

**SUPREME COURT OF CANADA**

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| **Citation:** Nu-Pharm Inc. *v.* Canada (Attorney General),  2010 SCC 65, [2010] 3 S.C.R. 648 | **Date:** 20101223  **Docket:** 32830 |

**Between:**

**Nu-Pharm Inc.**

Appellant

and

**Her Majesty the Queen in Right of Canada,**

**Attorney General of Canada and Director-General,**

**Therapeutic Products Directorate of Health Canada**

Respondents

**Coram:** Binnie, LeBel, Deschamps, Abella, Charron, Rothstein and Cromwell JJ.

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| **Reasons for Judgment:**  (paras. 1 to 21) | Rothstein J. (Binnie, LeBel, Deschamps, Abella, Charron and Cromwell JJ. concurring) |

Nu-Pharm Inc. *v.* Canada (Attorney General), 2010 SCC 65, [2010] 3 S.C.R. 648

**Nu-Pharm Inc.** *Appellant*

*v.*

**Her Majesty The Queen in Right of Canada,**

**Attorney General of Canada and Director‑General,**

**Therapeutic Products Directorate of Health Canada** *Respondents*

**Indexed as:** Nu-Pharm Inc. ***v.*** Canada **(Attorney General)**

2010 SCC 65

File No.: 32830.

2010: January 20, 21; 2010: December 23.

Present:  Binnie, LeBel, Deschamps, Abella, Charron, Rothstein and Cromwell JJ.

on appeal from the federal court of appeal

*Courts* — *Federal Court* — *Procedure* — *Plaintiff bringing action in Federal Court against federal Crown for damages for various torts arising from decisions prohibiting sale of drug* — *Plaintiff not seeking judicial review of decisions* — *Whether plaintiff entitled to seek damages by way of action without first proceeding by way of judicial review* — *Federal Courts Act, R.S.C. 1985, c. F‑7, ss. 17, 18.*

In 1997, N applied unsuccessfully to Health Canada to obtain authorization to sell its drug Nu‑Enalapril in Canada. The decision was set aside on judicial review, and Health Canada issued a notice of compliance, but that decision was subsequently overturned on judicial review. As a result, N could no longer sell and market the drug. In 2001, N initiated an application for judicial review, alleging that Health Canada was acting unlawfully in requiring it to obtain a notice of compliance and by prohibiting the sale of the drug, but later discontinued its application. In 2002, N filed a statement of claim in the Federal Court against the Crown seeking injunctive and mandatory relief and damages for various torts. The Crown was successful in bringing a motion for summary judgment dismissing the action on the basis that, absent a successful challenge of the decisions of Health Canada by way of judicial review, the Federal Court did not have jurisdiction to hear the matter in light of *Canada v. Grenier*, 2005 FCA 348, [2006] 2 F.C.R. 287.

Held: The appeal should be allowed.

For the reasons given in *Canada (Attorney General) v. TeleZone Inc.*, 2010 SCC 62, [2010] 3 S.C.R. 585, the Federal Court should have decided N’s claim for damages without requiring it to first be successful on judicial review. Section 17 of the *Federal Courts Act* gives the Federal Court concurrent jurisdiction over claims for damages against the Crown. Section 18 of the Act does not derogate from this concurrent jurisdiction. Nothing in ss. 17 or 18 of the Act requires a plaintiff to be successful on judicial review before bringing a claim for damages against the Crown. N is currently authorized to distribute the drug across the country and, since the discontinuance of the claims for injunctive and declaratory relief, there is no longer any practical effect in seeking judicial review. The merits of the defence of statutory authority, if raised, may be determined at trial.

**Cases Cited**

**Applied:**  *Canada (Attorney General) v. TeleZone Inc.*, 2010 SCC 62, [2010] 3 S.C.R. 585; **overruled:** *Canada v. Grenier*, 2005 FCA 348, [2006] 2 F.C.R. 287; **referred to:** *Nu‑Pharm Inc. v. Canada (Attorney General)*, [1999] 1 F.C. 620; *Merck & Co. v. Canada (Attorney General)* (1999), 176 F.T.R. 21, aff’d (2000), 254 N.R. 68, leave to appeal refused, [2000] 1 S.C.R. xvii.

**Statutes and Regulations Cited**

*Federal Courts Act*, R.S.C. 1985, c. F‑7, ss. 17, 18.

*Food and Drug Regulations*, C.R.C., c. 870, ss. C.08.001, C.08.002(1).

*Patented Medicines (Notice of Compliance) Regulations*, SOR/93‑133.

APPEAL from a judgment of the Federal Court of Appeal (Linden, Nadon and Sexton JJ.A.), 2008 FCA 227, 387 N.R. 300, 67 C.P.R. (4th) 175, [2008] F.C.J. No. 1054 (QL), 2008 CarswellNat 2294, affirming a decision of Hugessen J., 2007 FC 977, [2007] F.C.J. No. 1273 (QL), 2007 CarswellNat 3146. Appeal allowed.

Andrew Brodkin and Cynthia L. Tape, for the appellant.

Christopher M. Rupar, Alain Préfontaine and Bernard Letarte, for the respondents.

The judgment of the Court was delivered by

1. Rothstein J. — The issue in this appeal is whether a plaintiff, who seeks damages for a decision by Health Canada to prohibit the sale of a drug, must first invalidate that decision by way of judicial review in the Federal Court.

I. Facts

1. Nu-Pharm is a generic drug manufacturing and distribution company. It produces the product “Nu-Enalapril”, a cardiovascular medication for the treatment of hypertension. In 1997, Nu-Pharm filed an abbreviated new drug submission with Health Canada in order to obtain authorization to sell Nu-Enalapril in Canada. In the submission, Nu-Pharm relied on a comparison with a generic version of a drug produced by Merck and Co. Health Canada refused to accept the abbreviated new drug submission because it failed to reference a valid Canadian reference product, a requirement under the *Food and Drug Regulations*, C.R.C., c. 870. Health Canada’s decision was set aside on judicial review at the Federal Court (*Nu-Pharm Inc. v. Canada (Attorney General)*, [1999] 1 F.C. 620).
2. As a result, Health Canada reviewed the abbreviated new drug submission and issued a notice of compliance for Nu-Enalapril, which is a requirement for the advertisement and sale of the drug (*Food and Drug Regulations*, s. C.08.002(1)(*b*)). Merck applied for judicial review of the decision to grant the notice of compliance because Nu-Pharm had compared its product to the generic version of Merck’s drug but not the patented version, Vasotec. The application for judicial review was allowed at the Federal Court on the basis that the decision to issue a notice of compliance was in violation of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*Merck & Co. v. Canada (Attorney General)* (1999), 176 F.T.R. 21). The decision was upheld at the Federal Court of Appeal (*Merck & Co. v. Canada (Attorney General)* (2000), 254 N.R. 68). This Court dismissed Nu-Pharm’s leave to appeal application ([2000] 1 S.C.R. xvii).
3. As a result of these proceedings, Nu-Pharm no longer had a notice of compliance for the marketing of Nu-Enalapril. The Director General of the Therapeutic Products Directorate of Health Canada advised the provincial drug benefit managers and Registrars of Pharmacists that the sale or advertisement of Nu-Enalapril was now prohibited:

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.

1. Nu-Pharm wrote to the Director General advising that it disagreed with the position of Health Canada and the statements in the letters. Nu-Pharm argued that Nu-Enalapril was not a new drug, as defined in the regulations. Accordingly, a notice of compliance was not necessary for its lawful sale. In a further letter to the Director General, Nu-Pharm noted that the Therapeutic Products Directorate’s official policy provided that seven years after the initial date of marketing a medicinal substance, a drug containing that medicinal substance would no longer be considered “new”. Nu-Pharm requested that the Director General agree with its position that Nu-Enalapril was not a “new drug” and lift the prohibition on its sale and marketing.
2. The Director General responded to Nu-Pharm’s letters and indicated that he did not agree with Nu-Pharm’s position on the necessity of obtaining a notice of compliance for the marketing of Nu-Enalapril. Nu-Pharm and the Director General exchanged several more letters over the course of several months. Neither party changed its view on the matter.
3. On February 22, 2001, Nu-Pharm initiated an application for judicial review, alleging that the Director General was acting unlawfully in requiring Nu-Pharm to obtain a notice of compliance and by prohibiting the sale of Nu-Enalapril. Nu-Pharm later discontinued this application.
4. On February 12, 2002, Nu-Pharm filed a statement of claim in the Federal Court bringing an action against Her Majesty the Queen, the Attorney General of Canada and the Director General (collectively, the “Crown”). The statement initially sought:

• an order enjoining the Director General from publishing further statements advising that the sale of Nu-Enalapril is unlawful;

• a mandatory order requiring the Director General to retract the previous statements to the same effect; and

• damages for misfeasance in public office, abuse of authority, illegal interference with Nu-Pharm’s economic interests, and gross negligence, or alternatively negligence.

Nu-Pharm brought this action to mitigate its financial losses resulting from the prohibition on the marketing of its product.

1. During these proceedings, Nu-Pharm obtained authorization to market Nu-Enalapril in Canada. Therefore, the injunctive and mandatory orders that it sought are moot and Nu-Pharm no longer pursues these claims. All that remains of Nu-Pharm’s action against the federal Crown is the claim for damages incurred during the period between the Director General’s first letter and the moment it was able to market its product (approximately from March 2000 to October 2006).
2. On April 13, 2007, the Crown filed a notice of motion for summary judgment on the ground that “Nu-Pharm is not entitled to seek damages in an action resulting from the decisions of the Director-General without first proceeding by way of judicial review in order to have the decision invalidated” (R.R., vol. I, at p. 41).

II. Judicial History

A. *Federal Court, 2007 FC 977 (CanLII)*

1. Mr. Justice Hugessen allowed the Crown’s motion for summary judgment on the basis of *Canada v.* *Grenier*, 2005 FCA 348, [2006] 2 F.C.R. 287. He concluded that

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 . . . . 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. [para. 16]

1. Having determined that Nu-Pharm’s action was “fatally flawed by its failure to maintain its application for judicial review” (at para. 17), Hugessen J. considered possible alternative remedies. Hugessen J. ordered a temporary stay of his judgment to allow Nu-Pharm to seek an extension of time to file for judicial review and to pursue that course of action. If Nu-Pharm was successful on judicial review, Hugesson J.’s judgment could be vacated. If unsuccessful, the judgment would become permanent.

B. *Federal Court of Appeal, 2008 FCA 227, 387 N.R. 300*

1. Nu-Pharm’s appeal was dismissed at the Federal Court of Appeal, again on the basis of *Grenier*. Nadon J.A., writing for a unanimous court, concluded that Nu-Pharm’s action constituted a collateral attack on the decisions of the Director General. As the court had found in *Grenier*, the decisions could only be challenged by way of judicial review.

III. Relevant Provisions

1. *Food and Drug Regulations*, C.R.C., c. 870

**C.08.001.** For the purposes of the Act and this Division, “new drug” means

(*a*) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;

(*b*) a drug that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or

(*c*) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration, or duration of action and that has not been sold for that use or condition of use in Canada, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.

. . .

**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.

IV. Analysis

1. The Crown’s position is that the decisions by the Director General are decisions of a federal board, commission or tribunal, and, as such, any challenge to the lawfulness of these decisions must occur through an application for judicial review in the Federal Court.
2. For the reasons set out by Binnie J. in the companion case of *Canada (Attorney General) v.* *TeleZone Inc.*, 2010 SCC 62, [2010] 3 S.C.R. 585, the Crown’s argument must fail.
3. Unlike in *TeleZone*, the Federal Court’s jurisdiction is not at issue in this appeal. Nu-Pharm brought its action in the Federal Court. However, the correct procedure — action or application for judicial review — is at issue. Section 17 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, gives the Federal Court concurrent jurisdiction over claims for damages against the Crown. Section 18 of the *Federal Courts Act* does not derogate from this concurrent jurisdiction. There is nothing in ss. 17 or 18 that requires Nu-Pharm to be successful on judicial review before bringing its claim for damages against the Crown.
4. Nu-Pharm is now authorized to distribute Nu-Enalapril across the country. As Nu-Pharm has recognized by discontinuing its claims for injunctive and declaratory relief, there is no longer any practical effect in seeking judicial review. It now seeks to recover damages for loss that occurred as a result of, what it says, was intentional or negligent conduct on the part of the Director General. It brings its claim in tort.
5. It is true that the decisions by the Director General were made pursuant to federal legislation. Thus, it is expected that in the case on its merits, the Crown will argue the defence of statutory authority. However, that is an issue that will have to be resolved at trial.
6. For the reasons given in *TeleZone*, the Federal Court should have decided Nu-Pharm’s claim for damages without requiring it to first be successful on judicial review.

V. Conclusion

1. I would allow the appeal with costs throughout.

*Appeal allowed with costs.*

Solicitors for the appellant: Goodmans, Toronto.

Solicitor for the respondents: Attorney General of Canada, Ottawa.