

Case Law Update: Celgene Corp v Canada (Attorney General)

February 16, 2011

2011 SCC 1 (Released 20 January 2011)

Statutory Interpretation Patented Medicine Prices Review Board Consideration of Mandate Standard of Review

In this case, the Supreme Court of Canada upheld a regulatory board's decision to interpret its statutory mandate with reliance on a consumer protection purpose.

The issue before the Patented Medicine Prices Review Board ("Board") was the extent of the Board's jurisdiction over medicine "sold in any market in Canada". The Board is constituted under the Patent Act. This Act permits the Board to investigate the price of a medicine, or to require the patentee of that medicine to provide the Board with information on that medicine's price, where the medicine "is being or has been sold in any market in Canada".

New Jersey-based Celgene made Thalomid. Since 1995, Celgene sold Thalomid directly to medical practitioners in Canada pursuant to the Special Access Programme. Under ordinary rules of commercial law, these sales took place in New Jersey Celgene prepared the invoices in New Jersey and sent them to the practitioner with the medicine, and practitioners paid Celgene by mailing payment to New Jersey, in U.S. dollars and without Canadian tax.

When Celgene obtained a Canadian patent for Thalomid in 2006, the Board requested pricing information since 1995. Celgene began to supply that information but then refused, arguing that Thalomid had been "sold" in New Jersey during the relevant period and so fell outside the Board's jurisdiction. In making this argument, Celgene chose an interpretation of "sold in any market in Canada" that relied on commercial law principles. The Board disagreed with this approach. It held that its mandate was consumer protection and was unrelated to commercial concerns. This would mean that the interpretation of "in any market in Canada" includes sales of medicine delivered and used in Canada, medicine regulated by Canadian law, and medicine for which Canadians will bear the cost.

Justice Abella agreed on behalf of a unanimous Supreme Court of Canada. She held that although "sold in any market in Canada" may have a commercial law purpose in some contexts, the Board was correct in interpreting the phrase through the Board's consumer protection mandate. The legislative history underlying the Board's establishment supported this interpretive choice. The result is that the Board has jurisdiction to monitor and regulate prices of medicine that, while on a technical commercial interpretation is "sold" in a foreign market, is brought into Canada for use by Canadians, is regulated by the public laws of Canada (i.e., through the Special Access Programme), and for which Canadian patients or taxpayers bear the cost.

Both parties proceeded on the basis that the applicable standard of judicial review was correctness, although neither presented argument on this point. Justice Abella, like Evans J.A. in the Federal Court of Appeal below, questioned whether this was the applicable standard. The Board is a specialized tribunal interpreting its home legislation, and should be accorded deference, such that the operative standard is reasonableness. While Abella J. commented that parties should not be able, by agreement, to contract out of

the appropriate standard of review, the Board's decision ultimately could be upheld under either standard.

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