Federal Court of Appeal | Cour d'appel fédérale

Date: 20091223

Docket: A-177-09

Citation: 2009 FCA 378

CORAM: **EVANS J.A.**
SHARLOW J.A.
RYER J.A.

BETWEEN:

ATTORNEY GENERAL OF CANADA

Appellant

and

CELGENE CORPORATION

Respondent

Heard at Ottawa, Ontario, on December 1, 2009.

Judgment delivered at Ottawa, Ontario, on December 23, 2009.

REASONS FOR JUDGMENT BY: EVANS J.A.

CONCURRED IN BY: SHARLOW J.A.

DISSENTING REASONS BY: RYER J.A.

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REASONS FOR JUDGMENT

EVANS J.A.

A. INTRODUCTION

[1] In law, as in life, meaning depends heavily on context, although selecting the appropriate context is not always easy. The question in the present case is whether consumer protection provisions in the *Patent Act*, R.S.C. 1985, c. P-4, should be interpreted in the context of common law principles or the purpose of the statutory scheme. In this case, contemporary approaches to the interpretation of regulatory legislation favour the latter.

[2] This is an appeal of a decision of the Federal Court (2009 FC 271) in which Justice Campbell set aside a decision of the Patented Medicine Prices Review Board ("Board"), dated January 21, 2008. The Board held that it had jurisdiction under paragraph 80(1)(*b*) of the *Patent Act*, to require Celgene Corporation ("Celgene") to provide information about the pricing of the drug Thalomid since January 1995. It rejected Celgene's argument that it had no jurisdiction over the pricing of Thalomid because it was not being sold in Canada.

[3] The question before the Board was whether a patented medicine, sold by an American company and shipped f.o.b. from its factory in New Jersey to a physician in Canada to treat a patient in Canada, was thereby "sold in any market in Canada" within the meaning of paragraph 80(1)(*b*), even though it is agreed that common law commercial principles would regard the sale of the medicine as having occurred in New Jersey.

[4] The sale and advertisement of a new drug in Canada is generally prohibited without a Notice of Compliance ("NOC") issued by Health Canada when it is satisfied that the medicine is safe and effective: *Food and Drug Regulations*, C.R.C., c. 870, C.08.002(1) ("Regulations"). Celgene has not applied for an NOC to market Thalomid in Canada. However, despite the absence of an NOC, the 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 Programme ("SAP") for the emergency treatment of a patient: Regulations, C.08.010(1), 08.011(1), (2).

[5] In my respectful opinion, the Applications Judge misinterpreted the words “sold in any market in Canada” by giving insufficient weight to their statutory context and the purpose of the regulatory scheme of which they are an integral part.

[6] The purpose of this scheme, created by sections 79-103 of the *Patent Act* and administered by the Board, is to protect consumers in Canada (or their insurers) from being charged excessive prices for patented medicines. To interpret these consumer protection provisions as not including patients whose treatment requires medicines imported under an SAP authorization is, in my view, contrary to the statutory objectives.

[7] Accordingly, I would allow the appeal and restore the order of the Board. The statutory provisions relevant to this appeal are contained in an Appendix to these reasons.

B. FACTUAL BACKGROUND

[8] In the 1960s, thalidomide, the active ingredient of Thalomid, was linked to severe birth defects in babies born to women who had taken thalidomide as an antiemetic during pregnancy. It is now used to treat other medical conditions, including leprosy and some forms of cancer.

[9] Although Thalomid has been approved by the Food and Drug Administration in the United States for the treatment of these illnesses, Celgene has never made an application for an NOC, a lengthy and expensive process. Instead, Thalomid has been made available in Canada since 1995 under SAP authorizations, especially for the treatment of certain forms of cancer.

(i) Special Access Program

[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] It is not altogether clear why the Regulations provide that the sale by the patentee must be to the requesting "practitioner", whether a physician or a veterinarian. However, it may simply be to provide a convenient mechanism for preventing distribution of the medicine to persons other than the patient for whom it has been prescribed, for ensuring that any amount not needed for the patient's treatment is returned and, when requested, for providing accountability with respect to the quantity of medicine received and any adverse outcomes attributable to the use of the medicine. Designating the practitioner as the purchaser may also facilitate payment of the patentee for the medicine. For these reasons, the physician may purchase the medicine from the patentee as agent of the patient on whose behalf the request to purchase it was made. However, this is not an issue that needs to be decided in this appeal.

[12] SAP authorizations have been issued with respect to Thalomid for 14 years for "medical emergency". They 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.

[13] Medicines sold under an SAP authorization comprise only a small portion of the Canadian pharmaceutical market. Thus, in 2006, 26,000 requests were granted with respect to 43 drugs. Of these requests, 4,500 were for Thalomid, making it the drug most often requested under the SAP and, because of its success in the treatment of multiple myeloma, sales have increased significantly.

[14] The standard SAP authorization procedure was followed in the present case. A physician in Canada requested Health Canada for permission to purchase a specified quantity of Thalomid to treat a particular "medical emergency" of a patient under the care of the physician. Health Canada authorized the sale of a month's supply of the medicine, on condition that the patient provided a negative pregnancy test, and any amount of the medicine not used by the patient was returned to Celgene.

[15] The authorization was sent to the manufacturer, Celgene, which shipped the medicine f.o.b. from its plant in New Jersey to the physician in Canada. After the arrival of the medicine in Canada, the physician paid for it in U.S. dollars in accordance with the terms of the invoice. Presumably, it was later consumed by the patient on whose behalf it had been requested.

(ii) Patented Medicine Prices Review Board

[16] The mandate of the Board is to ensure that patentees do not abuse the monopoly created by the grant of a patent with respect to a medicine by charging excessive prices to consumers in Canada. The regime administered by the Board replaced the system of compulsory licensing, which was abolished in 1993. Price regulation during the life of the patent, rather than the injection of competition through compulsory licensing, thus became the means of protecting consumers from excessive prices for patented medicines.

[17] The present case originated in a motion to the Board by the Board's staff to require Celgene to provide information concerning the pricing of Thalomid since 1995, when it was first made available in Canada through the SAP. Celgene had supplied the recent pricing information requested by the staff, but without prejudice to its position that the Board had no jurisdiction to demand it. However, it did not provide pricing information on sales in Canada going back to 1995.

[18] Hence, the only issue before the Board was whether it had legal authority to require Celgene to produce information about Thalomid specified in paragraph 80(1)(*b*) of the *Patent Act*. Information gathered by the Board under subsection 80(1) may assist it to determine if a patentee of an invention pertaining to a medicine is selling the medicine "in any market in Canada" at a price that in the Board's opinion is excessive. If the Board so finds, it may make orders designed to offset the patentee's excess revenues. These regulatory powers are conferred on the Board by section 83.

C. DECISION OF THE BOARD

[19] The Board (at para. 6) states Celgene's argument to be that, since the Board has no jurisdiction over sales of Thalomid outside Canada, it cannot oblige Celgene to provide information about the price charged for the medicine to Canadian purchasers. The bases of Celgene's argument were as follows.

[20] First, the Board's jurisdiction over the pricing of patented medicines only applies to those marketed in Canada under an NOC, not to those sold under an SAP authorization. The Board's rejection of this argument was not challenged on judicial review and need not be considered further.

[21] Second, by virtue of the rules of commercial law, the sale of Thalomid occurred in New Jersey, and it was therefore not sold "in any market in Canada". Although an SAP authorization only permits, but does not require, the patentee to supply a medicine for the treatment in Canada of a medical condition, the Board, for the following reasons, rejected the argument that, when Celgene supplied Thalomid pursuant to an SAP authorization, it was not thereby "sold in any market in Canada".

[22] First, every sale is closely regulated by Health Canada. Second, the function of the words "in any market in Canada" is to enable the Board to oversee the price of medicines in Canada, either generally or in specific markets defined by geography, political boundaries, or classes of customers, including "purchasers receiving medicines through the SAP" (at para. 21). Third, the mandate of the

Board to protect customers from excessive prices for patented medicines supports this view of its jurisdiction. Thus, the Board (at para. 22) could see

> no reason why Canadians purchasing medicines through the SAP are any less deserving of protection or needful of protection by the Board, than Canadians purchasing medicines for which an NOC has been issued.

Indeed, since the volume of medicines sold under the SAP is relatively small, and competition is generally less than for medicines sold under an NOC, the Board has a particularly important role in protecting consumers from excessive prices.

[23] The Board agreed that the principles of commercial common law located the sale of Thalomid in New Jersey, where it was shipped f.o.b. to the physician in Canada authorized under the SAP to purchase it. However, it did not regard the location of the sale as determinative, because the common law rules are concerned to resolve disputes between seller and buyer by, for example, selecting the law governing the contract. In contrast, the Board is a public law institution regulating in the public interest the price that Canadians pay for patented medicines.

D. DECISION OF THE FEDERAL COURT

[24] The Applications Judge applied the correctness standard to review the Board's interpretation of paragraph 80(1)(*b*), on the ground that it defined the Board's jurisdiction. Dismissing as of little relevance the authorities relied on by the Attorney General as showing a broad approach to the jurisdiction of the Board, the Judge held (at para. 26) that "a commercial meaning" should be given to the words "sold in any market in Canada".

[25] This is because, he reasoned (at para. 27), the *Patent Act* "functions within a commercial reality". In support of this position, the Judge cited cases in which the provisions of the Act had been given "a commercial meaning" (at para. 28), as well as *Canada (Deputy Minister of National Revenue) v. Mattel Canada Inc.*, 2001 SCC 36, [2001] 2.S.C.R. 100 at para. 33 ("*Mattel*"), where the Court held that the phrase in the *Customs Act*, "a condition of the sale of the goods for export to Canada" should be interpreted as depending on the basis of "concepts which are intrinsic to commercial law."

[26] Turning to paragraph 80(1)(*b*), the Judge rejected an interpretation of "market" as a demand for a good or service. He held (at para. 31) that for a market to exist in Canada "in the commercial sense", there must be a purchase and sale in Canada and, on the basis of commercial law principles, the sale of Thalomid occurred in New Jersey. The Judge could not find in the purpose of the relevant provisions of the *Patent Act* any indication that Parliament intended paragraph 80(1)(*b*) to have a meaning other than "that expressed in the plain meaning of the words used" (at para. 36).

E. ISSUES AND ANALYSIS

(i) Standard of review

[27] On the basis of earlier decisions, including the decision of this Court in *ICN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board)*, [1997] 1 F.C. 32 ("*ICN*"), counsel agreed that the issue in dispute in this case involves the jurisdiction of the Board and is therefore reviewable on a standard of correctness.

[28] However, since the issue concerns the interpretation of a provision of the Board's enabling statute, I doubt whether it is now appropriate to characterize it as "jurisdictional": see my reasons in *Public Service Alliance of Canada v. Canadian Federal Pilots Association* 2009 FCA 223 at paras. 36-52. Nonetheless, because the standard of review is not, in my opinion, material to the disposition of this appeal, I am prepared to review the Board's determination on the standard of correctness.

(ii) The decision under review

[29] This case was argued before the Board on the basis that, if the Board has power under paragraph 80(1)(*b*) to require the production of pricing information about a patented medicine, it may also regulate the price at which the patentee has sold the medicine "in any Canadian market" under section 83. The Board also seems to have proceeded on this assumption: see, for example, paras. 5 and 20 of its reasons.

[30] However, the only question before the Board was whether Thalomid was being "sold in any market in Canada" within the meaning of paragraph 80(1)(*b*) of the *Patent Act*, so as to enable the Board to require the patentee, Celgene, to provide pricing information about it. The Board's reasons concluded by finding that it had jurisdiction "to make a remedial order concerning the pricing of Thalomid from and after January 12, 1995".

[31] In the proceedings before both the Board and in the Federal Court, the case was argued on the basis that the only relevant sale of Thalomid was that by Celgene to the physician, and that if the Board could require Celgene to provide the information described in paragraph 80(1)(*b*), it could

also make an excessive price determination, and issue orders against Celgene under section 83, even though that section applies only when the patentee has sold the medicine Canada.

[32] Unlike section 83, paragraph 80(1)(*b*) does not expressly require that the medicine in respect of which pricing information was being sought was sold by the patentee. Consequently, it might be arguable that, even if the sale of Thalomid by Celgene to the physician occurred in New Jersey, there was also a sale of it in Canada by the physician to the patient that would engage paragraph 80(1)(*b*), but not section 83. Counsel for the Attorney General suggested that it was implicit in paragraph 80(1)(*b*) that the sale must be by the patentee.

[33] However, since the case was argued on the basis of the sale by Celgene to the physician, I shall not explore this point further. Thus, like both the Board and the Federal Court, my view of the Board's authority to require Celgene to provide pricing information about Thalomid applies also to its authority under section 83 to make excessive price determinations and to issue remedial orders, so as to protect consumers from excessive prices for medicines sold in any market in Canada by the patentee.

(iii) "sold in any market in Canada and elsewhere "; « vendu sur les marchés canadien et étranger »

[34] The appellant argues that "market" is the important word in this phrase in paragraph 80(1)(*b*). "Market", counsel argues, connotes the existence in Canada of a demand for a medicine, which is satisfied when it is purchased by a physician for the treatment of a patient in Canada. In other words, the phrase "in Canada" identifies the location of the market, not of the sale. Any other

interpretation, counsel says, would create two classes of patient: those whose medicine is sold by a manufacturer outside Canada pursuant to an SAP authorization, and all others. The former are not protected against excessive prices, the others are. This distinction, counsel submits, is so plainly contrary to the purposes of the statutory scheme that it cannot have been intended by Parliament.

[35] The respondent, on the other hand, says that the statutory text is so clear that Parliament's purpose in enacting the disputed phrase, and the regulatory scheme of which it is part, play little role in its interpretation. In counsel's submission, the words "sold in Canada" have an "ordinary meaning", that is, that the sale occurred in Canada as determined on the basis of private international law principles pertaining to contractual disputes.

[36] In my view, the following quotation from *Canada Trustco Mortgage Co. v. Canada*, 2005 SCC 54. [2005] 2 S.C.R. 601 at para. 10, accurately captures the modern approach to statutory interpretation:

> The interpretation of a statutory provision must be made according to a textual, contextual and purposive analysis to find a meaning that is harmonious with the Act as a whole. When the words of a provision are precise and unequivocal, the ordinary meaning of the words play a dominant role in the interpretive process. On the other hand, where the words can support more than one reasonable meaning, the ordinary meaning of the words plays a lesser role. The relative effects of ordinary meaning, context and purpose on the interpretive process may vary, but in all cases the court must seek to read the provisions of an Act as a harmonious whole. (Emphasis added)

[37] Thus, the interpretative exercise cannot stop at the text of a statutory provision, but must also include a purposive and contextual analysis of the disputed words, although the relative weight

to be afforded to each may vary. The ordinary meaning of "precise and unequivocal" statutory words will be a particularly important, but not necessarily determinative, factor in the analysis.

[38] However, language is malleable and subtle, and, as any dictionary makes clear, the "ordinary meaning" of words normally connotes a range of meanings. Nonetheless, when a legislature uses words that constitute a legal term of art, it is to be presumed that that is their intended meaning.

(a) the text

[39] Despite the argument repeated by counsel for Celgene, the Act does not provide that a patented medicine must be sold in Canada before the Board may exercise its powers under either paragraph 80(1)(*b*) or section 83. Celgene is, in effect, reading out the words "in any market in Canada", contrary to the interpretative presumption that meaning should be given to every word of a statutory text. Before the case reached this Court, Celgene had argued that "in any market in Canada" meant that the Board only had jurisdiction over the price charged for medicines marketed in Canada under an NOC.

[40] I doubt whether even "sold in Canada" rises to the level of a legal term of art. When a sale has a connection with more than one jurisdiction it may be necessary to decide which law governs the sale when the relevant law of these jurisdictions is not the same, or in which jurisdiction should the parties litigate any contractual dispute. Identifying the jurisdiction with which a contract is more

closely connected for conflict of laws purposes typically involves a multi-factor analysis, including the place where the contract was performed.

[41] In addition, whether a sale of goods occurred in Canada or elsewhere may be relevant for determining if the vendor can be liable in Canada for infringing a patent: *Dole Refrigerating Products Ltd. v. Canadian Ice Machine Co.* (1957), 28 C.P.R. Section II, 32 (Exch. Ct.) ("*Dole Refrigerating*"); *Domco Industries Ltd. v. Mannington Mills Inc.* (1990), 29 C.P.R. (3d) 481 (F.C.A.) ("*Domo Industries*"). Whether goods were "sold in Canada" may also be relevant in some statutory contexts, such as determining liability for customs duty.

[42] On the other hand, like "condition of the sale" considered in *Mattel*, "sold" is a term of legal art and, when used in legislation, presumptively connotes the existence of a contract of sale as understood in private law: *Pfizer Canada Inc. v. Canada (Attorney General)*, 2009 FC 719. It is undisputed in the present case that Celgene sold Thalomid to a physician in Canada for the treatment of a patient under his or her care.

[43] In any event, the phrase in paragraph 80(1)(*b*) is "sold in any market in Canada", not "sold in Canada". The French version supports the appellant's contention that "in Canada" is more closely linked to the location of the "market" than of the sale. It reads: « *le prix de vente … du médicament sur les marchés canadien et étranger* ».

[44] Counsel submits that it would have been easy for Parliament to have said "sold for the treatment of a patient in Canada" if this is what it had meant. True enough, except that it would have been equally easy for it to have said "sold in Canada" if it had meant this. In fact, since the situation being considered here was probably not foreseen by the drafters, Parliament has provided no clear answer.

[45] In these circumstances, the Court must resolve the ambiguity by selecting from the possible meanings that the text may reasonably bear that which best implements the objectives of the legislation. Parliament is taken to intend the legislation that it enacts to be effective in achieving its objectives: compare *Interpretation Act*, R.S.C. 1985, c. I-21, section 12. Regulatory legislation administered by administrative agencies is called "enabling" precisely because its function is to enable them to discharge their mandates, and should be interpreted from this perspective.

[46] In concluding that the words "sold in any market in Canada" should not be interpreted by reference to common law commercial legal principles for determining the location of a sale, I have also taken into account the recent admonition by the Supreme Court of Canada in *Association des courtiers et agents immobiliers du Québec v. Proprio Direct Inc*., 2008 SCC 32, [2008] 2 S.C.R. 195 at para. 34, where, writing for the majority of the Court, Justice Abella said:

> The Court of Appeal's interpretive error, with respect, was to view the legislation through the lens of freedom of contract and competition, rather than through the vision of [the statute in question] as protective consumer legislation.

As applied to the facts of the present case, this sentiment can be rephrased as follows. The interpretive error of the Applications Judge was, with respect, to view the legislation through the

lens of a commercial law dispute, rather than through the vision of the price regulation provisions of the *Patent Act* as protective consumer legislation.

[47] Accordingly, I am unable to conclude that the text of paragraph 80(1)(*b*) is so "precise and unequivocal" as to be accorded more weight than that of statutory purpose and context.

(b) statutory purpose

[48] The purpose of the provisions of the *Patent Act* creating the system for regulating the price of patented medicines is to strike a balance between the public interests in encouraging research and the development of new medicines through the award and protection of a patent, and "the need to ensure that Canadians have access to patented medicines which are reasonably priced": *ICN* at para. 3.

[49] This purpose is advanced by interpreting paragraph 80(1)(*b*) to apply to all patented medicines sold for consumption by patients in Canada for which they or their insurers (public or private) will have to pay. It is inconsistent with legislative intent to interpret the Act in a manner that deprives patients in Canada of the protection of price regulation when the medicines that they need happen to be neither the subject of an NOC, nor available under the SAP from a manufacturer in Canada.

[50] Counsel for the Attorney General also argued that, in addition to falling short of implementing the statutory purpose in the manner described above, Celgene's interpretation over

extends the Board's reach. This is because, if the location of the sale, rather than that of the market, determines whether the price of a medicine is subject to regulation by the Board, it would follow that the price of a patented medicine sold by a Canadian patentee for export from Canada and shipped f.o.b. to, say, Germany, would be subject to regulation by the Board.

[51] Such a result would be incongruous, because Canadian consumer protection legislation is not aimed at regulating the price at which Canadian patented medicines are sold into foreign markets. However, paragraph 80(1)(*b*) expressly authorizes the Board to require a patentee to provide pricing information relating to a medicine that is being sold in any Canadian market and elsewhere.

[52] Counsel for Celgene argued that, to the limited extent that legislative purpose is relevant to interpreting the phrase "sold in any market in Canada", the purpose of the scheme is to regulate the price of medicine sold in Canada. I do not agree. This is, in my view, an unrealistically narrow formulation of the statutory purpose underlying the regulatory scheme and is inconsistent with the broader view expressed in *ICN*.

(c) statutory context

[53] Two points may be made here. First, the disputed phrase appears in a public law context: a regulatory scheme, administered by a specialized tribunal, to prevent the abuse of the monopolistic market power, created by a patent, through the charging of excessive prices for medicines used to treat patients in Canada. In my view, this context provides a more reliable guide to the meaning of

the phrase than private law principles designed to resolve commercial disputes between seller and buyer or, as in *Dole Refrigeraton* and *Domco Industries*, to locate where a patent infringement occurred.

[54] Second, it was argued that the Board's interpretation gives an extra-territorial effect to the legislation by enabling the Board to issue orders respecting the price of medicines sold outside Canada, which it could not enforce. Parliament, counsel said, should not be held to have legislated to no practical effect. I do not agree that this necessarily follows from the Board's interpretation.

[55] The Board has a legitimate interest in the price paid for medicine purchased under the SAP by a physician (perhaps as agent of the patient for whose treatment it has been prescribed) from a patentee outside Canada, because this is the price that will be paid for the medicine by the ultimate consumer in Canada. For the Board in these circumstances to find that the price charged by the patentee, and ultimately paid by a patient, an insurer or an institution in Canada, is excessive, and to order the patentee to reduce the price of sale, is not, in my view, to give the legislation extra-territorial effect.

[56] For one thing, the patentee may decide that it will no longer sell the medicine in Canada below the price found by the Board to be excessive. However, this is a course of action open to the patentees of all medicines in response to an order of the Board. Alternatively, if it decides to flout the Board's order by continuing to sell the medicine at a price that the Board has found excessive,

the Board may not be able to enforce its order if the patentee has no presence in Canada. However, these hypothetical responses by a patentee to a Board order are speculative.

[57] In my view, it is at least as likely that the patentee would be prepared to comply and to sell the drug at a permitted price. The Board has no interest in finding a price to be excessive, on the basis of the criteria contained in section 85 and the guidelines developed after consultation with industry, consumers and Health Canada, when it has reason to believe that the patentee would not be willing sell the medicine for less.

[58] Hence, in my opinion, the statutory and regulatory contexts support the Board's interpretation of paragraph 80(1)(*b*).

F. CONCLUSIONS

[59] For these reasons, I agree with the Board's interpretation of the phrase "sold in any market in Canada" in sections 80(1), 83 and 85 of the *Patent Act*. I would therefore allow the appeal with costs here and below, set aside the order of the Applications Judge, and dismiss Celgene's application for judicial review.

"John M. Evans"
J.A.

"I agree.
K. Sharlow J.A."

APPENDIX

Patent Act, R.S.C. 1985, c, P-4

Pricing information, etc., required by regulations	Renseignements réglementaires à fournir sur les prix
80. (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting	80. (1) Le breveté est tenu de fournir au Conseil, conformément aux règlements, les renseignements et documents sur les points suivants :
…	[…]
(b) the price at which the medicine is being or has been sold in any market in Canada and elsewhere;	*(b)* le prix de vente — antérieur ou actuel — du médicament sur les marchés canadien et étranger;
…	[…]
Order re excessive prices	Ordonnance relative aux prix excessifs
83. (1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.	83. (1) Lorsqu'il estime que le breveté vend sur un marché canadien le médicament à un prix qu'il juge être excessif, le Conseil peut, par ordonnance, lui enjoindre de baisser le prix de vente maximal du médicament dans ce marché au niveau précisé dans l'ordonnance et de façon qu'il ne puisse pas être excessif.
(2) Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or	(2) Sous réserve du paragraphe (4), lorsqu'il estime que le breveté a vendu, alors qu'il était titulaire du brevet, le médicament sur un marché canadien à un prix qu'il juge avoir été excessif, le Conseil peut, par ordonnance, lui enjoindre de prendre l'une ou plusieurs des mesures suivantes pour compenser, selon lui,

more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:

(a) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

(b) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or

(c) pay to Her Majesty in right of Canada an amount specified in the order.

…

Factors to be considered

85. (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

(a) the prices at which the medicine has been sold in the relevant market;

(b) the prices at which other medicines in the same therapeutic class have

l'excédent qu'aurait procuré au breveté la vente du médicament au prix excessif :

(a) baisser, dans un marché canadien, le prix de vente du médicament dans la mesure et pour la période prévue par l'ordonnance;

(b) baisser, dans un marché canadien, le prix de vente de tout autre médicament lié à une invention brevetée du titulaire dans la mesure et pour la période prévue par l'ordonnance;

(c) payer à Sa Majesté du chef du Canada le montant précisé dans l'ordonnance.

…

Facteurs de fixation du prix

85. (1) Pour décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil tient compte des facteurs suivants, dans la mesure où des renseignements sur ces facteurs lui sont disponibles :

(a) le prix de vente du médicament sur un tel marché;

(b) le prix de vente de médicaments de la même catégorie thérapeutique

been sold in the relevant market;

(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

(d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.

sur un tel marché;

(c) le prix de vente du médicament et d'autres médicaments de la même catégorie thérapeutique à l'étranger;

(d) les variations de l'indice des prix à la consommation;

(e) tous les autres facteurs précisés par les règlements d'application du présent paragraphe.

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

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.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 ;

[…]

Sale of New Drug for Emergency Treatment

C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if

(a) the practitioner has supplied to the Director information concerning

(i) the medical emergency for which the drug is required,

(ii) the data in the possession of the practitioner with respect to the use, safety and efficacy of that drug,

(iii) the names of all institutions in which the drug is to be used, and

(iv) such other data as the Director may require; and

(b) the practitioner has agreed to

(i) report to the manufacturer of the new drug and to the Director on the results of the use of the drug in the medical emergency, including

Vente d'une drogue nouvelle pour un traitement d'urgence

C.08.010. (1) Le Directeur général peut fournir une lettre d'autorisation permettant la vente d'une certaine quantité d'une drogue nouvelle d'usage humaine ou vétérinaire à un praticien nommé dans la lettre d'autorisation pour le traitement d'urgence d'un malade traité par ledit praticien, si

(a) le praticien a fourni au Directeur général des renseignements concernant

(i) l'état pathologique urgent pour laquel la drogue est requise,

(ii) les données que possède le praticien à propos de l'usage, de l'innocuité et de l'efficacité de ladite drogue,

(iii) le nom de tous les établissements où la drogue doit être utilisée, et

(iv) les autres renseignements que le Directeur général pourrait lui demander; et

(b) le praticien a consenti à

(i) faire part au fabricant de la drogue nouvelle et au Directeur général des résultats de l'usage de la drogue au cours de l'urgence, y compris

information respecting any adverse reactions encountered, and

(ii) account to the Director on request for all quantities of the drug received by him.

(2) The Director shall, in any letter of authorization issued pursuant to subsection (1), state

(a) the name of the practitioner to whom the new drug may be sold;

(b) the medical emergency in respect of which the new drug may be sold; and

(c) the quantity of the new drug that may be sold to that practitioner for that emergency.

…

C.08.011. (1) Notwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a letter of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that letter that does not exceed the quantity specified in the letter.

(2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the Act and these Regulations.

les renseignements se rapportant à toute réaction défavorable qu'il aura observée, et

(ii) rendre compte au Directeur général, sur demande, de toutes les quantités de la drogue qu'il aura reçues.

(2) Le Directeur général doit, dans toute lettre d'autorisation fournie conformément au paragraphe (1), spécifier

(a) le nom du praticien auquel la drogue nouvelle peut être vendue;

(b) l'état pathologique urgent pour lequel la drogue nouvelle peut être vendue; et

(c) la quantité de la drogue nouvelle qui peut être vendue audit praticien pour ledit cas urgent.

…

C.08.011. (1) Nonobstant l'article C.08.002, un fabricant peut vendre à un praticien mentionné dans une lettre d'autorisation fournie conformément à l'article C.08.010, une quantité de la drogue nouvelle nommée dans ladite lettre qui n'excède pas la quantité spécifiée dans la lettre.

(2) La vente d'une drogue nouvelle faite en conformité du paragraphe (1) n'est pas soumise aux dispositions de la Loi et du présent règlement.

RYER J.A. (Dissenting reasons)

[60] With respect, I am unable to agree with the conclusion of my colleague, Justice Evans. In my view, the correct interpretation of paragraph 80(1)(*b*) of the *Patent Act*, R.S.C. 1985, c. P-4 (the "Act") is that the Patented Medicines Prices Review Board (the "Board") has no power to request information of the type contemplated by that provision respecting the price at which a particular medicine is sold unless that medicine is being or has been sold in Canada. In other words, the jurisdiction of the Board is not engaged unless it is established that the medicine in question has been the subject of a sale that takes place in Canada. Accordingly, I agree with the decision of Justice Campbell that the decision of the Board, dated January 1, 2008, should be set aside.

[61] In support of this conclusion and to address certain of the reasons of my colleague, I wish to make the following observations.

[62] First, in my view, the textual, contextual and purposive approach espoused by the Supreme Court of Canada in *Canada Trustco Mortgage Co. v. Canada*, [2005] 2 S.C.R. 601, 2005 SCC 54, mandates reliance on the ordinary meaning of the words of the provision under consideration when those words are precise and unequivocal. To me, the words " sold in any market in Canada", as contained in paragraph 80(1)(*b*) of the Act, contemplate sales of the medicine in question occurring in Canada, whether or not that phrase, or any portion of it, can be said to be a "legal term of art".

[63] Secondly, my colleague appears to favour an interpretation of the phrase "sold in any market in Canada" that places more emphasis on the location of the market than on the place of sale of the

medicine. Thus, under this approach, the Board would have the power to request information in relation to a sale of the medicine by Celgene that occurs in a market in Canada. But how is it that a sale of the medicine that admittedly occurred in the United States could also occur in a market in Canada? In my view, this conundrum illustrates the insurmountable difficulty with respect to an interpretation that focuses on the requirement for a market in Canada. Clearly, any sale that occurs in Canada will also occur in a market in Canada.

[64] Without engaging in a debate with respect to the meaning of the French word “marché”, I note that counsel for the appellant states, at paragraph 45 of his factum:

> The corresponding definition of the word marché specifically refers to the geographical area where commodities and services are transacted… [Emphasis added.]

In my view, sale transactions cannot be “transacted” in a geographical area without the presence of both the buyer and the seller in that area. Moreover, a mere demand for a commodity is insufficient to bring about a transaction with respect to that commodity.

[65] Thirdly, the interpretation of my colleague seems to rewrite the particular phrase so that it would become “sold into any market in Canada”. This interpretation stretches the meaning of the phrase into something beyond its ordinary meaning. If Parliament had intended the phrase “sold in any market in Canada”, in paragraph 80(1)(*b*) of the Act, to have an extended meaning, it could have done so as it did when it inserted an extended meaning of “patentee” in section 79 of the Act. That extended meaning operates for the purposes of section 79 to 103 of the Act. In my view, the absence of an extended meaning in the Act for the phrase “sold in any market in Canada” indicates

that the phrase should be given its ordinary meaning. Since Parliament did not stipulate that the words in issue were to be given a meaning outside their ordinary meaning, with respect, I am not persuaded that it is this Court's mandate to do so.

[66] Fourthly, the issue before the Board, the Federal Court and this Court is the jurisdiction of the Board to make information requests under paragraph 80(1)(*b*) of the Act. With respect, the jurisdiction of the Board to make an order against Celgene under section 83 of the Act was not in issue, and was not fully argued, before this Court. As such, I would leave the scope of the Board's jurisdiction over Celgene under that provision to be argued in a proceeding in which that issue actually arises.

[67] Finally, I am not inclined to view the Act as consumer protection legislation. Indeed, the Board itself appears to believe that its mandate was broader than that. At paragraph 5 of its reasons, the Board states:

> 5. The mandate of the Board includes balancing the monopoly power held by the patentee of a medicine, with the interests of purchasers of those medicines. The patentee of a medicine sold in Canada is subject to the jurisdiction of the Board, and this jurisdiction requires the patentee to report information to the Board concerning the price at which it has been selling the patented medicine in any market in Canada. The Board compares this price to the price of comparable medicines, and to the price at which the medicine is sold in other countries, to determine whether or not its price in Canada is excessive. In consultation with industry, government and consumer stakeholders, the Board has developed detailed guidelines that patentees and Board Staff use to ensure that the prices of patented medicines in Canada are not excessive (the "Guidelines"). [Emphasis added.]

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

"C. Michael Ryer"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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