Patented Medicine Prices Review Board's Jurisdiction Limited to Factory-Gate Prices of Patented Medicines

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The Federal Court released a decision that impacts the authority of the Patented Medicine Prices Review Board (the "Board") in respect of a patentee's reporting requirements.[1] More particularly, the Federal Court has held that the Board does not have the authority to look beyond the factory gate price of a patentee's product when assessing whether a patentee's product is excessively priced.

The Board is a quasi-judicial body established under the *Patent Act* to regulate the prices that patentees can charge for patented medicines in Canada. The Board monitors the pricing of patented medicines through reporting obligations of the patentee as defined in subsections 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations (*the *"Regulations")*.

In August of 2008, the Board released a "Stakeholder Communiqué"[2] that, in effect, considerably expanded the reporting requirements on patentees. Under subsection 4(1)(f)(i) of the *Regulations* a patentee must provide the Board with information in respect of "the average price … in which the medicine was sold by the patentee … to each class of customer." Under subsection 4(4) of the*Regulations*, when calculating the average price of a patented medicine the Board must include"rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature". According to the Communiqué, "rebates" was interpreted by the Board as including rebates/payments made to third parties.

Subsequent to the release of the Communiqué, two judicial review applications were commenced.By order of a prothonotary, the two applications were heard together. At issue before the Federal Court in both applications was whether subsections 4(1)(f)(i) and 4(4) of the *Regulations* authorized the Board to require patentees to report rebates/ payments made to third parties in respect of patented medicines for inclusion in the calculation of the average price for the medicine's sales.

In the instant case, the provinces are characterized as third parties in situations where they haveentered into negotiated agreements with patentees to list a patented medicine on a provincial formulary at a specified price. In this scenario, payments may be made by the patentee as consideration for the province's agreement to list the patentee's product on the provincial formulary.[3]

In rendering its decision, the Federal Court noted that the federal jurisdiction conferred by the *Patent Act* is limited to the regulation of the "factory-gate" prices of patented medicines. The industry would generally understand "factory-gate" to refer to the transaction between the patentee and the "first" purchaser of the product in question.[4] Moreover, the *Act* and *Regulations* clearly contemplate a sale by a patentee to a customer. For example, subsection 4(1)(f)(i) of the *Regulations* specifically states that a patentee must provide the Board with information in respect of "the average price … in which the medicine was sold by the patentee … to each class of customer."[5] Accordingly, even if payments made to the provinces by a patentee in respect of a patented medicine could be characterized as a "refund", a

"discount" or "any other benefit of a like nature," the provinces could not be characterized as the patentee's customer in the true sense of the word, and as contemplated by subparagraph 4(1)(f)(i).[6]

The Federal Court noted that this interpretation "is consistent with the constitutional limitation on the Board's ability to look beyond the factory-gate price of patented medicines, to consider contractual arrangements involving patentees and entities further down the distribution chain."[7]

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[1] *Pfizer Canada Inc. v. Attorney General of Canada*; *Canada's Research-Based Pharmaceutical Companies et al. v. Attorney General of Canada,* 2009 FC 719, http://decisions.fct-cf.gc.ca/en/2009/2009fc719/2009fc719.html
[2] http://www.pmprb-cepmb.gc.ca/CMFiles/communique_aug2008-e42LDF-8182008-8637.pdf
[3] *Supra* note 1 at para 20.
[4] *Supra* note 1 at paras 61-62.
[5] *Supra* note 1 at paras 66-67.
[6] *Supra* note 1 at para 89.
[7] *Supra* note 1 at para 83.