Federal Court of Appeal  Cour d'appel fédérale

Date: 20120410

Docket: A-215-11

Citation: 2012 FCA 106

CORAM: **BLAIS C.J.**
NOËL J.A.
STRATAS J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

THE MINISTER OF HEALTH and
SANOFI-AVENTIS CANADA INC.

Respondents

Heard at Toronto, Ontario, on March 19, 2012.

Judgment delivered at Ottawa, Ontario, on April 10, 2012.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: BLAIS C.J.
NOËL J.A.

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REASONS FOR JUDGMENT

STRATAS J.A.

[1] This is an appeal and cross-appeal from the Federal Court's dismissal of an application for judicial review brought by the appellant, Teva Canada Limited: 2011 FC 507 (*per* Justice Campbell).

[2] In 2007, the Minister of Health placed Sanofi-Aventis Canada Inc.'s drug, Eloxatin, on a register of "innovative drugs" maintained by her under C.08.004.1(9) of the *Food and Drug*

Regulations, C.R.C., c. 870. As will be seen, the presence of Eloxatin on the register has meant that Teva cannot market its own version of Eloxatin.

[3] In 2010, Teva requested that the Minister remove Eloxatin from the register because it does not meet the definition of an "innovative drug" under subsection C.08.004.1(1) of the *Regulations*. Under that definition, to be an "innovative drug" Eloxatin must contain "a medicinal ingredient [oxaliplatin] not previously approved in a drug by the Minister." In Teva's view, the Minister has "previously approved" it: since 1999, the Minister authorized thousands of uses of Eloxatin by way of emergency treatment under the Special Access Programme set out in the *Regulations*.

[4] The Minister decided to reject Teva's request. This is the decision that is the subject of Teva's application for judicial review in the Federal Court and its appeal to this Court. The Minister interpreted the *Regulations* and concluded that authorizations under the Special Access Programme do not constitute a previous approval for the purposes of the definition of "innovative drug."

[5] For the reasons set out below, like the Federal Court, I find that the Minister's interpretation of the *Regulations* was correct. The Minister correctly found that Eloxatin met the definition of "innovative drug" and so she was right to keep it on the register of innovative drugs. Therefore, I would dismiss the appeal.

[6] Sanofi-Aventis' cross-appeal concerns certain preliminary objections to Teva's standing and ability to assert this matter in the Federal Court and on appeal to this Court. It raised these

objections in the Federal Court and was unsuccessful. For reasons set out below, these objections should not have been advanced by way of cross-appeal and, in any event, they are not well-founded. Therefore I would dismiss the cross-appeal.

A. The standard of review that should apply to the Minister's decision

[7] At the heart of the Minister's decision is a question of legislative interpretation: whether authorizations under the Special Access Programme can constitute a "previous approv[al]" under subsection C.08.004.1(1) of the *Regulations*. The Federal Court held that the Minister's decision should be reviewed on the basis of correctness.

[8] Before us, Sanofi-Aventis and the Minister submit that the Minister's decision should be reviewed on the basis of the deferential standard of reasonableness: see *Dunsmuir v. New Brunswick*, 2008 SCC 9 at paragraph 50, [2008] 1 S.C.R. 19.

[9] In my view, the Minister's interpretation of the *Regulations* was correct and so this question need not be determined.

B. Can previously granted authorizations under the Special Access Programme make a drug "previously approved" under subsection C.08.004.1(1) of the *Regulations*?

[10] The Minister answered this question in the negative. Teva answers it in the affirmative.

[11] As mentioned previously, the definition of "innovative drug" is found in subsection C.08.004.1(1) of the *Regulations*:

C.08.004.1. (1) The following definitions apply in this section	**C.08.004.1.** (1) Les définitions qui suivent s'appliquent au présent article.
…	…
"innovative drug" means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (*drogue innovante*)	« drogue innovante » S'entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d'un ingrédient médicinal déjà approuvé tel un changement de sel, d'ester, d'énantiomère, de solvate ou de polymorphe. (*innovative drug*)

[12] The term "previously approved" in the definition of "innovative drug" is not itself defined.

[13] Teva says that "previously approved" must be interpreted to include mass authorizations under the Special Access Programme. To hold otherwise is to give Sanofi-Aventis an inordinate and unjustifiable monopoly for a number of years. In this case, Eloxatin had been widely available abroad for many years to treat colorectal cancer. It had been widely available in Canada for more than eight years under the Special Access Programme. It had been genericized in Canada and around the world. Yet, in 2007, the Minister granted it "innovative" status, forcing generics off the market. Teva says that that is against the purpose of section C.08.004.1 and the *Regulations* generally.

[14] Teva also submits that the Minister incorrectly interpreted "previously approved" as meaning whether a drug has received market authorization, *i.e.*, whether a notice of compliance or drug identification number allowing the drug to be marketed was previously issued under the *Regulations*. In Teva's view, had the Minister adopted an interpretive approach mindful of the need to avoid an inordinate and unjustifiable monopoly, she would have made a different decision.

[15] In Teva's view, an interpretation of "approved" that encompasses authorizations under the Special Access Programme would allow for other relevant questions to be asked, all of which are in accordance with the purposes of section C.08.004.1 and the *Regulations* generally. Had the drug been made widely available with the assent of the Minister? In granting so many authorizations under the Special Access Programme, had the Minister satisfied herself of the drug's safety and efficacy?

[16] Finally, Teva submits that "innovative drug" must be read consistently with Canada's obligations under paragraphs 5 and 6 of Article 1711 of the *North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, Can. T.S. 1994 No. 2 and paragraph 3 of Article 39 of the *Agreement on Trade Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299. Teva says that these treaty provisions compel consideration of whether the drug contains a new chemical entity, whether the drug submission contains undisclosed data necessary to determine safety and efficacy, and whether this data involved considerable effort. Focusing on marketing approval (i.e., the granting of a notice of

compliance and a drug information number), or what Teva calls market authorizations, ignores these considerations and, thus, is inconsistent with the treaty provisions.

[17] I disagree with Teva's submissions for three main reasons:

(1) *The wording, architecture and purpose of the Regulations.* Teva sees the definition of "innovative drug" in subsection C.08.004.1(1) and more broadly the *Regulations* as being aimed at achieving a compromise between providing monopolies to innovators for a period of time and allowing generics to obtain timely market access. This is the prism through which Teva interprets the word "approved" in subsection C.08.004.1 of the *Regulations*. But the wording, architecture and purpose of the *Regulations* suggest a different prism, that of the safety and efficacy of drugs, a matter that is evidenced only by approvals based on data and studies, strictly defined under the *Regulations*.

(2) *Lack of clarity and uncertainty*. Accepting Teva's position would create uncertainty and lack of clarity, something that the *Regulations* try to eliminate.

(3) *Subsection C.08.004.1(1) of the Regulations is a limited, special purpose provision.* The definition of "innovative drug" in subsection C.08.004.1(1) of the *Regulations* was aimed at a limited, specific purpose, that of implementing Canada's specific treaty obligations. Teva's interpretation of the subsection, which unduly narrows the

> definition of "innovative drug," would run counter to these treaty obligations. The Minister's interpretation – defining "approved" as meaning the existence of a notice of compliance and a drug identification number – is consistent with Canada's treaty obligations.

I develop these reasons below.

(1) The architecture and wording of the *Regulations*

[18] Teva's essential submission is that previous authorizations under the Special Access Programme can make a drug "previously approved" under section C.08.004.1 of the *Regulations*. A full understanding of the architecture and wording of the *Regulations* shows that that cannot be so.

[19] Under the *Regulations*, a new drug may not be marketed in Canada unless its manufacturer has first obtained a notice of compliance and a drug identification number: section C.08.004 and subsection C.01.014(1) of the *Regulations*. In order to obtain these, broadly speaking and as explained below, there must be a demonstration directly or indirectly founded upon data and studies that, in the Minister's view, have established safety and effectiveness.

[20] Notices of compliance can be obtained by one of two routes. Each route is founded upon the preparation and provision of data and studies that, in the Minister's view, have established safety and effectiveness:

- The first route is to file a new drug submission: section C.08.002 of the *Regulations*. Typically, a new drug submission will contain voluminous clinical trial data and detailed studies. On the basis of the data and studies, the Minister evaluates the safety and effectiveness of the drug. If satisfied, the Minister grants a notice of compliance.

- The second route is to file an abbreviated new drug submission: section C.08.002.1 of the *Regulations*. Generic drug manufacturers often follow this route. It allows these manufacturers to copy a marketed drug without having to provide clinical data demonstrating safety and effectiveness. Instead, the abbreviated drug submission need only show that the generic drug is bioequivalent to the marketed drug. Where that is shown, the generic drug can piggyback on the data and studies concerning the marketed drug and the safety and effectiveness of the generic drug is established.

[21] As for drug identification numbers, no manufacturer may sell a drug in dosage form unless one has been assigned: *Regulations* at subsection C.01.014(1). A drug identification number is an eight-digit numerical code that identifies drug product characteristics including manufacturer, brand name, medicinal ingredient, strength of the medicinal ingredient, pharmaceutical form, and route of administration. Through the drug identification number, a drug can readily be tracked or recalled in the event of an adverse drug reaction in the population.

[22] In the case of a new drug, a new drug submission or an abbreviated new drug submission filed under Division 8 of the *Regulations* serves as an application for a drug identification number.

[23] When a drug is not "new" (as that term is defined), it is not subject to the requirements of Division 8. In that case, the application for a drug identification number is made through a drug identification number submission, and the drug is regulated primarily under Part C, Division 1 of the *Regulations*. To receive a drug identification number, a drug manufacturer must file sufficient data to allow the Minister to evaluate the safety and efficacy of the drug for its intended use.

[24] As with notices of compliance, there is a demonstration directly or indirectly founded upon data and studies that, in the Minister's view, have established safety and effectiveness.

[25] The Special Access Programme is different. It allows for the use of certain drugs despite the absence of data and studies demonstrating the safety and efficacy of the drug.

[26] The Programme is set out in sections C.08.010 and C.08.011 of the *Regulations* under the heading "Sale of New Drug for Emergency Treatment."

[27] This Court has described the Special Access Programme in the following way:

> [4] …[T]he Director (Assistant Deputy Minister, Health Products and Food Branch, Health Canada) may authorize the sale of a new drug to a physician under the Special Access Programmeme ("SAP") for the emergency treatment of a patient.

…..

> [10] When requesting Health Canada for an authorization under the SAP, a physician must: (i) describe the patient's medical condition; (ii) explain why the medicine is the best choice for treating the condition; and (iii) provide data on the use, safety and efficacy of the medicine requested. If granted, an SAP authorization authorizes, but does not require, a manufacturer to sell a specified quantity of the medicine to the requesting physician for the emergency treatment of a specified condition of a named patient under the care of the physician. The physician must report to Health Canada on the use of the medicine, including any adverse effects.
>
> [11] SAP authorizations…are normally granted for serious or life-threatening conditions when conventional treatments have proved ineffective or are not suitable for the particular patient. Typically, medicines authorized under the SAP are treatments of last resort and are not subject to the same level of scrutiny for safety and efficacy as medicines for which an NOC has been issued. Nonetheless, Health Canada reviews the SAP request and any other available data on the new medicine in order to "manage the risk" of its use.

See *Canada (Attorney General) v. Celgene Corporation*, 2009 FCA 378, aff'd 2011 SCC 1, [2011] S.C.R. 3; see also *Hospira Healthcare Corp. v. Canada (Attorney General)*, 2010 FCA 345.

[28] Drugs available under the Special Access Programme are not founded upon data and studies that, in the Minister's view, have established safety and effectiveness. Rather, they are made available in emergency situations as a treatment of last resort where conventional treatments have failed or are unavailable. As this Court has already held, sales under the Special Access Programme alone are not evidence of a determination by the Minister of the safety and efficacy of a drug: *Hospira*, *supra* at paragraph 6. Indeed, it is theoretically possible that drugs available under the Special Access Programme are not entirely safe or effective, but, owing to the grievous circumstances of the patient, they may have some upside and are worth the risk. Authorizations

under the Special Access Programme are best seen as compassionate permissions, not as approvals for the drug.

(2) Lack of clarity and uncertainty

[29] Before us, Teva submitted that this is an unusual and exceptional case. In this case, the Minister has authorized thousands of uses of Eloxatin under the Special Access Programme. She received reports regarding any adverse effects and, by 2007, had sufficient information for her to evaluate the safety and effectiveness of Eloxatin. Indeed, Teva suggests that the information available to the Minister was massive. It characterizes the matter as, in effect, a huge clinical trial that yielded more information than what appears in many new drug submissions. On the basis of this information, Teva notes that the Minister continued to issue authorizations for its use. This, it says, must mean that, in this unusual and exceptional case, the medicinal ingredient in Eloxatin was "approved" within the meaning of the definition of "innovative drug" under subsection C.08.004.1(1) of the *Regulations*.

[30] Teva's submission creates lack of clarity and uncertainty, something that the *Regulations* try to eliminate.

[31] Whether or not a drug is approved and authorized for market and sale in Canada is of importance to the manufacturer, its competitors, medical professionals, pharmacists and patients. Clarity and certainty on this is essential. For this reason, the *Regulations* have been carefully drafted

to create clarity and certainty as to when a drug is approved. Under the *Regulations*, the magic moment of approval is signalled by the issuance of a notice of compliance and a drug identification number.

[32] Teva's interpretation would lead to complicated factual inquiries and difficult questions that run counter to the theme of clarity and certainty in the area of approvals under the *Regulations*. How many authorizations under the Special Access Programme would be required in order to make a drug "approved" under subsection C.08.004.1(1) of the *Regulations*? Does the basis underlying each authorization need to be examined? Do we need to examine exactly what information was received by the Minister in response to the authorizations? When does inaction by the Minister in response to that information mean that the drug is "approved"?

(3) Subsection C.08.004.1(1) of the *Regulations* is a limited, special purpose provision

[33] Many of Teva's submissions embody the view that subsection C.08.004.1(1) of the *Regulations* is about achieving a compromise between providing monopolies for a period of time to innovative drug manufacturers while allowing timely market access to generic drug manufacturers.

[34] In fact, this is not the case. Subsection C.08.004.1(1) of the *Regulations* is a limited, special purpose section. It is designed to implement certain specific treaty obligations undertaken by Canada: subsection C.08.004.1(2) of the *Regulations*. These obligations are found in three treaty provisions: paragraphs 5 and 6 of Article 1711 of the *North American Free Trade Agreement* and

paragraph 3 of Article 39 of the *Trade Related Aspects of Intellectual Property Rights Agreement*, both *supra*.

[35] Broadly speaking, these treaty provisions aim to protect an innovator who submits undisclosed data in support of an application for approval to market a drug containing a new chemical entity. The treaty provisions accomplish this by preventing others from using the innovator's data in support of their own applications for drug approval. This encourages the development of new drugs: *Apotex Inc. v. Canada (Health)*, 2010 FCA 334 at paragraph 117.

[36] As mentioned in paragraph 16, above, Teva emphasizes that the treaty provisions require consideration of whether the drug contains a new chemical entity, whether the drug submission contains undisclosed data necessary to determine safety and efficacy, and whether the data involved considerable effort. That may be true, but that does not shed direct light on the meaning of "previously approved" in subsection C.08.004.1(1) of the *Regulations*.

[37] Of more relevance to the meaning of "previously approved" is the repeated mention in these treaty provisions of the concept of marketing approval or, as Teva puts it, market authorization. Article 1171, paragraphs 5 and 6 of the *North American Free Trade Agreement* obligate Canada to protect data necessary for "approving of marketing" of pharmaceutical products for at least five years from when Canada granted "approval to the person that produced the data for approval to market its product." Article 39, paragraph 3 of the *Trade Related Aspects of Intellectual Property Rights Agreement* similarly refers to data required "as a condition of approving the marketing of

pharmaceutical" products. In Canada, market approval under the *Regulations* means the issuance of a notice of compliance and a drug information number.

[38] Given that the definition of "innovative drug" in subsection C.08.004.1(1) of the *Regulations* was intended to implement these treaty provisions, "previously approved" in subsection C.08.004.1(1) must mean a previous marketing approval, *i.e.*, the previous issuance of a notice of compliance and a drug information number. If someone has previously received a notice of compliance and a drug identification number for a particular drug, providing that person with data protection would go beyond the scope of the treaty provisions. Accordingly, the definition of "innovative drug" in subsection C.08.004.1(1) does not include drugs that have been "previously approved."

[39] Accepting Teva's interpretation – interpreting "previously approved" in subsection C.08.004.1(1) of the *Regulations* to include authorizations granted under the Special Access Program – would undercut the treaty provisions. The following scenario illustrates this. Suppose that a company submits undisclosed data to the Minister for a first-time approval of a drug containing a new chemical entity. Immediately after the submission, the Minister starts to grant authorizations for the emergency use of the drug under the Special Access Programme. Under Teva's interpretation, a certain number of authorizations would make the drug "previously approved," stripping the drug of its status as an "innovative drug," and allowing others to rely on the data submitted for their own applications for drug approval. Under this scenario, if Teva's interpretation is correct, the treaty protections would be undercut almost immediately.

[40] Another scenario is where the Minister starts to grant authorizations for the emergency use of the drug under the Special Access Programme before the manufacturer makes a submission. Under this scenario, if Teva's interpretation is correct, the treaty protections might never apply.

[41] These scenarios show that Teva's interpretation cannot be correct. Subsection C.08.004.1 of the *Regulations* is aimed at implementing the treaty provisions, not undercutting them.

[42] Therefore, I conclude that drugs for which previous authorizations under the Special Access Programme have been granted are not "previously approved" within the meaning of section C.08.004.1 of the *Regulations*. Although many authorizations had been granted for Eloxatin under the Special Access Programme, Eloxatin had not previously received a notice of compliance or a drug information number. It follows that in these circumstances the Minister was correct in deciding that Eloxatin was an "innovative drug" under subsection C.08.004.1(1) of the *Regulations* and that it should remain on the register of innovative drugs under C.08.004.1(9) of the *Regulations*.

C. The cross-appeal: Sanofi-Aventis' preliminary objections

[43] As mentioned at the outset of these reasons, Sanofi-Aventis advanced some preliminary objections to Teva's application for judicial review in the Federal Court. Sanofi-Aventis submitted that Teva lacked standing to bring its application for judicial review. It also submitted that the Minister's decision was not a fresh decision, but rather was just a repeat of its original decision, made some three years earlier, to list Eloxatin on the register of innovative drugs. The Federal Court dismissed these objections.

[44] In this Court, Sanofi-Aventis advances the same objections. It has chosen to do so in the form of a cross-appeal.

[45] But a cross-appeal does not lie in this case. The Federal Court's order does not adversely affect Sanofi-Aventis. The Federal Court's order gave Sanofi-Aventis exactly what it wanted – a dismissal of Teva's application for judicial review, with costs. See generally *Kligman v. M.N.R.*, 2004 FCA 152, [2004] 4 F.C.R. 477.

[46] In reality, Sanofi-Aventis' cross-appeal is directed against the Federal Court's reasons for dismissing the preliminary objections. A cross-appeal lies against judgments and orders, not reasons: *Froom v. Canada (Minister of Justice)*, 2004 FCA 352, [2005] 2 F.C.R. 195; *Federal Courts Rules*, SOR/98-106, Rule 341(1)(*b*).

[47] Even though Sanofi-Aventis has chosen the wrong mechanism for asserting its preliminary objections in this Court and even though I would dismiss Teva's appeal on its merits, nevertheless I will address the preliminary objections. We have had the benefit of full and helpful submissions on them and preliminary objections such as these may be asserted in similar cases.

[48] Sanofi-Aventis' first preliminary objection is that Teva is not a person "directly affected by the matter in which relief is sought" under subsection 18.1(1) of the *Federal Courts Act*, R.S.C. 1985, c. F-7.

[49] To consider this, the operation of the *Regulations* must be considered. When Eloxatin was placed on the register of innovative drugs, there were two main effects. First, Sanofi-Aventis, as the manufacturer of the drug, received an eight-year monopoly for Eloxatin. Second, for the first six years of the monopoly, Teva and all other generic manufacturers were prohibited from filing an abbreviated new drug submission relating to Eloxatin. This stopped them from seeking authorization to market their generic Eloxatin. (See generally subsections C.08.004.1(3) and (4) of the *Regulations*.)

[50] In both the Federal Court and in this Court, Sanofi-Aventis conceded that Teva would be a person "directly affected" by the Minister's refusal to delist Eloxatin if Teva had filed an abbreviated new drug submission for its generic drug. That is a fair concession. Those who file an abbreviated drug submission and have it rejected because of the listing of a drug on the register of innovative drugs are directly affected by that listing. They suffer an impact on their legal rights and

they are prejudicially affected in a practical sense. They have direct standing under subsection 18.1(1) of the *Federal Courts Act*: *League for Human Rights of B'Nai Brith Canada v. Odynsky*, 2010 FCA 307 at paragraph 58; *Rothmans of Pall Mall Canada Ltd. v. Canada (M.N.R.)*, [1976] 2 F.C. 500 (C.A.).

[51] However, Sanofi-Aventis maintains its objection to Teva's direct standing on two grounds.

[52] First, Sanofi-Aventis submits that there is no evidence that Teva filed an abbreviated new drug submission for its generic drug. On this, Sanofi-Aventis is wrong. There was evidence before the Federal Court to that effect: see pages 180-181 of the appeal book. Based on that evidence, the Federal Court found at paragraph 18 of its reasons that Teva did attempt to enter the market by filing an abbreviated drug submission.

[53] Second, Sanofi-Aventis submits that Teva needed to have direct standing at the time it brought its application for judicial review. At that time, however, it lacked standing. At that time, it had not attempted to file an abbreviated new drug submission.

[54] The Federal Court dismissed this ground of objection and so do I. The direct standing requirement is found in subsection 18.1(1) of the *Federal Courts Act* and, like all statutory provisions, it falls to be interpreted in accordance with its plain words, other words of the statute, and the purposes of the provision and the statute: *Bell ExpressVu Limited Partnership v. Rex*, 2002 SCC 42, [2002] 2 S.C.R. 559.

[55] Here, the purposes of the *Federal Courts Act* significantly bear upon this matter. Among other things, the Act is aimed at achieving justice, fairness, practicality, order, efficiency, and the minimization of cost, delay and waste in matters governed by the Act. The Act achieves these purposes by imposing various requirements, of which the requirement of direct standing is one. Those requirements must be interpreted and applied with a view to achieving the purposes of the Act – not with a view to laying traps for the unwary or providing fodder for the mischievous.

[56] I adopt the Federal Court's conclusion at paragraph 18 of its reasons that accepting Sanofi-Aventis' submission would "do nothing to improve delivery of justice" and would serve "no good purpose." In the face of a dismissal, Teva would simply restart its application, this time with direct standing. If necessary, it would seek an extension of time to do so and would likely get it. Then everyone would file the same evidence and, perhaps years later, would make the same submissions. All that will have been accomplished is pointless cost, delay and waste.

[57] Sanofi-Aventis raises one last preliminary objection. It notes that in 2007, the Minister had added Eloxatin to the register of innovative drugs. In 2010, in rejecting Teva's request to remove it, the Minister simply made the same decision. Sanofi-Aventis states that the Minister did not make a fresh "decision" within the meaning of subsection 18.1(2) of the *Federal Courts Act*.

[58] I disagree. The Minister is obligated to "maintain" the register of innovative drugs: subsection C.08.004.1(9) of the *Regulations*. This includes the power to add or delete information to

or from the register, as necessary: see *Merck Frosst Canada v. Canada* (1997), 74 C.P.R. (3d) 307, decided in the context of the Register maintained under subsection 3(2) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-103. The Minister's decision refusing Teva's request was a decision concerning the maintenance of the Register and was a fresh exercise of discretion. Accordingly, the Minister's decision was a "decision" susceptible to judicial review under section 18.1 of the *Federal Courts Act*. The presence or absence of entries on the list may also be reviewable as a "matter" under subsection 18.1(1) of the *Federal Courts Act*: *Air Canada v. Toronto Port Authority*, 2011 FCA 347 at paragraph 24. However, it is unnecessary in this case to consider that further.

D. Proposed disposition

[59] For the foregoing reasons, I would dismiss the appeal with costs. I would dismiss the cross-appeal with costs to the appellant and the respondent Minister. I thank all counsel for their helpful and excellent submissions.

"David Stratas"
J.A.

"I agree
Pierre Blais C.J."

"I agree
Marc Noël J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-215-11
APPEAL FROM AN ORDER OF THE HONOURABLE MR. JUSTICE CAMPBELL DATED MAY 2, 2011, NO. T-1172-10	
STYLE OF CAUSE:	Teva Canada Limited v. The Minister of Health and Sanofi-Aventis Canada Inc.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 19, 2012
REASONS FOR JUDGMENT BY:	Stratas J.A.
CONCURRED IN BY:	Blais C.J. Noël J.A.
DATED:	April 10, 2012

APPEARANCES:

Robert A. Staley Dominique T. Hussey Christopher D. Heer	FOR THE APPELLANT
Eric Peterson	FOR THE RESPONDENT, The Minister of Health
Judith Robinson Brian Daley	FOR THE RESPONDENT, Sanofi-Aventis Canada Inc.

SOLICITORS OF RECORD:

Bennett Jones LLP Toronto, Ontario	FOR THE APPELLANT
Myles J. Kirvan Deputy Attorney General of Canada	FOR THE RESPONDENT, The Minister of Health
Ogilvy Renault LLP Montreal, Quebec	FOR THE RESPONDENT, Sanofi-Aventis Canada Inc.