Date: 20100726

Docket: A-345-08

Citation: 2010 FCA 201

CORAM: NADON J.A.

LAYDEN-STEVENSON J.A.

STRATAS J.A.

BETWEEN:

GLAXOSMITHKLINE INC.

and

HER MAJESTY THE QUEEN

.

Appellant

Heard at Toronto, Ontario, on March 8, 2010.

Judgment delivered at Ottawa, Ontario, on July 26, 2010.

REASONS FOR JUDGMENT BY:

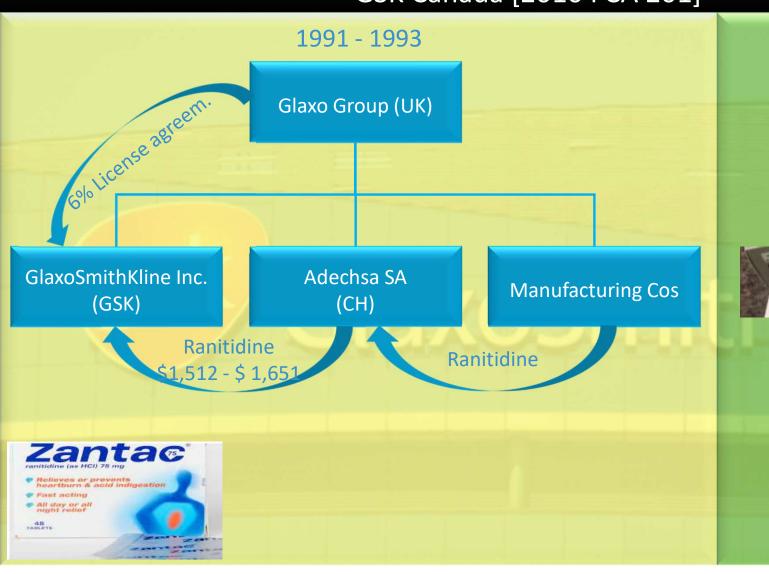
NADON J.A.

CONCURRED IN BY:

LAYDEN-STEVENSON J.A.

STRATAS J.A.







1991 - 1993

Golo License agreem. GlaxoSmithKline Inc.

(GSK)

Glaxo World used what is referred to as a resale-price method to determine the transfer price of the API [active pharmaceutical ingredient]. Glaxo World and its distributors agreed that a gross margin of 60 percent would be retained by the distributors and the ranitidine was priced accordingly. To use a very simple example, if the ranitidine product was sold for \$10 in Italy, the transfer price would be \$4; if the ranitidine product was sold for \$20 in France, the transfer price would be \$8. Appellant's counsel described the process as follows:

the starting point for determining the price to the distributor was the in-anitidine 150 mg market price for the finished ranitidine product;

from that in-market price the parties agreed, assuming specified conditions were satisfied, a gross profit margin to be retained by the distributor (approximately 60%); and

the remainder would be remitted back to Glaxo Group in the form of transfer price, royalties, [or both]. Where the distributor was to pay both transfer prices and royalties, they would be considered together to determine the distributor's gross profit margin after payment of the royalty.

Ranitidi 1.512 - \$



日爱胃妥®

Ano-Ranitidine ne Tablets USP

més de ranitidine USP

NE H2 RECEPTOR ANTAGONIST NISTE DES RECEPTEURS H2 DE L'HISTAMINE

150

0 mg

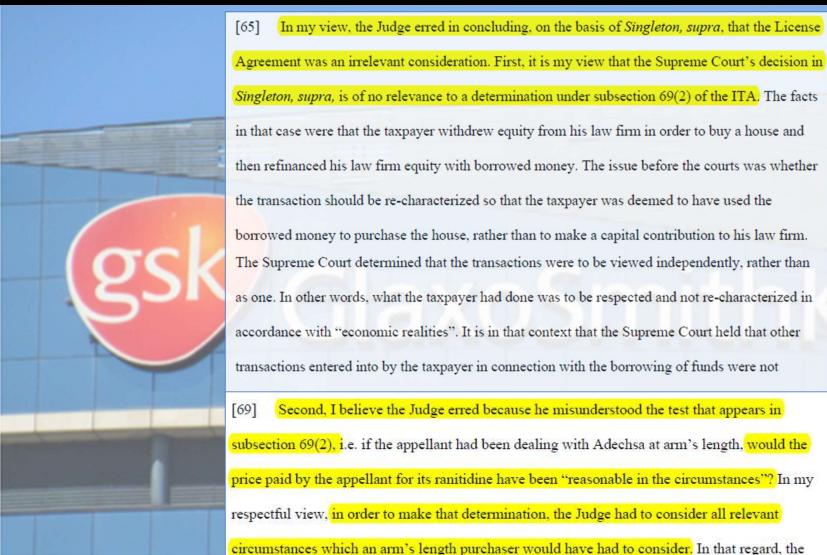
anitidine \$194-\$304 per kg

## Resale price method

Budget:	\$'000s
Gross sales	1000
Cost of sales	
<ul> <li>Other raw materials</li> </ul>	-50
Ranitidine	?
License fees	?
Sales force	-200
Gross profit/ Contribution (600/1000 = 60% margin)	600
Ranitidine (1000-50-200-600) =	150

Price per kilo:	<u>Kgs</u>
Estimated sales	100
Total price Ranitidine	150,000
Price per kilo	
150,000/100	\$1,500









[76] Clearly, in the circumstances of this case, the Judge's approach was mistaken. In a real business world, presumably an arm's length purchaser could always buy ranitidine at market prices from a willing seller. However, the question is whether that arm's length purchaser would be able to sell his ranitidine under the Zantac trademark. In my view, as a result of the approach which he took, the Judge failed to consider the business reality which an arm's length purchaser was bound to consider if he intended to sell Zantac.

[78] Because it was central to the appellant's business reality, and would be so if it were dealing at arm's length with Adechsa, the License Agreement with Glaxo Group was "a circumstance" which had to be taken into account by the Judge. In my respectful view, failing to consider that Agreement meant that the Judge made his determination in a fictitious business world where a purchaser is able to purchase ranitidine at a price which does not take into account the circumstances which make it possible for that purchaser to obtain the rights to make and sell Zantac.

[79] In my view, there are a number of "circumstances" which satisfy me that the License

Agreement was a crucial consideration in determining "the amount that would have been reasonable in the circumstances" if the appellant and Adechsa had been dealing at arm's length:

- Glaxo Group owned the Zantac trademark and would own it even if the appellant was an arm's length licensee.
- Zantac commanded a premium over generic ranitidine drugs.
- Glaxo Group owned the ranitidine patent and would have owned it even if the appellant had been in an arm's length relationship.
- 4. Without the License Agreement, the appellant would not have been in a position to use the ranitidine patent and the Zantac trademark. Consequently, in those circumstances, the only possibility open to the appellant would have been to enter the generic market where the cost of entry into that market would likely have been high, considering that both Apotex and Novopharm were already well placed and positioned.
- Without the License Agreement, the appellant would not have had access to the portfolio of
  other patented and trademarked products to which it had access under the License
  Agreement.

[80] The appellant submits, and I agree entirely with that view, that these circumstances do not arise from the non-arm's length relationship between the appellant and Adechsa or between the appellant and Glaxo Group. To the contrary, these circumstances, and I quote the appellant, "arose from the market power attaching to Glaxo Group's ownership of the intellectual property associated with ranitidine, the Zantac trademark and the other products covered by its License Agreement with Glaxo Canada". As the Administrative Appeals Tribunal of Australia stated in *Roche Product Pty Limited and Commissioner of Taxation*, [2008] AATA 639 (July 22, 2008) at paragraph 153:

It is the intellectual property which is really the product, not the pill or capsule by which it is dispensed. The intellectual property included patent rights. The intellectual property came from very substantial expenditure on research and development, much of which would have produced no result. The profits from the exploitation of the intellectual property rights was something to which [the parent company which invented the product] had a special claim even though the profit would be collected for Australian sales by the Australian subsidiary.

