

Federal Court



Cour fédérale

Date: 20090317**Docket: T-278-08****Citation: 2009 FC 271****Ottawa, Ontario, March 17, 2009****PRESENT: The Honourable Mr. Justice Campbell****BETWEEN:****CELGENE CORPORATION****Applicant****and****ATTORNEY GENERAL OF CANADA****Respondent****REASONS FOR ORDER AND ORDER**

[1] The present Application concerns the jurisdiction of the Patented Medicine Prices Review Board (Board) to regulate the price of a medicine, in this case Thalomid, currently sold in the United States under the auspices of the Special Access Programme (SAP) operated by Health Canada. The Applicant Celgene brings the present Application under s. 18.1 of the *Federal Courts Act*, R.S., 1985, c. F-7 to review the Board's January 21, 2008 decision in which it found that it has jurisdiction to require Celgene to provide pricing information concerning its sales of Thalomid in the United States.

[2] For the reasons that follow I find that the Board does not have the jurisdiction to regulate Celgene's sale of Thalomid in the United States under the SAP.

I. Standard of Review

[3] I find that the standard of review of the jurisdiction issue in the present Application is correctness (see *Dunsmuir v. The Queens* [2008], SCC 9 at para. 50; *Canada (Citizenship and Immigration) v. Khosa*, 2009 SCC 12; *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)*, 2005 FC 1552 at para. 110; and *Shire Biochem Inc. v. Canada (Attorney General)*, 2007 FC 1316 at para. 19).

II. The Context

A. Celgene

[4] Celgene is a multi-national innovative biopharmaceutical company incorporated in the State of Delaware, U.S.A.; its current corporate headquarters are in New Jersey.

[5] Celgene is the distributor of Thalomid, which contains the active ingredient thalidomide. Thalidomide was approved for sale by Health Canada in the early 1960s and was marketed primarily to pregnant women to assist with nausea and sleep loss. Sales of thalidomide were halted in Canada in 1962 after the drug was linked with birth defects. Currently, thalidomide is used for the treatments of leprosy, immune related conditions associated with AIDS, and certain forms of cancer. Since 1998, the American Food and Drug Administration has approved the medicine for the

treatment of leprosy, and since May 2006 for newly diagnosed multiple myeloma which is a form of cancer.

B. The regulation of thalomid in Canada

[6] Celgene is the current owner or licensee of several Canadian patents related to thalidomide including Canadian Patent Nos. 2,166,315; 2,270,887; and 2,157,288. However, Celgene does not have full market authorization from Health Canada via a Notice of Compliance (NOC) to market or sell Thalomid in Canada (see the *Food and Drug Regulations*, C.R.C., c. 870, Part C, Division 8). Notwithstanding the general prohibition under section C.08022(1) of the *Food and Drug Regulations*, Health Canada may permit sales of new drugs for medical emergencies by way of the Special Access Program in accordance with sections C.08.010 and C.08.001 of the *Food and Drug Regulations*. Essentially, the SAP permits the sale of a new drug that could not otherwise be sold in Canada because it does not hold an NOC. The sales of Thalomid under review in the present Application are regulated under the SAP.

C. The Patented Medicines Prices Review Board

[7] The Board was established in 1987, along with significant changes to the compulsory licensing scheme. Today the Board's essential mandate includes balancing the monopoly power held by the patentee of a medicine with the interests of purchasers of the medicine. The Board's creation reflects Parliament's intent to address the "mischief" that prices may rise to unacceptable levels during the patentee's exclusivity over a medicine (*ICN Pharmaceutical, Inc. et al. v. Staff of*

the Patented Medicine Prices Review Board (1996) 68 C.P.R. (3d) 417 (F.C.A.); *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)*, 2005 FC 1552).

[8] The Board takes its statutory authority from sections 79 to 103 of the *Patent Act*.

Particularly relevant to the present Application is s. 80:

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

(a) the identity of the medicine;

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

(c) the costs of making and marketing the medicine, where that information is available to the patentee in Canada or is within the knowledge or control of the patentee;

(d) the factors referred to in section 85; and

(e) any other related matters.

[Emphasis added]

80. (1) Le breveté est tenu de fournir au Conseil, conformément aux règlements, les renseignements et documents sur les points suivants :

a) l'identification du médicament en cause;

b) le prix de vente — antérieur ou actuel — du médicament sur les marchés canadien et étranger;

c) les coûts de réalisation et de mise en marché du médicament s'il dispose de ces derniers renseignements au Canada ou s'il en a connaissance ou le contrôle;

d) les facteurs énumérés à l'article 85;

e) tout autre point afférent précisé par règlement.

[Je souligne]

III. The Uncontested Facts

[9] Since 1995, Celgene has made Thalomid available under Health Canada's SAP to patients who reside in Canada through their doctor's request. The process begins with a physician in Canada making a request to Health Canada. Upon authorization being granted, Celgene in the U.S.A. acts on the request. Thalomid is packed in Celgene's facilities in the United States, and in the normal course, is then shipped Free on Board ("FOB") New Jersey, directly to the medical practitioner in Canada. Celgene then prepares its invoice in New Jersey and mails it to the medical practitioner in Canada. Celgene instructs the practitioner that payment is to be made in U.S. dollars and couriered or mailed to Celgene in the U.S.A. Payments are mailed to and paid to Celgene in New Jersey. No Canadian taxes are paid on these transactions and all such shipments have U.S.A. packaging and labeling. Celgene decides whether to fill an order for Thalomid and then sets the price. The drug is never to be redistributed in Canada and any unused portions must be returned for proper disposal to Celgene's Product Returns facility located in Pennsylvania.

[10] Celgene has given a measure of compliance with the provisions of s. 80 with respect to filing pricing information. In April 2006, shortly after the issuance of Canadian Patent No. 2,166,315, the Board contacted Celgene regarding Thalomid and requested compliance with s. 80. As requested, on May 1, 2006, Celgene provided the Board with its Form 1 "Medicine Identification Sheet" for Thalomid with patent and Health Canada regulatory information. Celgene indicated in an accompanying letter that it had not received general regulatory approval in the form of a NOC to market and sell Thalomid and the drug was supplied to Canadians living in Canada under Health Canada's SAP. On June 5 and July 10, 2006, Celgene provided the Board with Form

2 “Identity of Prices of Medicines”, including information on the identity and price of Thalomid for the period of April 6, 2006 to June 30, 2006, but not for the period of January 12, 1995 to April 5, 2006. In its appended correspondence Celgene made it clear that, by submitting the information, it did not waive its right to challenge the scope of the Board’s authority.

[11] On January 10, 2007, the Board requested that Celgene comply by providing the specific Form 2 information for the period January 12, 1995 to April 5, 2006 not previously submitted. The letter stated that, in the event that Celgene does not comply by February 9, 2007, the Board Staff would request that the Board issue an Order under s. 81 of the *Patent Act* requiring Celgene to file the requested information. On January 12, 2007, after a meeting between representatives from the Board and Celgene, Celgene agreed to file the requested Form 2 information for the period of July 2006 to December 2006, together with a statement of its position that sales of Thalomid under the SAP do not constitute sales in Canada. It was understood that if the Board Staff does not concur with the argument, then Celgene would have a further 30 days to provide the historical U.S. price and sales data for January 12, 1995 to April 5, 2006, failing which the matter would be referred to the Board’s Chair. On January 29, 2007, Celgene submitted the requested U.S. price and sales information for July 2006 to December 2006. On January 31, 2007, Celgene sent a letter stating its legal position respecting the Board’s jurisdiction to regulate the pricing of Thalomid. On April 12, 2007, Celgene was informed via email that the Board Staff were unable to agree with Celgene’s jurisdictional argument.

IV. The Board's Decision

[12] The Board Staff brought a motion to the Board for an order pursuant to sections 81 and 88 of the *Patent Act* requiring Celgene to provide the requested information. On January 21, 2008, a three person panel of the Board concluded that the Board has jurisdiction to make a remedial order concerning the pricing of Thalomid “from and after January 12, 1995”.

[13] Celgene made two main arguments to the panel as to why the Board does not have jurisdiction over the pricing of Thalomid: the drug is sold to Canadian purchasers pursuant to the SAP and not through general commercial marketing, and, by virtue of the rules of commercial law, the *locus* of the sale is New Jersey. Celgene has only pursued the second argument in the present Application.

[14] The Board rejected Celgene's interpretation of s. 80(1) (b) in favour of a broader interpretation. The Board determined that the words “any market” in the phrase “any market in Canada” are not intended to restrict the Board's jurisdiction to sales of medicines pursuant to commercial marketing efforts. That is, the words are present in the *Patent Act* to allow the Board to oversee the pricing of medicines in Canada generally, or in discrete markets, such as markets defined by geography, political boundaries such as provinces, or by class of customers such as hospitals or pharmacies. The Board found that purchasers of medicines through the SAP constitute a discrete market in Canada, and, as such, constitute a part of the general Canadian market for the sale of medicines. The Board concluded that the jurisprudence from the Federal Courts supports the rejection of a narrow interpretation of the term “market” and further concluded that there is no

indication in the *Patent Act* that Parliament intended the Board to leave any purchaser unprotected from its general remedial powers. Therefore, the Board found that it is reasonable to conclude that, whether or not Canadian purchasers receiving medicines through the SAP constitute a discrete market, they are part of the same Canadian market in which medicines with an NOC are sold.

[15] In reaching its decision, the Board accepted that, according to the principles of common law, New Jersey is the *locus* of Thalomid sales to Canadian patients. However, the Board dismissed this fact because it found that the *locus* of sale is a commercial choice and is not determinative of its jurisdiction.

[16] In conclusion, the Board stated that using a purposive approach to the interpretation of s. 80 of the *Patent Act*, it was not parliament's intention to leave medicine purchasers who are in Canada without the price protection of the Board.

V. Jurisprudence with respect to the Board's Jurisdiction

[17] As expressed above, the Board relied on jurisprudence of the Federal Courts as support for the conclusion that a narrow interpretation of s. 80 should be rejected. In my opinion, the jurisprudence relied upon does not assist the Board in coming to this conclusion.

[18] In *ICN, Hoechst Marion Roussel Canada Inc and Shire Biochem Inc. v. Attorney General of Canada*, 2007 FC 1316, the Federal Court of Appeal provides a framework supporting a broad, purposive construction of the sections of the *Patent Act* conveying jurisdiction to the Board and

establishes a test for determining the Board's jurisdiction. Justice Robertson at page 435 states a three-part test for the Board to acquire jurisdiction:

My analysis begins with the understanding that for the Board to acquire jurisdiction three condition precedents must be satisfied. First, the Board must determine that a party such as ICN is a patentee of an invention. Second, the patentee's invention must pertain to a medicine. As will be explained, this condition precedent consists of two sub-requirements. Third, the patentee must be selling the medicine in any market in Canada. These condition precedents can be extracted readily from subsection 83(1) of the Act, which bears repeating: ...[omitted] [Emphasis added]

The decision in *ICN* gave wide jurisdictional scope to the phrase "pertain to a medicine".

[19] In *Hoechst Marion Roussel Canada Inc.* referred to above, Justice Heneghan conducted a judicial review of two Board decisions regarding its jurisdiction. The judicial review revolved around issues of procedural fairness, interpretation of terms such as "medicine" and "patentee", and whether the Board had jurisdiction over patent applications prior to the issuance of any patent. Justice Heneghan supported the interpretation of the relevant terms in a broad and ordinary sense, as had been undertaken in *ICN*.

[20] In *Shire Biochem* referred to above, Justice Russell reviewed a decision by the Board in which it determined it had jurisdiction to review the pricing of Shire's drug product Adderall XR and Janssen Ortho's product Concerta, as sold in Canada for the period of time between the laying open and the granting of the relevant patents. Justice Russell upheld the Board's decision on the broad scope of its jurisdiction.

[21] The decisions in *ICN, Hoechst Marion Roussel Canada Inc., and Shire Biochem* involve an assessment of the jurisdiction of the Board with respect to domestic transactions only. Therefore, while these cases are instructive as to the approach to be taken on the interpretation of the *Patent Act*, I find they are not directly relevant because they do not involve the sales of medicine outside of Canada which is the contentious factual situation presently under consideration.

VI. Principles of Statutory Interpretation

[22] The dispute in the present Application respecting the jurisdiction of the Board depends on the correct interpretation of the phrase “sold in any market in Canada” found in s. 80 (1)(b) of the *Patent Act*.

[23] The approach to modern statutory interpretation is stated by the Supreme Court in *Trustco Mortgage Co. v. Canada*, [2005] 2 S.C.R. 601, at para. 10:

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.

[Emphasis added]

[24] Finding the correct interpretation requires a purposive analysis giving such fair, large and liberal construction and interpretation as best ensures the attainment of the *Patent Act's* objectives (see *Rizzo and Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27; *Interpretation Act*, R.S.C. 1985, c.1-12, s. 12). A purposive approach to statutory interpretation should be guided by the following interpretive propositions: all legislation is presumed to have a purpose and it is possible for courts to discover or adequately construct this purpose through interpretation; legislative purpose should be taken into account in every case and at every stage of interpretation, including the determination of a text's meaning; and in so far as the language of the text permits, interpretations that are consistent with or promote legislative purpose should be adopted, while interpretations that defeat or undermine legislative purpose should be avoided (see Ruth Sullivan in *Construction of Statutes*, 4th ed. (Toronto: Butterworths, 2002) at pages 195-196, 219).

[25] It is with these principles in mind that the task of interpreting s. 80(1)(b) of the *Patent Act* should be undertaken.

VII. The Correct Interpretation of s. 80 (1)(b) of the *Patent Act*

A. *The words in their grammatical and ordinary sense*

[26] In my opinion the words used in s. 80(1)(b) should be given a commercial meaning on the following grounds.

[27] While the *Patent Act* serves a public policy function, it functions within a commercial reality. Patents protect new products and processes and, in consideration of the invention's disclosure, patent law grants a time limited monopoly to the patentee on the use and marketing of the subject matter of the patent (*Kirkbi AG v. Ritvik Holdings Inc.* (2005, 43 C.P.R. (4th) 385 (S.C.C.)). This commercial reality is recognized by Justice Binnie in *Free World Trust v. Electro Sante Inc.* (2000), 9 C.P.R. (4th) 168 (S.C.C.) at p. 188 where he states that "the patent system is designed to advance research and development and to encourage broader economic activity."

[28] A commercial meaning of provisions of the *Patent Act* has been applied in the decisions of *Domco Industries v. Mannington Mills Inc.* (1990) 29 C.P.R. (3d) 481 (F.C.A.) (*Domco*) and *Dole Refrigeration Products Limited v. Canadian Ice Machine Co. and Americo Contact Plate Freezers Inc.* (1957), 28 C.P.R. 32 (F.C.) (*Dole*). In *Domco*, a commercial meaning is given to the term "vending in Canada" in s. 46 of the *Patent Act*, now s. 42. The decision in *Dole* finds that, while a purchaser might be physically in Canada, does not mean that the sale occurred in Canada. While Counsel for the Attorney General argues that the cases should be given little weight because they do not address the sections of the *Patent Act* presently under consideration and the specific factual situations and arguments are unrelated to those in the present Application, I find that the cases are instructive; they have resolved issues under the *Patent Act* by using commercial principles. I also note that the Supreme Court of Canada has stated that when interpreting words relating to commercial transactions, the interpretation is to be determined by commercial common law principles (*Mattell Canada Inc. v. the Queen*, 2001, SCC 36 at paras. 58-59).

1. The commercial meaning of “sold”

[29] It is not disputed that the commercial *locus* of the sale for Thalomid to Canadian patients is in the United States, specifically New Jersey. Counsel for Celgene emphasizes this as a main point in the argument against the Board’s assumption of jurisdiction. Thus, the question becomes, how can the medicine sold in the United States be sold “in any market in Canada”? Celgene’s argument is that it cannot: without a sale in Canada there is nothing for the Board to control.

2. The commercial meaning of “market”

[30] With respect to this issue, paragraph 24 of Counsel for the Attorney General’s written argument is as follows:

As set out above, Thalomid enters into Canada through the SAP administered by Health Canada. The SAP constitutes a “market in Canada”. Starkly put, the “end-users” are patients in Canada. The requests are made by physicians in Canada to Health Canada (a regulatory body in Canada) for permission to ask that a certain medicine be provided for use in Canada. It is those factors that determine a market. Remove any one of these factors and the sales at issue do not take place. By contrast, the sales transactions, the exchange of money for goods (in this case the medicine) could take place anywhere in the world. The location of the sales transaction does not affect where the medicine will be used and by whom. What this demonstrates is the SAP is a market in Canada.

In support of this argument which focuses on demand, Counsel cites the *Concise Oxford Dictionary* (10th Edition) for the definition of “market” as “a demand for a particular commodity or service”.

The argument in favour of accepting this definition is that, if you don’t have demand, you don’t have a sale. That is, since demand in Canada exists for Thalomid, both that demand and its consequent sales are within the jurisdiction of the Board. I do not accept this argument because I do

not accept that the “demand” definition is the correct commercial meaning of the term “market” in the present factual situation.

[31] The definition of “market” argued by Counsel for the Attorney General is but the third of three provided in the Dictionary quoted. The first defines “market” as “a regular gathering of people for the purchase and sale of provisions, livestock, and other commodities, an open space or covered building where vendors convene to sell their goods; and the second defines “market” as “an area or arena in which commercial dealings are conducted: the labour market” [emphasis added]. In my opinion, in the present context, the first definition is the correct definition. A market in the commercial sense cannot exist without a buyer and a corresponding seller. Therefore, for a “market” to exist in Canada for Thalomid, there must be both a purchase and sale in Canada.

[32] In my opinion, the commercial construction of the words used in s. 80(1)(b) are precise and unequivocal, thus, they play a dominant role in the interpretative process. This conclusion is in harmony with the purposive construction of the *Patent Act* as a whole.

B. The purposive construction of the Patent Act

1. The scheme of the Patent Act and the object of the Patent Act

[33] I am mindful of the fact that the *Patent Act* has a public policy objective and that s. 12 of the *Interpretation Act* provides that “every enactment is deemed remedial, and shall be given such fair, large and liberal construction and interpretation as best ensures the attainment of its objects.”

[34] However, there is no evidence on the record in the present Application that an object of the *Patent Act* is to provide jurisdiction over sales of medicines outside of Canada, and, in particular, sales of medicines in the United States.

2. The intention of Parliament

[35] At paragraph 28 of its decision, the Board finds that “sales of a medicine pursuant to the SAP are sales in a market in Canada, within the meaning of that phrase in the [*Patent Act*]”. In support of this conclusion, in paragraphs 25 and 33 to 35 of its decision, the Board makes the argument that, in effect, Parliament’s intention conveyed by s. 80 (1)(b) is to provide the Board with jurisdiction much broader than that allowed by the plain meaning of the words used in the provision, or the law of commercial transactions for that matter:

25. The Board could not fulfill its mandate, if it were unable to ensure that the Canadian purchasers of medicines through the SAP are not paying excessive prices for those medicines. The plain meaning of the words of the Act that is, that SAP purchasers constitute or are part of a market in Canada provides the Board with jurisdiction over SAP sales and allows the Board to perform its mandate. The interpretation advanced by Celgene premised on equating sales in a “market” with commercial “marketing” activities, fits with neither the plain meaning nor a purposive interpretation of the Act.

[...]

32. The Board accepts that the applicable principles of commercial common law establish New Jersey as the *locus* of Thalomid sales to Canadian patients. The Board does not consider this conclusion to be germane to, and certainly not determinative of, its jurisdiction. The commercial common law pertaining to the *locus* of a sale deals primarily with issues related to the physical location at which risk to the goods and the costs of transportation of the goods, pass from the vendor to the purchaser. The *locus* of the sale can also

be relevant to the law applicable to the enforcement of the commercial terms of the transaction.

33. However, the Board's jurisdiction is not related in any way to the law pertaining to the manner in which private parties have elected to allocate risk or the cost of transportation between themselves. Neither is the Board's jurisdiction related to the manner in which the common law establishes the choice of law to govern a private sale of goods transaction. The Board is a public institution, with a statutory mandate, and its jurisdiction derives from its enabling legislation and principles of public law.

34. Given the mandate of the Board to protect Canadians from paying excessive prices for patented medicines, sales of a patented medicine "in any market in Canada", within the meaning of the Act, 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.

35. Clearly, the words of the Act and not the mandate of the Board create jurisdiction, but the purposive interpretation of the words of the Act requires reference to the mandate of the Board. Interpreting the phrase "in any market in Canada" in the sense described in the preceding paragraph, involves ascribing a reasonable meaning to the phrase; indeed, it is the only meaning that can be ascribed to the phrase that makes proper sense of the Board's enabling legislation.

[36] I find that the Board's opinion is without basis in law. There is no evidence on the record in the present Application that Parliament has any intention other than that expressed in the plain meaning of the words used in s. 80(1)(b).

C. Conclusion

[37] In my opinion, a textual, contextual, and purposive analysis of s. 80(1)(b) does not support the Board's opinion of its own jurisdiction. Thalomid is sold to Canadians, but the medicine is not

being sold “in any market in Canada”; it is sold in the United States. Section 80(1)(b) is not capable of capturing these sales within the jurisdiction of the Board.

ORDER

For the reasons provided, I set aside the decision of the Patented Medicine Prices Review Board dated January 1, 2008.

By consent, the issues of further relief to be granted and costs are reserved for further argument.

“Douglas R. Campbell”

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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