

**SUPREME COURT OF CANADA**

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| **Citation:** Celgene Corp. *v.* Canada(Attorney General),  2011 SCC 1, [2011] 1 S.C.R. 3 | **Date:** 20110120  **Docket:** 33579 |

**Between:**

**Celgene Corporation**

Appellant

and

**Attorney General of Canada**

Respondent

**Coram:** McLachlin C.J. and Binnie, LeBel, Deschamps, Fish, Abella, Charron, Rothstein and Cromwell JJ.

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| **Reasons for Judgment:**  (paras. 1 to 35) | Abella J. (McLachlin C.J. and Binnie, LeBel, Deschamps, Fish, Charron, Rothstein and Cromwell JJ. concurring) |

Celgene Corp. *v.* Canada (Attorney General), 2011 SCC 1, [2011] 1 S.C.R. 3

**Celgene Corporation** *Appellant*

*v.*

**Attorney General of Canada** *Respondent*

**Indexed as:**Celgene Corp. ***v.* Canada (**Attorney General)

2011 SCC 1

File No.:  33579.

2010:  November 10; 2011:  January 20.

Present:  McLachlin C.J. and Binnie, LeBel, Deschamps, Fish, Abella, Charron, Rothstein and Cromwell JJ.

on appeal from the federal court of appeal

*Legislation ― Statutory interpretation ― Scope of the Patented Medicine Prices Review Board’s price‑regulating and remedial authority ― Meaning of “sold in any market in Canada” ― Whether concept should be interpreted in accordance with commercial law principles or be responsive to surrounding legislative context and purpose ― Patent Act, R.S.C. 1985, c. P-4, ss. 80(1)(b), 83(1), 85.*

*Administrative law ― Judicial review ― Standard of review ― Reasonableness of Patented Medicine Prices Review Board Board’s interpretation of its enabling legislation ― Patent Act, R.S.C. 1985, c. P‑4, ss. 80(1)(b), 81(1)(a), 83(1), 85.*

C is a New Jersey-based distributor of a pharmaceutical sold under the brand name Thalomid. Since 1995, C’s sales of this drug to Canadians have been made pursuant to the Special Access Programme (“SAP”) as C did not get a Notice of Compliance from Health Canada to sell the medicine in Canada. When a Canadian doctor orders Thalomid under the SAP, the medicine is packed in C’s facilities in the U.S. and shipped Free on Board to the doctor in Canada. C prepares an invoice in New Jersey, mails it to Canada, and directs that payment be made in U.S. dollars and couriered or mailed to C in New Jersey. No Canadian taxes are paid on these transactions. The drug is never redistributed in Canada and any unused portions must be returned to C’s facility in Pennsylvania.

When C obtained the Canadian patent in relation to Thalomid in 2006, the Patented Medicine Prices Review Board (“Board”) advised C that it now had jurisdiction to request pricing information from C from the time it first sold Thalomid through the SAP in 1995. C initially provided some pricing information; however, it refused to continue supplying the requested information, arguing that under commercial law principles, the medicine was “sold” in New Jersey and was outside the Board’s authority under s. 80(1)(*b*) of the *Patent Act*. The Board concluded that C’s Thalomid sales to Canadians pursuant to SAP were sales “in any market in Canada” and fell within both its authority for price investigation and its related remedial powers. The Board’s decision was initially reversed on judicial review but the Federal Court of Appeal agreed with the Board’s interpretation of its mandate.

Held: The appeal should be dismissed.

The legislative context and the consumer protection purpose of ss. 80(1)(*b*), 83(1) and 85 of the *Patent Act* support the Board’s conclusion that, based on the language of the provisions, it has authority over C’s sales of Thalomid to Canadians through the SAP. The Board was justified in concluding that in order to comply with its mandate, sales “in any market in Canada” for the purposes of the relevant provisions, should be interpreted to include sales of medicines that are regulated by the public laws of Canada, will be delivered and dispensed in Canada, and where, in particular, the cost of the medicine will be borne by Canadians. All of these prerequisites are satisfied in the case of C’s sales of Thalomid to Canadians through the SAP.

The Board’s interpretation of its mandate under the relevant provisions was consistent with its consumer protection purpose and should not be disturbed. The Board is responsible for ensuring that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian consumers. While words like “sold” may well have a commercial law meaning in some statutory contexts, accepting a technical commercial law definition in this context would undermine the Board’s consumer protection objectives by preventing it from protecting Canadian purchasers of medicine entering Canada through the SAP.

Although the Board’s decision is unassailable under either standard of review, the operative standard is reasonableness.

**Cases Cited**

**Distinguished:**  *Canada (Deputy Minister of National Revenue) v. Mattel Canada Inc.*, 2001 SCC 36, [2001] 2 S.C.R. 100; **referred to:***Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190; *Public Service Alliance of Canada v. Canadian Federal Pilots Assn.*, 2009 FCA 223, [2010] 3 F.C.R. 219; *Canada* *Trustco Mortgage Co. v. Canada*, 2005 SCC 54, [2005] 2 S.C.R. 601; *Dole Refrigerating Products Ltd. v. Canadian Ice Machine Co.* (1957), 28(2) C.P.R. 32; *Domco Industries Ltd. v. Mannington Mills, Inc.* (1990), 29 C.P.R. (3d) 481, leave to appeal refused, [1990] 2 S.C.R. vi; *ICN Pharmaceuticals Inc. v. Patented Medicine Prices Review Board* (1996), 108 F.T.R. 190, aff’d [1997] 1 F.C. 32; *Canada (Citizenship and Immigration) v. Khosa*, 2009 SCC 12, [2009] 1 S.C.R. 339;*Nolan v. Kerry (Canada) Inc.*, 2009 SCC 39, [2009] 2 S.C.R. 678.

**Statutes and Regulations Cited**

*Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C. 1987, c. 41.

*Food and Drug Regulations*, C.R.C. 1978, c. 870, ss. C.08.002, C.08.004, C.08.010, C.08.011.

*Patent Act*, R.S.C. 1985, c. P-4, ss. 80(1)(*b*), 81(1)(*a*), 83(1), 85.

*Patent Act Amendment Act, 1992*, S.C. 1993, c. 2.

**Authors Cited**

Canada. Health Canada. *Guidance Document for Industry and Practitioners: Special Access Programme for Drugs*. Ottawa: Health Canada, 2008.

Canada. House of Commons. *House of Commons Debates*, vol. I, 2nd Sess., 33rd Parl., November 20, 1986, pp. 1369, 1373.

Canada. House of Commons. *House of Commons Debates*, vol. XII, 3rd Sess., 34th Parl., December 10, 1992, pp. 14998, 15001.

APPEAL from a judgment of the Federal Court of Appeal (Evans, Sharlow and Ryer JJ.A.), 2009 FCA 378, 315 D.L.R. (4th) 270, 398 N.R. 233, 100 Admin. L.R. (4th) 244, 81 C.P.R. (4th) 93, [2009] F.C.J. No. 1666 (QL), 2009 CarswellNat 4439, setting aside a decision of Campbell J., 2009 FC 271, 344 F.T.R. 45, 81 C.P.R. (4th) 79, [2009] F.C.J. No. 668 (QL), 2009 CarswellNat 1499. Appeal dismissed.

William Vanveen and Henry S. Brown, Q.C.,for the appellant.

Christopher Rupar and Jan Brongers, for the respondent.

The judgment of the Court was delivered by

1. Abella J. — The Patented Medicine Prices Review Board (“Board”) has authority under ss. 80(1)(*b*) and 81(1)(*a*) of the *Patent Act*, R.S.C. 1985, c. P-4,to require a patentee of a medicine to provide it with information so it can investigate the price at which the medicine “is being or has been sold in any market in Canada”. If the Board finds that the price charged is excessive, under s. 83(1) it can order that the price be reduced. This appeal centres on a single issue: whether the concept of “sold in any market in Canada” in the relevant provisions should be interpreted strictly in accordance with commercial law principles, or whether its definition should be responsiveto the surrounding legislative context and purpose.

Background

1. Celgene Corporation is the New Jersey-based distributor of a pharmaceutical sold under the brand name Thalomid. This drug contains the active ingredient thalidomide. Thalomid has proven to be an effective treatment for conditions such as leprosy and multiple myeloma and is approved for those uses in the United States.
2. Most sales of medicines in Canada occur after Health Canada is satisfied of the medicine’s safety and effectiveness and has issued a Notice of Compliance (“NOC”) pursuant to ss. C.08.002 and C.08.004 of the *Food and Drug Regulations*, C.R.C. 1978, c. 870. Where the manufacturer has not applied for an NOC, or Health Canada has not yet granted one, medicines may in some cases be sold to medical practitioners through an alternate route — the Special Access Programme (“SAP”): see *Food and Drug Regulations*,ss. C.08.010 and C.08.011. The SAP has been interpreted to allow access to drugs not otherwise available in a particular market for the treatment of “serious or life-threatening conditions where conventional therapies have failed, are unsuitable, or are unavailable either as marketed products or through enrollment in clinical trials”: Health Canada, *Guidance Document for Industry and Practitioners: Special Access Programme for Drugs* (2008),at p. 1.
3. There is no limit on the volume of sales that can be made pursuant to the SAP, nor on the period of time that a manufacturer may supply the medicine through it. If Health Canada approves the request for sales pursuant to the SAP, the manufacturer is authorized to sell the medicine for the use of the specific patient or clinical trial identified in the request.
4. Celgene did not get an NOC for Thalomid. Since 1995, its sales of this drug to Canadians have been made pursuant to the SAP. Of the approximately 26,000 requests made under the SAP in 2006 by medical practitioners, approximately 4,500 were for Thalomid, making it the most frequently sourced drug under the SAP.
5. When a Canadian doctor orders Thalomid under the SAP, the medicine is packed in Celgene’s facilities in the United States and shipped Free on Board to the doctor in Canada. Celgene prepares an invoice in New Jersey, mails it to Canada, and directs that payment be made in U.S. dollars and couriered or mailed to Celgene in New Jersey. No Canadian taxes are paid on these transactions. The drug is never redistributed in Canada — any unused portions must be returned to a Celgene facility in Pennsylvania.
6. Celgene obtained a Canadian patent in relation to Thalomid on April 4, 2006. Seven days later, the Board advised Celgene that in view of this patent, the Board now had jurisdiction to request pricing information from Celgene from the time it first sold Thalomid through the SAP in 1995.
7. Celgene initially provided some pricing information without prejudice to its position that the Board lacked jurisdiction to obtain it. Ultimately, however, it refused to continue supplying the requested information, arguing that because, under commercial law principles, the medicine was “sold” in New Jersey, it was outside the Board’s authority under s. 80(1)(*b*), which extended only to medicine “sold . . . in Canada”.
8. A motion was brought to the Board seeking an order that Celgene provide the pricing information so a determination could be made by the Board as to whether the price charged to Canadian purchasers was excessive.
9. In its decision, the Board acknowledged that the medicine was sold through Celgene’s head office in New Jersey and that, as the parties freely acknowledged, New Jersey would be considered the *locus* of the sale for commercial law purposes (PMPRB-07-D1-THALOMID). But in the Board’s view, ordinary commercial law definitions of place of sale were not germane to, let alone determinative of its authority. While commercial law principles for determiningwherea sale took place are helpful in enforcing contractual terms and determining the physical location at which risk to the goods and transportation costs pass from the vendor to the purchaser, the Board concluded that its authority under the *Patent Act* is unrelated to allocation of risk, cost of transportation, or choice of law in a contractual dispute. Because its mandate includes protecting Canadians from excessive prices that may be charged for patented medicines, it concluded that sales “in any market in Canada” include sales of medicine that are regulated by Canadian law, that will be delivered and used in Canada, and where the cost of the medicine will be borne by Canadians. Since the SAP is a Canadian law, Celgene’s sales under this programme are included in this mandate.
10. Moreover, in the Board’s view, an interpretation that is based on the commercial law approach to the location of the sale would have the incongruous effect of giving it authority over commercial sales made in Canada to *foreign* purchasers. This would be inconsistent with its statutory mandate to protect *Canadian* consumers. It therefore concluded that Celgene’s Thalomid sales to Canadians pursuant to the SAP fell within both its authority for price investigation and its related remedial powers.
11. On judicial review, Campbell J. found that this was a jurisdictional issue and that the appropriate standard of review was correctness (2009 FC 271, 344 F.T.R. 45). In his view, although Thalomid is sold to Canadians, it is sold in the United States, not Canada, and cannot fall within the words “sold in any market in Canada”. e The Board therefore had no jurisdiction to order either the Thalomid pricing information or a price reduction.
12. The Federal Court of Appeal (2009 FCA 378, 315 D.L.R. (4th) 270) agreed with the Board’s interpretation of its mandate. The parties had jointly submitted that correctness was the appropriate standard of review, characterizing the question as jurisdictional in nature.Evans J.A. doubted that this was a proper characterization of either the standard or the question, but since in his view the standard of review did not materially affect the disposition of the appeal, he was prepared to accept the parties’ invitation to review the Board’s decision on a correctnessstandard (*Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190; *Public Service Alliance of Canada v. Canadian Federal Pilots Assn.*, 2009 FCA 223, [2010] 3 F.C.R. 219, at paras. 36-52).
13. Engaging in a textual interpretation of the relevant provisions, Evans J.A. noted that the interpretation should be based on the full phrase in s. 80(1)(*b*), namely, “sold in any market in Canada”, not just the words “sold in Canada”, as Celgene had urged. In his view, because the language was open todifferent interpretations, oneshould be chosen which best implemented the consumer protection objectives of the price-regulation provisions of the *Patent Act*. If the provisions were interpreted in a way that exempted Celgene’s Thalomid sales through the SAP, Canadians would be deprivedof the price protection that underlay the enactment of those provisions.
14. In his dissenting reasons, Ryer J.A. did not accept that the provisions were aimed at consumer protection. In his view, the jurisdiction of the Board is not engaged unless it is established that the medicine in question has been the subject of a sale taking place in Canada. Based on the ordinary commercial law meaning of the words “sold in any market in Canada”, the medicine was “sold” in the United States. This meant that the Board could not require Celgene to provide pricing information for Thalomid.
15. For the reasons that follow, I share Evans J.A.’s view that the Board’s decision should not be disturbed.

Analysis

1. The Board is responsible for monitoring and regulating the prices of patented medicines. Under s. 81(1)(*a*) of the *Patent Act*, the Board may order a patentee “of an invention pertaining to a medicine to provide the Board with information and documents respecting . . . any of the matters referred to in paragraphs 80(1)(*a*) to (*e*)”. The particular provision at issue in this case is s. 80(1)(*b*), which states that the Board is entitled to certain pricing information:

**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

. . .

(*b*) the price at which the medicine is being or has been sold in any market in Canada and elsewhere;

1. Section 83(1) of the *Patent Act* empowers the Board to order the reduction of the price at which a patentee is selling the medicine in any market in Canada when it is of the view that this price is excessive:

**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.

1. The Board’s decision to make a s. 83(1) remedial order depends on the factors listed in s. 85:

**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 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.

(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:

(*a*) the costs of making and marketing the medicine; and

(*b*) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

(3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.

1. The common language in ss. 80(1)(*b*), 83(1), and 85 is: sold (or selling) in any market in Canada. I acknowledge that these words may lend themselves to different interpretations. The question is whether the one selected by the Board is justified.
2. The parties both relied on the approach used in *Canada* *Trustco Mortgage Co. v. Canada*, 2005 SCC 54, [2005] 2 S.C.R. 601, at para. 10, which confirmed that statutory interpretation involves a consideration ofthe ordinary meaning of the words used and the statutory context in which they are found:

It has been long established as a matter of statutory interpretation that “the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament”:see *65302 British Columbia Ltd. v. Canada*, [1999] 3 S.C.R. 804, at para. 50.  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.

The words, if clear, will dominate; if not, they yield to an interpretation that best meets the overriding purpose of the statute.

1. But although the partiesagreed on the proper interpretive approach, they disputed its application. The Attorney General argued that the phrase “sold in any market in Canada” is broad and should not be given the limited, technical interpretation ascribed to it by Celgene. Celgene, on the other hand, argued that the word “sold” is so “precise and unequivocal” that it must play the determinative role in the interpretive process (*Canada Trustco*, at para. 10). Citing *Canada (Deputy Minister of National Revenue) v. Mattel Canada Inc.*, 2001 SCC 36, [2001] 2 S.C.R. 100, Celgene argued that “sold” is a legal term of art that should presumptively be given its private law, commercial meaning. In its view, the plain meaning of “sold in any market in Canada” connotes a commercial contract of sale occurring in Canada.
2. *Mattel* is of limited assistance in this case. It involved an interpretation of s. 48(5)(*a*)(iv) of the *Customs Act*, R.S.C. 1985, c. 1 (2nd Supp.), a provisionconcerned with whether royalties paid between two *private* parties in a commercial transaction were “a condition of the sale of the goods for export to Canada”. Major J. concluded that in the particular context of that provision — which assists in calculating customs duties on items imported into Canada — the word “condition” in the phrase “condition of the sale” had a settled meaning in sale of goods law which governed in interpreting this private transaction (see paras. 58-59).
3. I accept that, as *Mattel* demonstrates, words like “sold” may well have a commercial law meaning in some statutory contexts, including, for example, in other parts of the *Patent Act* (see *Dole Refrigerating Products Ltd. v. Canadian Ice Machine Co.* (1957), 28(2) C.P.R. 32 (Ex. Ct.); *Domco Industries Ltd. v. Mannington Mills, Inc.* (1990), 29 C.P.R. (3d) 481 (F.C.A.), leave to appeal refused, [1990] 2 S.C.R. vi).
4. But that does not mean that the Board misinterpreted the words “sold” and “selling” in the context of ss. 80(1)(*b*), 83(1) and 85. In rejecting the technical commercial law definition, the Board was guided by the consumer protection goals of its mandate, concluding that Celgene’s approach would undercut these objectives by preventing the Board from protecting Canadian purchasers of Thalomid and other foreign-sold SAP patented medicines.
5. The Board’s interpretive choice issupported by the legislative history. The Board was established in amendments contained in Bill C-22, *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, which received Royal Assent on November 19, 1987, as S.C. 1987, c. 41. Introducing the Bill for second reading, the Hon. Harvie Andre made the following relevant comments about the Board’s objectives:

In essence, the amendments I propose in Bill C-22 will create a climate favourable to new investment in research and development by giving patent holding pharmaceutical firms in Canada a guaranteed period of protection. These changes will also ensure consumer protection by creating a drug prices review board to monitor drug prices. . . .

. . .

I humbly submit that anybody who takes an objective view of what we are proposing will see that we have in place enormous checks and balances to ensure that consumer prices of drugs remain reasonable. They should look at what we will get by way of research and development, and at the jobs this will create.

. . .

Whatever costs might be associated with this legislation will be minimal. They will not hit the consumer. [Emphasis added.]

(*House of Commons Debates*, vol. I, 2nd Sess., 33rd Parl., November 20, 1986,at pp. 1369 and 1373)

1. When the *Patent Act* was further amended in 1993 (*Patent Act Amendment Act, 1992*, S.C. 1993, c. 2), the then Minister of Consumer and Corporate Affairs and Minister of State (Agriculture), the Hon. Pierre Blais, reiterated the Board’s consumer protection mandate:

With Bill C-91, we also wanted to strengthen consumer protection, so that consumers can continue to obtain patented medicine at reasonable prices. I think that all Canadians are entitled to that.

. . .

. . . The board will thus be able to provide all Canadian consumers with even more effective price control. These new powers will authorize the board to order a reduction of prices it considers too high. . . .

. . . I am convinced that these new provisions will assure Canadian consumers, of reasonable prices, like those they have had since 1987.

(*House of Commons Debates*, vol. XII, 3rd Sess., 34th Parl., December 10, 1992, at pp. 14998 and 15001)

1. The Board’s consumer protection purpose was affirmed in *ICN Pharmaceuticals Inc. v. Patented Medicine Prices Review Board* (1996), 108 F.T.R. 190, aff’d [1997] 1 F.C. 32 (C.A.), where Cullen J. said:

Sections 79 to 103 of the *Patent Act*, creating the Patented Medicine Prices Review Board, were enacted in response to the abolition of the compulsory licensing regime.Parliament’s intent was certainly to address the “mischief” that the patentee’s monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels.Accordingly, the words of these sections of the *Patent Act* should be read purposively . . . . [Emphasis added; para. 24.]

1. This is the approach to its mandate that the Board applied, one that took into paramount account its responsibility for ensuring that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers:

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 . . . . [Emphasis added; para. 5.]

1. The Board therefore concluded that in order to comply with that mandate, sales “in any market in Canada” for the purposes of the relevant provisions, should be interpreted to“include sales of medicines that are regulated by the public laws of Canada, that will be delivered in Canada, to be dispensed in Canada, and where, in particular, the cost of the medicine will be borne by Canadians — patients or taxpayers, as the case may be” (para. 34). All of these prerequisites are satisfied in the case of Celgene’s sales of Thalomid to Canadians through the SAP.
2. The Board also found, and I agree, that a strict commercial law interpretation of “sold” in s. 80(1)(*b*) would givethe Board authority over sales which, while technically made “in Canada”, are destined for other countries, a result incongruous with the legislative purpose of regulating the price at which patented medicines are sold in *Canadian*, not foreign, markets:

. . . the Board does not have a statutory mandate to protect European purchasers of patented medicines, regardless of the *locus* of the sale at common law. The *locus* of the sale at common law, does not give rise to jurisdiction when the *locus* is Canada, and does not deprive the Board of jurisdiction when the *locus* is outside of Canada. [para. 36]

1. In my view, therefore, the legislative context and the consumer protection purpose of ss. 80(1)(*b*), 83(1) and 85 of the *Patent Act* support the Board’s conclusion that, based on the language of those provisions, it has authority over Celgene’s sales of Thalomid to Canadians through the SAP.
2. A final observation. In this Court, neither party presented any argument on the standard of review. Both had proceeded throughout the judicial review process on the basis that the applicable standard of review was correctness. While the parties should not be able, by agreement, to *contract out* of the appropriate standard of review, like Evans J.A. I am of the view that the Board’s decision would be upheld under either standard.
3. And like Evans J.A., I also question whether correctness is in fact the operative standard. This specialized tribunal is interpreting its enabling legislation. Deference will usually be accorded in these circumstances: see *Dunsmuir*, at paras. 54 and 59; *Canada (Citizenship and Immigration) v. Khosa*, 2009 SCC 12, [2009] 1 S.C.R. 339, at para. 44;and*Nolan v. Kerry (Canada) Inc.*, 2009 SCC 39, [2009] 2 S.C.R. 678. Only if the Board’s decision is unreasonable will it be set aside. And to be unreasonable, as this Court said in *Dunsmuir*,the decision must be said to fall outside “a range of possible, acceptable outcomes which are defensible in respect of the facts and law” (para. 47). Far from falling outside this range, I see the Board’s decision as unassailable under eitherstandard of review.
4. I would dismiss the appeal with costs.

*Appeal dismissed with costs.*

*Solicitors for the appellant:  Gowling Lafleur Henderson, Ottawa.*

*Solicitor for the respondent:  Attorney General of Canada, Ottawa.*