January 21, 2008

Decision: PMPRB-07-D1-THALOMID
Motion – Application for Board Order (Statutory Filings)

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended
AND IN THE MATTER OF Celgene Corporation (the "Respondent") and the medicine "Thalomid"

Introduction

1. This proceeding concerns a motion by the Staff of the Board ("Board Staff") for an order pursuant to sections 81 and 88 of the *Patent Act* (the "Act") requiring Celgene Corporation ("Celgene") to provide the information that patentees of patented medicines sold in Canada must report to the Board, as stipulated in sections 80 and 88 of the Act and in sections 3, 4 and 5 of the *Patented Medicines Regulations, 1994* (the "Regulations").

2. Paragraph 81(1)(a) of the *Patent Act* provides:

> **81.** (1) The Board may, by order, require a patentee or former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting
>
> (*a*) in the case of a patentee, any of the matters referred to in paragraphs 80(1)(*a*) to (*e*);

3. Paragraph 80(1)(b) of the *Patent Act* provides:

> **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…

4. Celgene is the patentee for three Canadian patents that pertain to the medicine Thalomid, the active ingredient of which is thalidomide. Thalidomide was initially used in the early 1960's as an antiemetic for pregnant women. Subsequent research has demonstrated that thalidomide is an effective treatment, and sometimes the only effective treatment, for some patients with diverse conditions. Patients in Canada have been purchasing Thalomid from Celgene since 1995. It has been particularly successful in slowing the progress of multiple myeloma, a form of cancer.

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").

6. Board Staff wish to know the prices that Canadian purchasers have been paying for Thalomid, so that they can determine whether or not that price is excessive according to the terms of the Guidelines. Celgene takes the position that the Board does not have jurisdiction over sales of Thalomid, with the consequence that Celgene should not be obliged to provide Board Staff with information concerning the price Canadian purchasers have been, and are, paying for Thalomid.

7. Celgene argues that the Board does not have any jurisdiction over the pricing of Thalomid for two reasons:

i. Thalomid has always been sold to purchasers in Canada pursuant to Health Canada's "Special Access Program" (SAP), not through general commercial marketing; and

ii. By virtue of the rules of commercial law, the *locus* of the sale of Thalomid to patients in Canada is deemed to be New Jersey, such that the Board, as a regulator of the pricing of medicines in Canada, does not have jurisdiction.

8. There is also disagreement between Board Staff and Celgene concerning the earliest date on which the Board could have had jurisdiction over the pricing of Thalomid, assuming that the two arguments described above are not persuasive. Board Staff rely on a recent decision of the Board to the effect that, provided that a patent has been issued to a patentee, the Board has jurisdiction to make a remedial order relating to the sales of the medicine to which the patent pertains, from the date on which the patent application was laid open to the public.[1] Celgene argues that, if the

[1] This decision was the subject of an application, by the patentee (Shire BioChem Inc.), for judicial review by the Federal Court. The application for judicial review was dismissed on December 14, 2007. The FC decision has been appealed.

Board has any jurisdiction over the pricing of Thalomid, its authority to make remedial orders pertaining to the pricing of Thalomid, does not apply until the first of the three Canadian patents (under which Celgene has rights pertaining to Thalomid) was actually issued by the Patent Office.

Sales under the Special Access Program

9. The various provisions of the Act that describe the sales of patented medicines over which the Board has jurisdiction, refer to sales "in any market in Canada", "in a market in Canada", or "in the relevant market".

10. Most sales of medicines in Canada occur after Health Canada has approved the commercial marketing of the medicines in a regulatory process that results in the issuance of a "Notice of Compliance" (NOC) for each medicine. The NOC specifies the illnesses for which the medicine may be marketed and/or prescribed as treatment.

11. However, some medicines may prove effective for some patients suffering from illnesses for which the manufacturer has not applied for, or Health Canada has not yet granted, an NOC. To deal with these situations, Health Canada established the Special Access Program (SAP) in 1966. The SAP establishes a process by which a physician may request that Health Canada give a manufacturer permission to sell a medicine for the treatment of an illness for which an NOC has not been granted. Such requests are typically made when other therapies have failed, or are unsuitable or unavailable to the particular patient.

12. There is no limit on the volume of sales of any particular medicine that can be made pursuant to the SAP, nor any limit on the period of time that a manufacturer may supply a medicine pursuant to the SAP. Health Canada cannot require a manufacturer to apply for an NOC; if there are to be any sales of medicines in the absence of an NOC, they must be pursuant to the SAP limitations.

13. If Health Canada approves a request for sales pursuant to the SAP, the manufacturer may sell the medicine for the use of a specific patient or clinical trial identified in the request. As noted, SAP authorization does not oblige a manufacturer to provide the medicine; it authorizes the manufacturer to do so. The sale of the medicine will only take place if the manufacturer is willing and able to supply it.

14. In 1998, the U.S. Food and Drug Administration (the "FDA") approved Thalomid for the treatment of leprosy. More recently, Thalomid's most promising and most widespread use has been in retarding the progress of the cancer multiple myeloma, and in 2006, the FDA approved Thalomid for the treatment of this disorder.

15. In 2006, Thalomid was the most frequently sourced drug under the SAP, accounting for approximately 4,500 SAP authorizations.

16. Celgene argues that its sales to Canadian purchasers are not sales "in any market in Canada" because there is no NOC for Thalomid, and an NOC is a legal pre-condition to commercial marketing of a medicine in Canada. Celgene argues that, because it is not "marketing" Thalomid in Canada, especially as that term has been defined in another context by the Federal Court,[2] it cannot be selling in any "market" in Canada in the sense of that expression in the Act. Put another way, Celgene argues that unless and until it has an NOC for Thalomid, it cannot be said to be selling in a market in Canada, regardless of sales under the SAP.

17. Board Staff take the contrary view. Board Staff argue that the very fact of the jurisdiction of Health Canada over sales of Thalomid and the administration of the SAP by Health Canada, demonstrates that the sales of Thalomid are sales in a market in Canada. A Canadian regulatory regime (Health Canada's SAP) oversees and controls the sales of Thalomid to Canadian purchasers, and accordingly, in the context of the Act, these sales are properly characterized as sales "in any market in Canada".

18. In support of this position, Board Staff indicate that section 3 of the *Patented Medicines Regulations, 1994* (the "Regulations"), passed pursuant to the Act, expressly requires patentees to report sales information on the earlier of the issuance of an NOC or the first sale in Canada, indicating that at least the Governor in Council did not see an NOC as a pre-requisite to sales that would fall under the Board's jurisdiction:

> **3.** (1) For the purposes of paragraphs 80(1)(*a*) and 80(2)(*a*) of the Act, information identifying the medicine shall indicate…
>
> (2) The information required under subsection (1) shall be provided if
>
> (*a*) a notice of compliance has been issued in respect of the medicine; or
>
> (*b*) the medicine is being offered for sale in Canada.
>
> (3) The information referred to in subsection (1) shall be provided within the earlier of
>
> (*a*) 30 days after the date on which the first notice of compliance is issued in respect of the medicine, and
>
> (*b*) 30 days after the date on which the medicine is first offered for sale in Canada.

[2] AstraZeneca Canada Inc. v. Canada (Minister of Health), (2004) 36 C.P.R. (4th) 519 at 538

19. The Board agrees that the administration of the sales of Thalomid by Health Canada is one of the indicia that the sales are in a market in Canada, within the meaning of that expression in the Act. Every element of each sale of Thalomid to Canadian purchasers is regulated by Health Canada. The Board also considers SAP sales to be sales in a market in Canada for the following reasons.

20. The question of whether a sale of a medicine is a "sale in any market in Canada" within the meaning of the Act is a question of statutory interpretation involving the specialized jurisdiction of the Board. With respect to the words "any market" in the phrase "any market in Canada", it is the view of the Board that these words are not intended to restrict the Board's jurisdiction to sales of medicines pursuant to commercial marketing efforts. Rather, the words "any market" are present in the Act for the purpose of allowing the Board to oversee the price of a medicine in Canada generally, or in discrete markets, such as markets defined by geographic or political descriptions (regions, provinces or territories, for example) or classes of customers (hospitals, pharmacies, etc.). In this regard, the Hearing Panel (the "Panel") notes that the Board receives annual sales and pricing information from patentees for each province and by class of customer.

21. The Board believes that purchasers receiving medicines through the SAP can be said to constitute a discrete market in Canada, in the same sense as sales to any other class of customer, or to constitute a part of the general Canadian market for the sale of medicines.

22. In addressing this issue, the Board also takes its mandate into consideration, i.e., the protection of customers from excessive prices for patented medicines, and sees no reason why Canadians purchasing medicines through the SAP are any less deserving or needful of protection by the Board, than Canadians purchasing medicines for which an NOC has been issued. Though the volume of sales pursuant to a SAP authorization is relatively small compared to the volume of sales pursuant to NOCs, the impact on individual purchasers is the same regardless of the regulatory authorization governing the sale. Indeed, inasmuch as the purchase by individuals of medicines that are not formally approved for their condition are not going to be bulk purchases (for example, by hospitals, pharmacies or provinces), it is unlikely that there would be any material competition associated with such sales. Accordingly, patients purchasing medicines pursuant to SAP authorizations may have little or no market protection to temper the price of the medicines.

23. It is also 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, and over which the Board's jurisdiction is not disputed; that is, the market of Canadian customers who purchase patented medicines. The Board sees no indication in the Act that Parliament

intended the Board to leave any purchaser unprotected from the general remedial powers of the Board.

24. Also, the Board has been given a remedial jurisdiction and must be mindful of the impact on its mandate of the interpretation of its enabling legislation. The Board does not know why Celgene applied for FDA approval for the use of Thalomid in the United States, but has not applied for an NOC for Thalomid in Canada. The consequence is that all sales of Thalomid in Canada have been, and currently are, pursuant to the SAP. Celgene has made substantial SAP sales of Thalomid over the course of the past 12 years, and the volume of those sales is increasing markedly, apparently because of Thalomid's recently established success in the treatment of multiple myeloma.

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.

26. In *ICN Pharmaceuticals v. Canada*, an appeal from the dismissal of an application to review a decision of this Board, the Federal Court of Appeal addressed the Board's jurisdiction to regulate the price of medicines sold pursuant to the SAP (then named the Emergency Drug Release Program). Section 83 of the Act refers to a patentee "selling the medicine in any market in Canada". ICN argued that sales pursuant to the SAP were not sales of a "medicine" within the meaning of the Act, because the sales were for uses that were not covered by the patentee's NOC.

27. The Federal Court of Appeal rejected ICN's narrow definition of "medicine", expressly holding that such a narrow definition would be inconsistent with the purpose of the Act, in that it would defeat the Board's jurisdiction over sales pursuant to the SAP. While the *ICN* case dealt with the definition of "medicine" and Celgene's position is premised on the definition of "market", the Hearing Panel (the "Panel") believes that the reasoning in the *ICN* case, rejecting a narrow definition of "medicine", should lead to the rejection of a narrow definition of "market".

Conclusion on *Sales under the Special Access Program*

28. For these reasons, the Panel 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 Act.

The location of the sales of Thalomid to Canadian patients

29. Celgene is a Delaware corporation, with its head office in Summit, New Jersey. To summarize the evidence on this point, all of the commercial features of the sales of Thalomid to Canadian patients are established by, and administered through, this New Jersey office. Celgene placed particular emphasis on the fact that most of the invoices provided to Canadian patients for purchases of Thalomid were stamped "F.O.B. New Jersey". In consequence, the rules of commercial common law would establish New Jersey as the *locus* of the sale. Celgene argues that the New Jersey *locus* of the sale of Thalomid to Canadian patients is determinative in excluding the Board's jurisdiction, because the Board only has jurisdiction over sales of patented medicines in "any market in Canada".

30. On this point, Board Staff argue that the sales are in Canada, within the meaning of the Act, because they are sales to Canadians that are fully regulated by Health Canada pursuant to the SAP.

31. Again, the Board accepts this as a relevant factor, but would add the following reasons for its conclusion that sales of Thalomid to Canadian patients are sales in Canada within the meaning of the pertinent sections 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. It should also be noted that there are sales of patented medicines in Canada to persons outside of Canada – such as sales by Canadian pharmaceutical companies to European purchasers – where the *locus* of the sale at common law indisputably would be Canada. However, the Board would not have, and does not attempt to assert, jurisdiction over such sales. That is because there is no reasonable interpretation of the Act that would support such a jurisdiction: 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. The commercial law pertaining to the sale transaction is not germane to, and is certainly not determinative of, the Board's jurisdiction.

Conclusion on *The location of the sales of Thalomid to Canadian patients*

37. For these reasons, the Panel concludes that the sales of Thalomid to Canadians pursuant to the SAP are sales in Canada within the meaning of the Act, regardless of the *locus* of the sale as determined by the common law pertaining to the sale of commercial goods.

The Commencement of the Board's Jurisdiction

38. The first Canadian patent for Thalomid was laid open to the public in 1995. The patent was not issued until 2006. The Panel has considered the arguments of Celgene and Board Staff on this point, and has considered the decision of the Board on the same issue in the proceeding relating to the medicine Adderall XR (the "Adderall XR decision"). Though this Panel is not bound by the decisions of the Board in earlier proceedings, this Panel is persuaded that the Adderall XR decision is persuasive and should be followed. The Panel notes that, between the argument of this motion and the issuance of this decision, the Federal Court of Canada dismissed an application for judicial review of the Adderall XR decision.

Conclusion on *The Commencement of the Board's Jurisdiction*

Accordingly, this Panel concludes that the Board has jurisdiction to make a remedial order concerning the pricing of Thalomid from and after January 12, 1995.

Board Members: Dr. Brien G. Benoit
Anne Warner La Forest
Anthony Boardman

Board Counsel: Gordon Cameron

Original signed by

Sylvie Dupont
Secretary of the Board