Current Intelligence

Patents

■ Scope of the Patented Medicine Prices Review Board's authority

Celgene Corp v Canada (Attorney General), 2011 SCC 1, Supreme Court of Canada, 20 January 2011

The Supreme Court of Canada has now ruled on the scope of the Patented Medicine Prices Review Board's authority to regulate the pricing of a patented drug shipped directly to physicians in Canada from the USA.

Legal context

Section 80(1) of Canada's Patent Act, RSC 1985, c P-4 provides that:

> 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 . . .

Section 83(1) allows the Patented Medicine Prices Review Board to order a price reduction where it finds a price charged for a drug to be excessive. A number of factors listed in section 85(1) guide the Board in respect of whether to make a remedial order under section 83. Most of these factors concern comparative pricing information.

Drugs in Canada are normally sold after Health Canada has approved the drug in relation to safety and effectiveness. Once satisfied, Health Canada will issue a Notice of Compliance under the Food and Drug Regulations (CRC, c 870). However, where a manufacturer has not obtained a Notice of Compliance, there is an alternative route. Some medicines that treat serious or life-threatening conditions for which conventional therapies are unavailable or inappropriate may be sold only to medical practitioners through the Special Access Programme ('SAP'). That programme exists as a result of the Food and Drug Regulations as well.

Facts

Since 1995, the appellant had produced a drug sold through the SAP called Thalomid. It has been the most requested drug by medical practitioners in Canada. Although Celgene was not granted a Notice of Compliance for the drug, it did obtain a Canadian patent for it in 2006.

Celgene sold Thalomid to Canadian physicians by shipping it from their facilities in USA. Celgene would prepare invoices in New Jersey and send them to Canada, with a direction that payment be made in US funds and sent to New Jersey. Canadian taxes were not paid on the sales, nor was the drug ever redistributed in Canada; any leftovers had to be returned to Celgene.

After Celgene obtained the Canadian patent for Thalomid, the Board requested pricing information from Celgene for its sales under the SAP from 1995 onward. Celgene complied with the request, though without prejudice to its position that the Board lacked the jurisdiction to make the request. Eventually, Celgene refused to continue complying with the request for information, arguing that commercial law principles governed the situation and, as the medicine was sold in New Jersey, the sales did not fall within the Board's scope under section 80(1)(b). That position led to the dispute at hand.

Procedural history

In a motion before the Board for an order requiring Celgene to provide the pricing determination, the Board agreed that for the purposes of commercial law, New Jersey would be considered the 'locus' of the sale. However, commercial law principles were not determinative of the matter. Rather, the Board explained that its authority under the Patent Act was unrelated to such commercial law principles as allocation of risk, cost of transport, or choice of law clauses: its mandate did, however, include protecting Canadians against the excessive pricing of patented drugs. Accordingly, the Board concluded that sales 'in any market in Canada' will include 'sales of medicine that are regulated by Canadian law, that will be delivered and used in Canada, and where the costs of the medicine will be borne by Canadians.' (para 10). Celgene's SAP therefore fell within these factors.

On judicial review, Justice Campbell of the Federal Court (2009 FC 271) held that the correctness standard of review applied to what he characterized as a jurisdictional issue. He held that Thalomid was sold in the USA and as such, could not be considered to be 'sold in any market in Canada'. Accordingly, the Board did not have the jurisdiction to order Celgene's pricing information for Thalomid, or to order a price reduction.

A majority of the Federal Court of Appeal (2009 FCA 378) concurred with the Board's decision. The parties agreed that the standard of review was that of correctness, also characterizing the issue as a jurisdictional one. Although the standard of review did not affect the

outcome of the appeal, Justice Evans noted that it was doubtful whether the dispute was truly jurisdictional in nature, and therefore whether the standard of review would in fact be correctness. In any event, after a textual interpretation of section 80, Justice Evans concluded that the language was open to different interpretations. As a result, he held that the interpretation to be chosen ought to be the one which best implemented the objectives of the relevant provisions: that of consumer protection. Accordingly, Justice Evans would not have disturbed the decision of the Board.

Analysis

On appeal to the Supreme Court of Canada, the judgment of Justice Evans was upheld. Justice Abella, writing for a unanimous court, purposively interpreted sections 80, 83, and 85 to discern their proper legislative intent. She noted that the Board's interpretive decision came as a result of its mandate of consumer protection, and was guided by those policy objectives.

Justice Abella referred to legislative readings of Bill C-22 (Act to Amend the Patent Act and to Provide For Certain Matters in Relation Thereto) to support her view that the Board's interpretive choice was supported by the legislative history (para 26). At the Bill's second reading for instance, the Honourable Harvie Andre stated that the proposed changes would 'ensure consumer protection by creating a drug prices review board to monitor drug prices . . .' (para 26). Indeed, when further amendments to the Patent Act came in 1993, the consumer protection mandate was again reiterated by the Honourable Pierre Blais, the then Minister of Consumer and Corporate Affairs (para 27). Finally, Justice Abella cited *ICN Pharmaceuticals Inc v Patented Medicine Prices Review Board* ((1996), 108 FTR 190, aff'd [1997] 1 FC 32 (CA) with approval where the applications judge expressly indicated that Parliament's intent in creating the Review Board was to 'address the "mischief" that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels' (*ICN*, para 24).

The Board took an approach congruent with this overall Parliamentary intent, according to Justice Abella. In her view, the Board was therefore correct in concluding that to comply with its mandate, the words 'sales in any market in Canada' ought to be interpreted to include sales of medicines that are regulated by the public laws of Canada, to be delivered within Canada, dispensed in Canada, and where the cost will be borne by Canadians. All of those factors were satisfied in the case at bar.

Justice Abella also agreed with the Board's conclusion that a narrow commercial law approach to the definition of 'sold' under section 80(1)(b) would give the Board authority over sales which, although made in Canada, were destined for other countries. That result would be inconsistent with the legislative intent behind the price regulations: that is, to protect *Canadians* from excessive prices. The provisions were never meant to be concerned with the prices of medicines being sold outside of Canada.

Obiter, Justice Abella also doubted whether correctness would have been the proper standard of review. She recognized that the Board was a specialized tribunal interpreting its own enabling legislation. Deference will usually be appropriate in that situation (para 34). However, like Justice Evans of the Federal Court of Appeal, Justice Abella agreed that the Board's decision would have been upheld on either a correctness standard or on a more deferential standard (reasonableness). To be unreasonable, according to seminal Supreme Court of Canada decision in this area (*Dunsmuir v New Brunswick*, 2008 SCC 9), the decision must fall 'outside of a range of possible, acceptable outcomes which are defensible in respect of the facts and law' (para 47). In this case, the Board's decision was 'far from falling outside this range' (para 34).

Practical significance

The Supreme Court of Canada has clearly set out the legislative intent and policy objectives of both the Patent Act and Patented Medicine Prices Review Board in protecting Canadians from excessive drug pricing. That it was authored by one of most progressive and humanistic judges of the Court is mere jurisprudential icing on a non-excessively priced cake.

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