Date: 20070928

Docket: T-227-02

Citation: 2007 FC 977

Ottawa, Ontario, September 28, 2007

PRESENT: The Honourable Mr. Justice Hugessen

BETWEEN:

NU-PHARM INC.

Plaintiff

and

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

Defendants

REASONS FOR ORDER AND ORDER

INTRODUCTION

[1] This is a summary judgment motion brought by the defendant Crown. It seeks the dismissal of the plaintiff's action for damages on the ground that the plaintiff's whole case is contingent upon the Court's making a finding that certain decisions by the Director-General were illegal and that, in accordance with the decision of the Federal Court of Appeal in the case of *Grenier v. Canada*, 2005 FCA 348 such a finding can only be made in an application for judicial review, not in an action. The difficulty presented by the motion is not to know whether or not the plaintiff's action is fatally flawed for it clearly is, but rather whether it can be saved, and if so, how.

FACTS

[2] On September 11, 1997, the plaintiff filed an abbreviated new drug submission (ANDS) for Nu-Enalapril, relying on a comparison with Apo-Enalapril, itself a generic of Merck's Vasotec. Health Canada refused to review the plaintiff's ANDS on the basis that, since it referred to a generic drug, it did not make reference to a valid Canadian Reference Product. Without notifying Merck, the plaintiff applied for judicial review of this decision, and Health Canada's decision was quashed (*Nu-Pharm v. Canada*, [1999] 1 F.C. 620 1721 (T.D.)).

[3] On February 25, 1999, Health Canada issued the Notice of Compliance (NOC) for Nu-Enalapril. However, on March 5, 1999, Merck applied to have Health Canada's decision quashed. The Federal Court granted Merck's application, and this decision was upheld on appeal on March 13, 2000, on the basis that the plaintiff had to comply with the requirements of section 5 of the *Patented Medicine (Notice of Compliance) Regulations* (*Merck v. Canada* (1999), 176 F.T.R. 21 (T.D.), aff'd (2000), 254 N.R. 68 (F.C.A.)).

[4] On March 22, 2000, the Director-General sent a letter to Provincial Drug Benefit Managers advising them that the NOC for Nu-Enalapril was no longer valid and that:

> 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.

[5] On March 31, 2000, the Director-General sent another letter to Provincial Drug Benefit Managers and Colleges/Registrars of Pharmacists stating that the NOC for Nu-Enalapril was invalid from the date of the Court of Appeal's judgment. This letter also stated that:

> Continued sale or advertisement of Nu-Enalapril by anyone is contrary to section C.08.002 of the *Food and Drugs Regulations.* This includes the distributing or dispensing of existing stock of the drug purchased from Nu-Enalapril prior to the Judgment.

[6] On April 3, 2000, the plaintiff sent a letter to the Director-General alleging that Nu-Enalapril is not a 'new drug' and therefore no NOC is required for it to be sold. However, the Director-General, after receiving the plaintiff's representations over the course of several months, determined that there was no reason to change the conclusion that Nu-Enalapril could not be sold without a valid NOC.

[7] On February 22, 2001, the plaintiff filed an application for judicial review of this decision, in file number T-315-01, seeking a declaration that the Minister had no authority to state that the sale of Nu-Enalapril would be in contravention of the *Food and Drugs Regulations*, that the Minister acted unlawfully in treating Nu-Enalapril as a 'new drug', and requiring the Minister to retract all statements to the effect that the sale of Nu-Enalapril was 'unlawful'. On February 12, 2002, the plaintiff filed the present statement of claim. On June 24, 2002, after Merck had been granted leave to intervene, the plaintiff filed a notice of discontinuance of the judicial review application.

[8] The plaintiff claims that Enalapril drugs have been approved for more than seven years. It also submits that it knows of no other case where a contested revocation of an NOC on patent grounds has been sustained, or where the Director-General has made such a communication to others. It further states that it discontinued the judicial review after the addition of Merck as an intervenor because this slowed the application down considerably and Nu-Pharm's damages were increasing. Nu-Pharm says it sought other ways to deal with the Director-General's decision by combining the judicial review into an action or staying the judicial review, but on June 26, 2002, counsel for the Director-General informed the plaintiff that "it is our view that the particular circumstances surrounding the two proceedings are such that it would not be appropriate to consolidate them".

ISSUES

[9] The defendant submits that the relief the plaintiff seeks in this action is inextricably linked to its allegations of unlawful conduct by the Director-General. In particular, the plaintiff's claim is that the Director-General had no authority to make the determination that marketing Nu-Enalapril in the absence of an NOC was unlawful, or to communicate that decision to others.

[10] In the defendant's submission jurisdiction to review decisions such as those of the Director-General has been granted exclusively to the Federal Court and only through section 18 of the *Federal Courts Act* (*Canada v. Grenier*, [2006] 2 F.C.R. 287 (C.A.) ; *Canada v. Tremblay*, [2004] 4 F.C. 165 (C.A)). To allow the plaintiff to proceed by way of an action would be to disregard

Parliament's clearly expressed intention in subsection 18(3) of the *Federal Courts Act* that remedies such as orders binding on the Director-General must be exercised only by way of judicial review.

[11] Although it disputes the applicability of *Grenier*, above, the plaintiff clearly understood from the beginning that the impugned decisions of the Director-General could and should be attacked by way of judicial review for that is exactly what it did. The issue is to know what the legal consequence of all this should be and whether it can be put to rights.

DISCUSSION

[12] It is obvious that the plaintiff's difficulties arise from its own deliberate decisions to institute the present action seeking substantially the same relief as it had already claimed in the judicial review application together with damages, and then subsequently to discontinue that application altogether.

[13] To appreciate the substantive identity between the present action and the judicial review application it is enough to read the plaintiff's own pleadings.

[14] This is the operative part of the relief claimed in the application for judicial review of February 2001:

> **THE APPLICANT, NU-PHARM INC. ("NU-PHARM"), MAKES APPLICATION FOR:**
>
> 1. An Order declaring that the Respondent, Minister of Health, and his delegates (collectively the "Minister") had and have no lawful authority to declare that the sale or

advertisement of Nu-Pharm's cardiovascular medication, Nu-Enalapril tablets, is contrary to section C.08.002 of the *Food & Drug Regulations* or is otherwise unlawful;

2. An Order declaring that, in purporting to treat Nu-Enalapril as a New Drug under section C.08.001 of the *Food & Drug Regulations*, the Minister has acted and continues to act without lawful authority and in an unfair, discriminatory, arbitrary and irrational fashion;

3. An Order requiring the Minister to retract all statements that the sale of Nu-Enalapril tablets is unlawful.

[15] The amended statement of claim in the present action claims relief as follows:

1. The Plaintiff, Nu-Pharm Inc. ("Nu-Pharm"), claims:

(a) an Order enjoining the Director-General of the Therapeutic Products Directorate of Health Canada ("TPD"), or any other Crown servant, from publishing any statements which expressly or impliedly advise that the sale of Nu-Enalapril tablets is unlawful;

(b) a mandatory Order requiring the Director-General of the TPD to retract any and all statements made to provincial regulatory authorities, third party pharmacists, distributors of pharmaceutical products, public and private insurers and any other person, which advise that the sale of Nu-Enalapril tablets is unlawful;

(c) 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 other

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 due process and the opportunity to present evidence demonstrating that the sale of Nu-Enalapril tablets was and is not unlawful;

[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.

[17] Foreseeing, as is in fact the case, that the Court was virtually bound to find its action to be fatally flawed by its failure to maintain its application for judicial review, the plaintiff now seeks alternative remedies either by reviving its discontinued judicial review application, obtaining an extension of time to start a new application, or converting the present action into a judicial review and then in turn converting the latter into an action pursuant to subsection 18.4(2) of the *Federal Courts Act*.

[18] In support of its claim for this alternative relief the plaintiff relies on the affidavit of its own solicitor which is the only evidence filed by it on the present motion.

[19] That affidavit is improper in several respects. The deponent is the partner of counsel who appeared and pleaded the motion on behalf of the plaintiff. Worse, the affidavit is tendentious and

argumentative in the extreme; it goes far beyond merely formal matters or the simple production of documents. On those grounds alone I would refuse to give it any consideration. But there is more.

[20] Paragraph 23 of the solicitor's affidavit reads as follows:

> 23. While the Defendants disputed the Plaintiff's entitlement to the remedy sought in subparagraphs 1(a), and 1(b) of the Amended Statement of Claim – which claimed prohibitory and mandatory injunctive relief – in the context of an action, the Defendants did not dispute Nu-Pharm's' entitlement to claim the relief sought in the balance of paragraph 1 on any procedural or jurisdictional grounds, or otherwise assert that the damages sought in subparagraph 1(c) could not be awarded without first obtaining a determination of the lawfulness of the impugned actions in a judicial review. Indeed, the Statement of Defence has never been amended to plead that the relief sought in this proceeding, other than that set out in subparagraphs 1(a) and 1(b), could not be obtained in the present action for any procedural or jurisdictional reason. Attached hereto as Exhibit "J" are copies of Nu-Pharm's Amended Statement of Claim dated August 7, 2002, and the Defendants' Statement of Defence dated August 30, 2002.

[21] I find this paragraph to be at best disingenuous. The statement of defence to which the solicitor refers reads in relevant part as follows:

> 1. In response to the Claim as a whole, he says that the Attorney General of Canada (the "Attorney General") and the Director-General, Therapeutic Products Directorate Of Health Canada (the "Director General") should be struck out as Defendants in this action, and that subparagraphs 1(a) and 1(b) of the Amended Statement of Claim should be struck out, for the following reasons.
>
> > a. Neither the Attorney General nor the Director General are proper defendants in an action for damages against the Crown.
> >
> > b. Where Her Majesty the Queen is named as a Defendant, naming the Attorney General as a Defendant is redundant and unnecessary.

> c. The Director General acts on behalf of the Minister of Health and is a federal board, commission or tribunal. Accordingly, the remedies sought against him by the Plaintiff may be obtained only on an application for judicial review. The Court is without jurisdiction to grant in this action the relief sought against him in subparagraphs 1(a) and 1(b) of the Amended Statement of Claim.

[22] I have already indicated that in my view the damages claimed in paragraph 1(c) of the amended statement of claim are wholly dependent upon a finding under paragraphs 1(a) or (b) that the actions and decisions of the Director-General were unlawful. The quoted portions of the statement of defence clearly object on “procedural or jurisdictional grounds” to the relief claimed in those two paragraphs; to assert, under oath at that, that the dependent claim for damages is not also so objected to is to blind oneself to reality and to succumb to wishful thinking. On the very pleadings relied on by the solicitor the action, including the claim in negligence, must be dismissed.

[23] This brings me to the alternative remedies sought by the plaintiff. In my view they are simply not available on the present state of this record, even assuming that they had been properly sought by way of a motion, which they have not. In order to somehow revive the plaintiff's discontinued judicial review application I would have to have grounds to set aside the discontinuance; the solicitor's affidavit does not provide them. There is no credible suggestion that the plaintiff's discontinuance was filed in error or in other than full knowledge of the facts. Likewise, to grant now an extension of time to file a new application long out of time I would need to be persuaded that the plaintiff has met the conditions established by the case law for the grant of such an extension; those conditions are not addressed in the affidavit and their existence is far from

being self-evident. Finally, in order to do as plaintiff suggests and convert the present action into a judicial review application and then re-convert it into an action I would need both to grant now an extension of time (the action having been brought long out of time) and to find that the conditions for conversion of an application into an action had been met; neither is the case.

[24] It remains, however, that the grounds invoked by the Crown in support of its motion for summary judgment are essentially procedural in nature. The Court is under an obligation to make every attempt to allow the plaintiff's claim to be decided on its merits, assuming that it has any. This is the challenge to which I adverted at the beginning of these Reasons. Rules 3 and 57 make it plain to me that I should not put the plaintiff out of court simply because it has employed the wrong procedure. I think that it is possible to do so and to rescue the plaintiff from its own ill-advised actions provided that it is able to convince the Court of the existence of the necessary pre-conditions.

CONCLUSION

[25] For the reasons stated I am going to allow the defendant's motion. I shall also, however, stay the present judgment for a period of 30 days to allow the plaintiff to seek an extension of time to file a new 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.

[26] Nothing in the present Reasons or Order should be construed as inhibiting the Court's power in any way to consolidate the present action or the proposed application or both of them if that should appear to be advisable at the time.

[27] The defendant is entitled to its costs fixed and determined in the lump sum of $5,000 payable forthwith and in any event of the cause.

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.

"James K. Hugessen"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-227-02
STYLE OF CAUSE:	NU-PHARM INC. and HER MAJESTY THE QUEEN IN RIGHT OF CANADA, et al
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	SEPTEMBER 12, 2007
REASONS FOR ORDER AND ORDER:	HUGESSEN J.
DATED:	SEPTEMBER 28, 2007

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