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Soji John

CANADA UPDATE: SUPREME COURT SUPPORTS THE PMPRB'S ABILITY TO CONTROL PRICES OF PATENTED MEDICINES SOLD ABROAD TO CANADIANS

*Soji John**

I. INTRODUCTION

IN January, the Supreme Court of Canada bolstered the government's ability to regulate the prices charged for patented medicines used by Canadians.[1] In *Celgene Corp. v. Attorney General of Canada*, the court unanimously affirmed the Federal Court of Appeals decision and held that the Patented Medicine Price Review Board (PMPRB) has the ability to control the prices of Canadian patented medicines sold in foreign countries to Canadian consumers.[2] Relying primarily upon the legislative intent of the Patent Act in creating the PMPRB, the court approved the Board's interpretation of its authority over drugs sold by Celgene in the United States subsequently shipped to Canadian patients.[3] In doing so, the court pronounced that the clear purpose of the enabling legislation would control the interpretation of what it understood to be a textual ambiguity regarding the Board's jurisdiction.[4] The court also indicated that it would apply a deferential standard of review when a tribunal is interpreting its enabling legislation.[5]

II. BACKGROUND

This case stemmed from the refusal of Celgene, a global pharmaceutical company, to submit sales records of its brand-name drug Thalomid as requested by the PMPRB.[6] Celgene, formed in 1980 as a spinoff from the merger of the Celenese and Hoechest corporations, obtained approval from the U.S. Food and Drug Administration in 1998 to promote

* Candidate for Juris Doctor, SMU Dedman School of Law 2011.

1. *See generally* Celgene Corp. v. Att'y Gen. of Can., 2011 SCC 1 (Can.).
2. *Id.* ¶¶ 32, 35.
3. *Id.* ¶¶ 1, 26.
4. *See id.* ¶¶ 25, 32, 35.
5. *Id.* ¶ 33.
6. Celgene Corp. v. Attorney Gen. of Can., [2009] F.C.R. 271, ¶¶ 10, 11 (Can.).

Thalomid as a treatment for leprosy and related illnesses.[7] Later, in 2006, Celgene obtained approval for Thalomid's use in the treatment of multiple myeloma, a form of cancer.[8] But Canada has generally banned the use of thalidomide, the primary active ingredient in Thalomid, since the early 1960s, when it was identified as causing birth defects in the children born to women taking the drug to combat nausea and sleep loss during pregnancy.[9] Until recently, Thalomid was only available to Canadians through the Special Access Program (SAP).[10]

Under the SAP, physicians are able to obtain drugs that are not approved for general use in Canada on behalf of specific patients "with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable."[11] The Therapeutics Product Directorate in Health Canada reviews each application under the SAP, and allows the physician to prescribe and order the drug once it determines that the "need is legitimate" and that the physician is qualified.[12] In its analysis, the Directorate will consider each application for the drug on an individual basis using factors such as urgency and condition of the patient.[13] Even with approval, the SAP Program limits the amount of drug available per approval to a six-month supply and requires the sponsoring physicians to monitor and report adverse reactions to Health Canada.[14]

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7. *History of Celgene Corporation*, CELGENE, http://www.celgene.com/about-celgene/biopharmaceutical-company-about.aspx (last visited Feb. 17, 2011).
8. *See Thalomid Authorization For Sale in Canada*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/thalidomide_fs_fd-eng.pdf (last visited Feb. 17, 2011).
9. *Id.*
10. *See id.*
11. *Special Access Programme–Drugs,* HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapfs_pasfd_2002-eng.pdf (last visited Feb. 17, 2011). In the typical process for drug development and approval, a pharmaceutical company obtains a Canadian patent for the new drug and conducts preclinical testing on tissue cultures and small animals. *Drugs from Research Lab to Pharmacy Shelf*, CANADIAN PHARMACISTS ASS'N, http://www.pharmacists.ca/content/hcp/resource_centre/drug_therapeutic_info/pdf/DrugApprovalProcess.pdf (last visited Feb. 17, 2011). Once the drug is found to be promising, a formal application is made to Health Canada to start a clinical trial. *Id.* With approval, the company conducts several phases of clinical trials culminating in a review process by the Therapeutic Products Directorate within the Health Products and Food Branch. *Id.* With successful completion of the review process and upon authorization of the "new drug and its manufacturing process," Health Canada provides a Notice of Compliance (NOC) and a Drug Identification Number allowing the company to manufacture, market, and sell the drug within Canada. *Id.*
12. *How Drugs Are Reviewed in Canada*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/reviewfs_examenfd-eng.pdf (last visited Feb. 17, 2011).
13. Janet N. Chong, *The Canadian Special Access Program*, DEETH WILLIAMS WALL, http://www.dww.com/dww/wp-content/uploads/2007/06/SpecialAccess-Chong.pdf (last visited Mar. 29, 2011).
14. *Special Access Programme–Drugs, supra* note 11. Since this case was originally brought, Thalomid has been made available through a new program called RevAid. *Thalomid Authorization For Sale in Canada, supra* note 8. In the RevAid "controlled distribution program," specially registered physicians are able to register patients. *Id.* This program essentially forgoes the individualized ap-

Celgene has made Thalomid available under the SAP since 1995.[15] But until 2006, Celgene had not been issued a Canadian patent for its brand name drug.[16] Celgene's Canadian patents in this case involve methods for the formation of thalidomide and its use in combination with other drugs for the treatment in a variety of health problems.[17] Once Celgene was granted its first patent, 2,166,315, in April of 2006, the PMPRB contacted the company and requested pricing information regarding Thalomid.[18] This request was based upon section 80 of the Patent Act which allows the Board to obtain "information and documents . . .[regarding] the price at which medicine is being or has been sold in any market in Canada and elsewhere."[19] As a result, although Thalomid was already being sold under the SAP unregulated by the PMPRB, once Celgene obtained a patent and restricted others' use of thalidomide in the Canadian market, the PMPRB sought information to appropriately regulate the price paid by Canadians for the drug.[20]

In response to the PMPRB, Celgene provided pricing information for the period after it received its patent, April 5, 2006; however, the Board requested pricing information for all times after Celgene had made Thalomid available to the Canadian market after the publication of its patent application—January 12, 1995.[21] Celgene refused to provide this information and brought a jurisdictional challenge to the board's ability to regulate the pricing of Thalomid, arguing that the Board could not regulate the price charged because the drug was sold under the SAP program rather than "general commercial marketing" and because commer-

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proval required through the SAP while allowing Health Canada to obtain and retain data concerning benefits and risks. *See id.*

15. Geoffrey North & Catherine Newnham, *Supreme Court of Canada Finds Patented Medicine Prices Review Board Has Jurisdiction Over Price of Thalomid in Canada*, CANADIAN TECH. & IP L., Jan. 25, 2011, http://www.canadiantechnologyiplaw.com/2011/01/articles/intellectual-property/patents-1/supreme-court-of-canada-finds-patented-medicine-prices-review-board-has-jurisdiction-over-price-of-thalomid-in-canada/.
16. *See* Muller, George W., "Process for the Preparation of Thalidomide," Can. Patent No. 2,166,315 filed Jul 1, 1994, and issued April 4, 2006; *see also*, D'Amato, Robert J., "Methods and Compositions for Inhibition of Angiogenesis," Can. Patent No. 2,270,887 filed Nov. 4, 1997 and issued March 21, 2006; *see also*, D'Amato, Robert, "Methods and Compositions for Inhibition of Angiogenesis," Can. Patent No. 2,157,288 field Feb. 24, 1994 and issued Nov. 8, 2005. At roughly the same time, the U.S. Food and Drug Administration approved the use of "thalidomide in combination with dexamethasone for the treatment of multiple myeloma." *Thalomid Authorization For Sale in Canada*, *supra* note 8.
17. *See generally* Can. Patent Nos. 2,166,315, 2,270,887, and 2,157,288, *supra* note 16.
18. *Celgene Corp.*, [2009] F.C.R. 271, ¶ 10.
19. Patent Act, R.S.C. 1985, c. P-4, § 80(1)(b) (Can.).
20. *See Thalomid Authorization For Sale in Canada*, *supra* note 8; *see also* William A. W. Neilson, Robert G. Howell & Souichirou Kozuka, *Intellectual Property Rights and Competition Law and Policy: Attempts in Canada and Japan to Achieve A Reconciliation*, 1 WASH. U. GLOBAL STUD. L. REV. 323, 338 (2002); *Celgene Corp.*, [2009] F.C.R. 271, ¶ 10.
21. Can. Patent No. 2,166,315, *supra* note 16; *see also Celgene Corp*, [2009] F.C.R. 271, ¶ 10; Steven Mason, *The PMPRB's Jurisdiction–Back to the Date of Publication*, MCCARTHY TETRAULT, Dec. 20, 2007, http://www.mccarthy.ca/article_detail.aspx?id=3809.

cial law defined the sale as occurring in the United States.[22] The PMPRB's judicial arm rejected this challenge, and Celgene brought the matter before the Federal Court pursuing the argument that, per commercial law, the sale should be designated as occurring extra-territorially such that the Board lacked authority over the sale because the payment was made in U.S. dollars, in New Jersey, and the product was shipped free on board.[23] Upon judicial review, the court accepted this argument and held that the Board lacked jurisdiction under § 80(1)(b) of the Patent Act to regulate prices when the sales occur outside of Canada.[24] The Attorney General of Canada, representing the Board, appealed, and the Federal Court of Appeals reversed, relying primarily upon the legislative purpose of the PMPRB, and found that the Board could regulate prices of Canadian Patented medicines to Canadian consumers when sold from abroad into the Canadian market.[25]

III. REGULATION OF CANADIAN MEDICINE PRICE AND THE PMPRB

Canadian health care is administered provincially through its Medicare plan, providing universal health care under "criteria set forth in the 1984 Canadian Health Care Act."[26] Since the system is publicly financed, the government has a strong incentive to regulate the price charged for pharmaceuticals.[27] In order to limit exorbitant pricing, Canada originally used compulsory licensing whereby generic drug manufacturers could forcibly take a license—a government enforced limitations of the right of exclusivity of the patent owner.[28] The generic manufacturer would then be able to produce a drug and market it, typically for a lower price than the patent holder would charge.[29] Because compulsory licensing tended to act as a disincentive to drug development, the government sought to catalyze innovation by allowing patent holders a right to completely exclude for a limited period of time and amended the Patent Act.[30] But to control prices, in the amendment, the government also established the Patented Medicines Price Review Board with the ability to regulate prices based on a market median price in seven western industrialized

22. *Celgene Corp.*, [2009] F.C.R. 271, ¶ 11.
23. *Id.* ¶¶ 9-11. Per free on board, delivery occurs when a seller relinquishes goods at a port for shipment, in this case, the United States. *See FOB Free on Board*, INT'L CHAMBER OF COMM., (2000), http://www.iccwbo.org/incoterms/preambles/pdf/FOB.pdf.
24. *Celgene Corp.*, [2009] F.C.R. 271, ¶ 37.
25. Att'y Gen. of Can. v. Celgene, [2009] F.C.A. 378, 315 D.L.R. 4th 270, ¶¶ 55-59 (Can. C.A.).
26. Jennifer L. Halser, *Canadian Pharmacies: A Prescription For a Public Health Disaster*, 54 DEPAUL L. REV 543, 549 (2005).
27. Michael B. Moore, *"Open Wide" (Your Pocketbook That Is)–A Call for the Establishment in the United States of a Prescription Drug Price Regulatory Agency*, 1 SW. J. L. & TRADE AM. 149, 162 (1994).
28. *Id.*
29. *Id.*
30. *Id.* at 163.

nations.[31] For excessive prices, the PMPRB is able to "order the patentee to reduce the price and take measures to offset any excess revenues it may have received."[32]

In order to determine whether a price is excessive, the PMPRB typically relies upon sales information that the company provides.[33] Without direct information from the drug companies, the PMPRB could not effectively evaluate the prices charged for medicines; they would have to rely upon "highly subjective statistical data produced by the drug companies," to determine whether "the drug companies [were obtaining] a fair return on their investment."[34] In addition to the sales data provided, the PMPRB also takes into account other factors such as comparing prices of drugs already on the Canadian market with similar therapeutic benefits and the amount invested by drug companies in development.[35] The PMPRB indicates that in 2009, of the 1,003 patented drugs sold in Canada, 91.5% were sold at prices within the prescribed PMPRB guidelines.[36] The PMPRB's analysis also indicates that the prices spent by Canadians on these patented medicines is roughly twenty percent higher than that of the lowest of the seven comparative industrialized nations but seventy-one percent lower than the highest of the seven nations.[37] Thus, the steps taken by the PMPRB have been effective in ensuring that Canadians have access to medicines at a reasonable price in a system that encourages new drug development.[38]

IV. THE SUPREME COURT OF CANADA PRIORITIZES CONSUMER PROTECTION

In finding on behalf of the PMPRB, the Supreme Court of Canada held that the overarching purpose for the implementation of the Board controlled over a commercial law contractual understanding regarding the sale of an item.[39] The primary argument that Celgene proposed was that because the sale occurred in the United States, the Board lacked jurisdiction over the price charged for Thalomid.[40] Celgene argued that its sale of Thalomid in a foreign country, albeit to Canadian citizens, does not implicate the Board's powers to regulate the price because the jurisdic-

31. Jenifer A. Orange, *Canada and U.S. Approaches to Cross-Border Sales of Pharmaceuticals*, 31 CAN.-U.S. L. J. 317, 318 (2005). These nations include United Kingdom, France, Germany, Italy, Switzerland, Sweden, and the United States. *Id.*
32. *Patented Medicine Price Review Board, Annual Report 2009*, TREASURY BD. OF CAN. SECRETARIAT, http://www.pmprb-cepmb.gc.ca/cmfiles/ar09-en-online.pdf (last visited Mar. 8, 2011).
33. *See* Moore, *supra* note 27, at 163.
34. *Id.*
35. Davina Rosen, *Balancing Business & National Health: The Impact of Legislation on Pharmaceutical Drug Prices*, 26 TEMP. J. SCI. TECH. & ENVTL. L. 341, 355 (2007).
36. *Patented Medicine Price Review Board, Annual Report 2009*, *supra* note 32, at 10.
37. *Id.* at 29, T. 11.
38. *Id.*
39. *Celgene Corp.*, 2011 SCC 1, ¶¶ 24, 25.
40. *See id.* ¶ 6.

tion of the Board is limited to sales in Canada.[41]

But in conferring authority to the Board, the Patent Act states that a "patentee of an invention pertaining to a medicine shall . . . provide the Board with such information and documents . . . respecting . . . the price at which the medicine is being sold . . . in any market in Canada and elsewhere."[42] Moreover, Patent Act § 83(1) states that the Board's remedial power applies to "a patentee of an invention pertaining to a medicine [that] is selling the medicine in any market in Canada."[43] Celgene argued that because the words of the statute are clear and unambiguous, they should have priority over any interpretation of the "overriding purpose of the statute."[44]

For example, in *Canada Trustco Mortgage Co. v. R.*, the Supreme Court of Canada had relied upon a textual reading of the relevant statute and the common interpretation of the term "cost" as the "price that the taxpayer gave up in order to get the asset" and would not stray to redefine "cost" as "money at risk."[45] Celgene argued that, in the same way, the court should rely on the common interpretation of a "sale" as understood in the commercial context.[46] Celgene attempted to strengthen its position by providing evidence of the commercial meaning of the term "sale," so that "sale in any market in Canada" per § 83(1) of the Patent Act limits the PMPRB's regulatory authority to a commercial sale occurring in Canada.[47] To define "sale," Celgene relied upon *Deputy Minister of National Revenue v. Mattel Canada, Inc.* where the court analyzed in detail the vending process by a foreign entity for "export to Canada under s[ection] 48(4) of the *Customs Act*."[48] But the court found that while Mattel does discuss "sale," it considered it from an import duty context, which was not relevant to the understanding of "sale" in the context of the PMPRB's jurisdiction.[49]

The court, however, did not find the issue of the commercial meaning of "sale" to be determinative.[50] The court also considered "sale" as it relates to patents.[51] In *Domco Industries Ltd. v. Mannington Mills Inc.* the plaintiff's claim of infringement failed because an alleged infringer

41. *See id.*
42. Patent Act, § 80(1).
43. *Id.* § 83(1).
44. *See Celgene Corp.*, 2011 SCC 1, ¶ 21.
45. Can. Trustco Mortg. Co. v. R., [2005] 2 S.C.R. 601, ¶¶ 69-71 (Can.). The court's accepted definition was supported by the respondent's interpretation of the purpose of the Income Tax Act.
46. *Celgene Corp.*, 2011 SCC 1, ¶ 21.
47. *Id.* ¶¶ 22-23.
48. Deputy Minister of Nat'l Revenue v. Mattel Can. Inc., [2001] 2 S.C.R. 100, ¶ 8 (Can.).
49. *Celgene Corp.*, 2011 SCC 1, ¶ 23; *see Mattel Can. Inc.*, [2001] 2 S.C.R. 100, ¶¶ 34-53.
50. *See Celgene Corp.*, 2011 SCC 1, ¶¶ 24, 25.
51. *See id.*; *Mattel Can. Inc.*, [2001] 2 S.C.R. 100, ¶ 35.

did not *sell* the patented item within Canada.[52] In *Domco*, the court stated that when delivery occurs outside of Canada and where the contract for sale of infringing goods are not proven to be within Canada, there is no vending of the goods locally to infringe the patent per the Patent Act § 46.[53] This result is supported by the commonly accepted view that patent laws are territorial.[54] Despite the fact that commercial laws and patent laws could define "sale" as having occurred abroad, the court felt the purpose of the statute—protecting Canadians from excessive drug prices—allowed the PMPRB to regulate drugs which relied on Canadian patents and avail the Canadian market.[55] Moreover, the court considered that accepting a purely commercial law interpretation of "sale" as controlling would result in the PMPRB having authority over Canadian pharmaceuticals sold in Canada for export.[56] Because the jurisdiction of the PMPRB should not extend to foreign consumers, the court felt justified in avoiding an outcome based purely on the commercial and patent law interpretation of "sale."[57]

The court concluded that the PMPRB was authorized to seek Celgene's sales records to 1995 for two reasons.[58] First the court gave deference to the PMPRB and used a reasonableness standard of review.[59] In this regard, the court followed it prior holding from *New Brunswick v. Dunsmiur* where it stated that "[d]eference will usually result where a tribunal is interpreting its own statute or statutes closely connected to its function."[60] In this case, the PMPRB was interpreting its jurisdiction under the Patent Act, which created the Board, and thus the court would only set aside the Board's decision if it were to fall outside a range of possible, acceptable outcomes which are defensible in respect of the facts and law.'"[61]

Second, because the court felt that the textual authority was unpersuasive, it turned to the purpose of the PMPRB for guidance and found consumer protection to be mandated by the legislative history.[62] The PMPRB was formed with the amendment of the Patent Act, which, at the same time, limited the availability of compulsory licensing.[63] The court noted that in introducing the Bill C-22 that created the PMPRB, the Hon. Harvie Andre stated that "[t]hese changes will also ensure consumer protection by creating a drug prices review board to monitor drug prices."[64]

52. *Mattel Can. Inc.*, [2001] 2 S.C.R. 100, ¶ 35; *see* Domco Indus. Ltd. v. Mannington Mills Inc., [1990] 107 N.R. 198, ¶ 35 (Can.).
53. *Domco Indus.*, 107 N.R. 198, ¶ 35; Patent Act, § 46.
54. *See* Neilson, Howell & Kozuka, *supra* note 20, at 337.
55. *Celgene Corp.*, 2011 SCC 1, ¶ 32.
56. *See id.* ¶ 11.
57. *Id.*
58. *See id.* ¶¶ 33, 34.
59. *Id.* ¶ 34.
60. Dunsmuir v. N.B. Bd. of Mgmt., [2008] 1 S.C.R. 131, ¶ 54 (Can.).
61. *Celgene Corp.*, 2011 SCC 1, ¶ 34; *Dunsmuir*, [2008] 1 S.C.R. 131, ¶ 47.
62. *Celgene Corp.*, 2011 SCC 1, ¶ 28.
63. Halser, *supra* note 26, at 553.
64. *Celgene Corp.*, 2011 SCC 1, ¶ 26.

Moreover, with the later amendment of the Patent Act in 1993, the Hon. Pierre Blaise, "reiterated the Board's consumer protection mandate."[65] As a result of the legislative history and with prior holdings, the court found support for the consumer protection mandate and the holding of the PMPRB.[66]

V. CONCLUSION

In summary, the Supreme Court of Canada has supported the PMPRB's mandate in protecting Canadian consumers from excessive drug prices. The court determined that the PMPRB was justified in asking Celgene to provide the prices it charged for Thalomid even when sold extraterritorially and shipped under the SAP policy. For Celgene, the outcome may be of little practical concern as Thalomid has been recently approved for sale through the RevAid process, and the original volumes in the SAP process, though a significant percentage of total SAP sales, were inconsequential in terms of absolute numbers.[67] This case demonstrates the court's approval of regulation by the PMPRB and its increasing broadening of the PMPRB's jurisdiction.[68] As such, *Celgene v. Attorney General of Canada* is a case that drug manufacturers that pursue the Canadian marketplace should consider.[69]

65. *Id.* ¶ 27.
66. *See id.* ¶¶ 26-30.
67. *Thalomid Authorization For Sale in Canada, supra* note 8 (noting that in 2009 the SAP received 6300 requests for Thalomid and that Celgene earned $108 Million in total Thalomid sales for 2009); *Celgene Reports Record Fourth Quarter and Full Year 2009 Product Sales and Operating Income*, FIERCE BIOTECH, Jan. 28, 2010, http://www.fiercebiotech.com/press-releases/celgene-reports-record-fourth-quarter-and-full-year-2009-product-sales-and-operating-.
68. Mason, *supra* note 21.
69. Borden Ladner Gervais, Barbara McIsaac & Kristen Crain, *Supreme Court of Canada Confirms Patented Medicine Prices Review Board Interpretation of the Term "Sold in Any Market in Canada" and Underlines the Consumer Protection Purposes of the Board's Role*, ASS'N. OF CORP. COUNSEL, Jan. 21, 2011, http://www.lexology.com/library/detail.aspx?g=3ed289f0-ca43-4f41-bc03-91ce43c27dd6.