.002(1) of the Regulations prohibits the sale or advertising of a new drug unless the Minister has issued, in accordance with section C.08.004, a NOC to the manufacturer thereof. Section C.08.002(1) 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. [Emphasis added]	**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)* 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)* 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)* l'avis de conformité relatif à la présentation n'a pas été suspendu aux termes de l'article C.08.006; *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 drogue

> nouvelle, ainsi qu'une déclaration indiquant la date à laquelle il est prévu de commencer à utiliser ces étiquettes.
>
> [Non souligné dans l'original]

[35] Although Nu-Pharm has indeed filed with the Minister an ANDS, it is without a valid NOC as a result of this Court's decision of March 13, 2000. By reason thereof, the Director General has taken the position and has so advised Nu-Pharm and others that the sale or advertising of NU-ENALAPRIL is contrary to section C.08.002 of the Regulations.

[36] In my view, the decisions of the Director General which Nu-Pharm initially challenged in its judicial review application and, subsequently, in its action for damages before the Federal Court, clearly constitute decisions rendered by a federal board as that expression is defined in subsection 2(1)*(h)* of the *Federal Courts Act*. I am satisfied that in declaring that, in the absence of a valid NOC, no one could sell or advertise NU-ENALAPRIL and in making his decision known both to Nu-Pharm and to others, the Director General was "… exercising or purporting to exercise jurisdiction or powers conferred by or under an Act of Parliament or by or under an order made pursuant to a prerogative of the Crown, …".

[37] I now turn to the question of whether or not Nu-Pharm's action constitutes a collateral attack on or an indirect challenge to the decisions rendered by the Director General. In my view, there can be no doubt whatsoever that that question must be answered in the affirmative. In other words, I am of the opinion that the success of Nu-Pharm's action in damages, in the words of Hugessen J. found

at paragraph 16 of his Reasons, "… is entirely dependant upon the plaintiff [Nu-Pharm] showing the unlawful character of the Director General's decisions …".

[38] As a result, sections 18 and 18.1 of the *Federal Courts Act* come into play. The relevant portions of these provisions read as follows:

18. (1) Subject to section 28, the Federal Court has exclusive original jurisdiction (a) to issue an injunction, writ of certiorari, writ of prohibition, writ of *mandamus* or writ of *quo warranto*, or grant declaratory relief, against any federal board, commission or other tribunal; and (b) to hear and determine any application or other proceeding for relief in the nature of relief contemplated by paragraph (a), including any proceeding brought against the Attorney General of Canada, to obtain relief against a federal board, commission or other tribunal.	**18.** (1) Sous réserve de l'article 28, la Cour fédérale a compétence exclusive, en première instance, pour : a) décerner une injonction, un bref de *certiorari*, de *mandamus*, de prohibition ou de *quo warranto*, ou pour rendre un jugement déclaratoire contre tout office fédéral; b) connaître de toute demande de réparation de la nature visée par l'alinéa a), et notamment de toute procédure engagée contre le procureur général du Canada afin d'obtenir réparation de la part d'un office fédéral.
…	[…]
(3) The remedies provided for in subsections (1) and (2) may be obtained only on an application for judicial review made under section 18.1.	(3) Les recours prévus aux paragraphes (1) ou (2) sont exercés par présentation d'une demande de contrôle judiciaire.
18.1 (1) An application for judicial review may be made by the Attorney General of Canada or by anyone directly affected by the matter in respect of which relief is sought.	**18.1** (1) Une demande de contrôle judiciaire peut être présentée par le procureur général du Canada ou par quiconque est directement touché par l'objet de la demande.
(2) An application for judicial review in respect of a decision or an order of a federal board, commission or other tribunal shall be made within 30 days after the time	(2) Les demandes de contrôle judiciaire sont à présenter dans les trente jours qui suivent la première communication, par l'office fédéral, de sa décision ou de son

the decision or order was first communicated by the federal board, commission or other tribunal to the office of the Deputy Attorney General of Canada or to the party directly affected by it, or within any further time that a judge of the Federal Court may fix or allow before or after the end of those 30 days.	ordonnance au bureau du sous-procureur général du Canada ou à la partie concernée, ou dans le délai supplémentaire qu'un juge de la Cour fédérale peut, avant ou après l'expiration de ces trente jours, fixer ou accorder.

[39] Section 18 clearly provides that the Federal Court has exclusive original jurisdiction with respect to the granting of declaratory reliefs against any federal board and that such remedies can only be obtained by way of an application for judicial review made under section 18.1 which, in turn, provides that such an application must be commenced within 30 days of the decision sought to be challenged.

[40] Consequently, I am satisfied that this Court's pronouncement in *Grenier, supra*, finds full application in the present matter and that, as a result, Nu-Pharm cannot avoid sections 18 and 18.1 of the *Federal Courts Act*. In other words, Nu-Pharm cannot bypass the requirement that if it seeks to challenge the decisions of the Director General, it must do so by commencing an application for judicial review. I again reproduce the remarks of Létourneau J.A. found at paragraphs 25 and 26 of his Reasons in *Grenier, supra*:

> [25] To accept that the lawfulness of the decisions of federal agencies can be reviewed through an action in damages is to allow a remedy under section 17. Allowing, for that purpose, a remedy under section 17 would, in the first place, disregard or deny the intention clearly expressed by Parliament in subsection 18(3) that the remedy must be exercised only by way of an application for judicial review. The English version of subsection 18(3) emphasizes on the latter point by the use of the word "only" in the expression "may be obtained only on an application for judicial review".

> [26] It would also judicially reintroduce the division of jurisdictions between the Federal Court and the provincial courts. It would revive in fact an old problem that Parliament remedied through the enactment of section 18 and the granting of exclusive jurisdiction to the Federal Court and, in the section 28 cases, the Federal Court of Appeal. It is precisely this legislative intention that the Quebec Court of Appeal recognized in the *Capobianco* case, supra, in order to preclude the action in damages filed in the Superior Court of Québec attacking the lawfulness of the decisions of federal boards, commissions or other tribunals from leading, in fact and in law, to a dysfunctional dismemberment of federal administrative law.

[41] I therefore conclude that in allowing the respondents' motion for summary judgment, Hugessen J. made no error of law nor did he misconstrue or mischaracterize the evidence before him. More particularly, Hugessen J. correctly understood and applied this Court's decision in *Grenier, supra*. It is my view that the reasons given by the learned Judge in reaching his conclusion are, in the circumstances of this case, unassailable.

DISPOSITION

[42] For these reasons, I would dismiss the appeal with costs.

"M. Nadon"

J.A.

"I agree.
A.M. Linden J.A."

"I agree.
J. Edgar Sexton J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-486-07
(APPEAL FROM THE ORDER OF THE FEDERAL COURT IN COURT FILE DOCKET NO. T-227-02.)	
STYLE OF CAUSE:	NU-PHARM INC. v. HER MAJESTY THE QUEEN et al
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	MAY 26, 2008
REASONS FOR JUDGMENT BY:	NADON J.A.
CONCURRED IN BY:	LINDEN J.A. SEXTION J.A.
DATED:	July 3, 2008

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