Docket: 98-712(IT)G

BETWEEN:

GLAXOSMITHKLINE INC.,

Appellant,

and

HER MAJESTY THE QUEEN,

Respondent.

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Appeals heard on February 27, 28, March 1, 2, 5, 6, 7, 8, 9, 20, 21, 22, 23, 27, 28, 29, 30, April 3, 4, 5, 6, 11, 12, 24, 25, 26, 27, May 1, 2, 3, 4, 15, 16, 17, 18, 29, 30, 31, June 1, 5, 6, 7, 12, 13, July 17, 18 and 19, 2006 at Toronto, Ontario.

Before: The Honourable Gerald J. Rip, Associate Chief Justice

Appearances:

| | |
|---|---|
| Counsel for the Appellant: | Pierre Barsalou, Sébastien Rheault, Eleni Kouros, McShane Jones and Ben Tomlin |
| Counsel for the Respondent: | Naomi Goldstein, Myra Yuzak and Karen Janke |

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## JUDGMENT

The appeals from the assessments made under the *Income Tax Act* for the 1990, 1991, 1992 and 1993 taxation years and assessments made under Part XIII of the *Act* with respect to the alleged failure of the appellant to withhold tax on dividends deemed to be paid to a non-resident shareholder in 1990, 1991, 1991 and 1993 are allowed and the matters are referred back to the Minister of National Revenue for reconsideration and reassessments only to decrease the excess amounts (as described in the reasons for judgment) paid by the appellant for ranitidine by $25 per kilogram and to adjust the amounts of withholding tax accordingly.

Costs shall be paid by the appellant; the parties may make representations as to the quantum of costs.

Signed at Ottawa, Canada, this 30th day of May 2008.

"Gerald J. Rip"

Rip A.C.J.

Citation: 2008TCC324
Date: 20080530
Docket: 98-712(IT)G

BETWEEN:

GLAXOSMITHKLINE INC.,

Appellant,

and

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## REASONS FOR JUDGMENT

Rip A.C.J.

Note to Reader

In order not to add to lengthy reasons for judgment, four appendices have been attached to these reasons and form part of the reasons. The appendices include a ruling on a motion by the appellant pursuant to section 100 of the *Tax Court of Canada Rules (General Procedure)* (Appendix I), a diagram of the corporate structure of the Glaxo corporations headed by Glaxo Holdings (Appendix II), a List of Witnesses and the subject of their testimony, listed in order of appearance at trial (Appendix III) and a Glossary of terms used during trial, some of which are included in these reasons (Appendix IV). [The Glossary was adapted from a Glossary submitted by the appellant at trial.] There was an effort to have these appendices in as concise a form as possible for ease of reading.

[1] GlaxoSmithKline Inc. ("Glaxo Canada") appeals income tax assessments in which the Minister of National Revenue ("Minister"):

a) reassessed the appellant for its 1990, 1991, 1992 and 1993 taxation years by increasing its income for each year on the basis that the appellant overpaid its non-arm's length supplier for the purchase of ranitidine hydrochloride

("ranitidine"), applying sections 3, 4 and 9 and subsections 69(2) of the *Income Tax Act* ("*Act*")[1] ("Part I assessments"); and

b) assessed the appellant for tax under Part XIII of the *Act* for amounts deemed to have been paid by the appellant as dividends in 1990, 1991, 1992 and 1993 to its non-resident shareholder, Glaxo Group Limited ("Glaxo Group"), in accordance with subsections 56(2), 212(2) and 214(3) of the *Act*. Alternatively, the respondent says that the appellant, pursuant to paragraph 246(1)(*b*) of the *Act*, is deemed to have made payments in 1990, 1991, 1992 and 1993 to its shareholder to which Part XIII of the *Act* applies ("Part XIII assessments").

[2] The appeals were heard on common evidence.

INTRODUCTION

[3] Ranitidine is the active pharmaceutical ingredient ("API") in a drug that was marketed by the appellant in Canada under the brand name Zantac. The drug was prescribed to relieve stomach ulcers without the need for surgery. Before the discovery of ranitidine the most successful API used to relieve ulcers was cimetidine. Cimetidine was marketed by a competitor of the appellant under the brand name Tagamet. Ranitidine was discovered by the appellant's parent company in 1976 and was approved for sale in Canada in 1981. Zantac was launched by the appellant in 1982.

[4] During the period under appeal other pharmaceutical companies ("generic companies") were selling generic versions of Zantac in Canada. These companies purchased ranitidine for much less than the appellant. According to the Minister, a reasonable amount for the appellant to have paid for ranitidine was the price paid by these other companies.

[5] Glaxo Canada paid Adechsa S.A., a person with whom it did not deal at arm's length, the following amounts for ranitidine during the years in appeal:

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[1] See para. 9, below. These appeals have been referred to as "transfer price" appeals. Normally "transfer price" means the price charged for goods or services by an entity such as a corporation in one country to a related entity in another country. When used in the context of a tax dispute, "transfer pricing" usually connotes the tax authority's view that the transfer price has been set too high or too low so as to transfer profits from a high tax jurisdiction to a low tax jurisdiction.
Subsections 69(2) and (3) were repealed for taxation years beginning after 1997.

| Taxation Years | Price per kilogram[2] |
|---|---|
| 1990 | $1,512 |
| 1991 | $1,575 |
| 1992 | $1,635 |
| 1993 | $1,651 |

[6] At the same time the generic companies in Canada paid the following amounts to their suppliers of ranitidine:

| Taxation Years | Price per kilogram |
|---|---|
| 1990 | $292 - $304 |
| 1991 | $244 - $289 |
| 1992 | $220 - $253 |
| 1993 | $194 - $248 |

[7] In making the Part I assessments the Minister did not permit the appellant, in computing its income for the years in appeal, to deduct the amounts by which the purchase prices paid to Adechsa for a kilogram of ranitidine exceeded the highest price paid by the generic companies for a kilogram of ranitidine at the appropriate time.

[8] The appellant's position is that the Part I assessments have no basis because the price it paid for the ranitidine "closely mirrored [the price paid by] . . . independent third parties in comparable circumstances" and the amounts paid by the appellant were "reasonable in the circumstances" within the meaning of subsection 69(2) of the *Act*. The appellant also submits that its business model and circumstances are not comparable to those of the generic companies. The respondent's position is that the appellant did not pay a reasonable price for the purchase of ranitidine in order to minimize profit in Canada and move the profit to a related corporation in a low tax jurisdiction.

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[2] All amounts in these reasons are in Canadian dollars, unless otherwise indicated. The transactions between the appellant and Adechsa, the price paid for each transaction and the highest price paid by generic companies at the time are listed in Appendix A to the respondent's Amended Reply to the Amended Notice of Appeal.

Subsection 69(2) of the *Act*

[9] Subsection 69(2) of the *Act*, in force during the period in appeal, read as follows:

> Where a taxpayer has paid or agreed to pay to a non-resident person with whom the taxpayer was not dealing at arm's length as price, rental, royalty or other payment for or for the use or reproduction of any property, or as consideration for the carriage of goods or passengers or for other services, an amount greater than the amount (in this subsection referred to as 'the reasonable amount') that would have been reasonable in the circumstances if the non-resident person and the taxpayer had been dealing at arm's length, the reasonable amount shall, for the purpose of computing the taxpayer's income under this Part, be deemed to have been the amount that was paid or is payable therefor.
>
> Lorsqu'un contribuable a payé ou est convenu de payer à une personne non-résidente avec qui il avait un lien de dépendance, soit à titre de prix, loyer, redevance ou autre paiement pour un bien ou pour l'usage ou la reproduction d'un bien, soit en contrepartie du transport de marchandises ou de voyageurs ou d'autres services, une somme supérieure au montant qui aurait été raisonnable dans les circonstances si la personne non-résidente et le contribuable n'avaient eu aucun lien de dépendance, ce montant raisonnable est réputé, pour le calcul du revenu du contribuable en vertu de la présente partie, correspondre à la somme ainsi payée ou payable.

Preliminary Facts

[10] Glaxo Canada is a wholly owned subsidiary of Glaxo Group, a United Kingdom corporation, which in turn is a wholly owned subsidiary of Glaxo Holdings PLC, also a corporation headquartered in the United Kingdom. Glaxo Holdings headed an integrated multinational group of entities, which discovered, developed, manufactured and distributed pharmaceutical products throughout the world. Glaxo World[3] products are sold through subsidiaries and unrelated distributors in local markets.

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[3] In these reasons the term "Glaxo World" or "World" refers to all or any one or more corporations controlled, directly or indirectly by, or affiliated with, Glaxo Holdings PLC and includes, for example, Glaxo Group Limited, Adechsa S.A., Glaxo Canada, Glaxochem (Pte) Ltd. and Glaxochem Ltd. See a corporate organization chart of Glaxo World in Appendix III to these reasons.

[11] Pharmaceutical products are manufactured in two basic stages, referred to as primary manufacturing and secondary manufacturing. Primary manufacturing is making the active pharmaceutical ingredient for a pharmaceutical product. Secondary manufacturing includes the process of putting the active ingredient into a delivery mechanism or packaging, such as a tablet, liquid, or gel.

[12] Two Glaxo World companies carried on the primary manufacturing of ranitidine: Glaxo Pharmaceuticals (Pte) Limited[4], a corporation incorporated and carrying on business in Singapore, and Glaxochem Ltd., a United Kingdom corporation located in Montrose, U.K. Upon completion of the primary manufacturing process, the ranitidine was sold at a uniform price by the primary manufacturer to one of two Glaxo World clearing companies: Adechsa S.A., a Glaxo World company based in Switzerland, and Glaxo Far East. The clearing companies then sold the API to local companies in various countries at a variety of prices. Glaxo Holdings established the price of the API based on the price the local company could expect to fetch on sales of Zantac in its local market. During the period in appeal, the ranitidine purchased by the appellant was manufactured in Singapore and sold to the appellant by Adechsa.

[13] Adechsa had an agreement with the Swiss tax authorities under which it agreed to pay tax on the basis that it earned a minimum profit of four percent.[5] Few taxes were paid by the Singapore manufacturer because it qualified for a ten-year pioneer relief tax holiday that began in 1982. After the expiry of the ten-year period, the tax rate was ten percent. Under the pioneer relief program, Glaxo World benefited from "tax sparing" between Singapore and the United Kingdom. Glaxo World's Singapore company did not pay any tax on the profits earned in Singapore; income apparently was deemed by the United Kingdom tax authority to have been fully taxed at the current Singapore tax rate. When the profits were brought into the United Kingdom in the form of dividends, United Kingdom tax was payable only on any excess in terms of the United Kingdom tax rate over the Singapore tax rate. Glaxo World's transfer pricing arrangements allowed Singapore to earn gross profits of around ninety percent in Singapore on the sale of ranitidine to Adechsa during the period 1990 to 1993. During the same period, Glaxo Canada was earning gross profits of around 57 percent. According to a memorandum by

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4 Up to and including 1990, ranitidine was produced in Singapore by Glaxochem (Pte) Ltd. In 1991, there was a corporate reorganization and Glaxo Pharmaceuticals (Pte) began to produce ranitidine.

5 If profit from sales exceeded four percent, tax would be calculated on the actual profit.

Lionel Halpern, the "Group" taxation controller of Glaxo Holdings, Glaxo World's strategy to minimize its taxes worldwide was:

1. to make as much profit as possible in Singapore;

2. to make as much of the remainder of the Group's profit as possible in the U.K.; and

3. to ensure the Group does not pay tax on the same profit twice.[6]

AGREEMENTS

[14] Glaxo Canada had two contracts with respect to Zantac: a "Licence Agreement" dated July 1, 1988 with Glaxo Group and a "Supply Agreement" with Adechsa dated October 1, 1983.[7] Under the terms of the Licence Agreement, which applied to all drugs and not just Zantac, Glaxo Canada paid a six percent royalty to Glaxo Group on its net sales of Zantac and Glaxo Group provided the following services and intangibles to Glaxo Canada:

a. right to manufacture, use and sell products;

b. right to the use of the trademarks owned by Glaxo Group, including Zantac;

c. right to receive technical assistance for its secondary manufacturing requirements;

d. the use of registration materials prepared by Glaxo Group, to be adapted to the Canadian environment and submitted to the Health Protection Branch ("HPB");

e. access to new products, including line extensions;

f. access to improvements in drugs;

g. right to have a Glaxo World company sell Glaxo Canada any raw materials;

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6 a) There is nothing obscene or objectionable in a taxpayer making as much profit as possible and to make legitimate efforts to pay minimal tax on the profits and I draw no negative conclusion in a taxpayer doing so.
b) To the extent it makes a difference, I assume that in using the word "Group", Mr. Halpern is referring to Glaxo Group Ltd. as opposed to the Glaxo Group of companies.

7 Prior agreements were entered into evidence but those have no bearing on these appeals.

h. marketing support; and

i. indemnification against damages arising from patent infringement actions.

[15] The Supply Agreement between Glaxo Canada and Adechsa granted the appellant the right to purchase ranitidine and set out the price of the ranitidine. The transfer price was established by Glaxo Holdings. Adechsa's role was to administer the transfer prices. The Supply Agreement also provided protection against foreign currency exchange, indemnity insurance and the provision of intellectual property to "the extent that [the appellant] shall not previously have received it or shall not otherwise receive it directly from [Glaxo Group]".

[16] The respondent argued that the only item of value received under the Supply Agreement was the ranitidine. Respondent's counsel submitted that the protection against foreign currency fluctuations was largely irrelevant given that under the Agreement either party could change the currency. Glaxo Canada was charged separately by Glaxo Group for indemnity insurance in each of the years under appeal. With respect to the additional intellectual property, the appellant’s general counsel, Mr. McTeague, admitted that he wasn't sure what intellectual property remained to be provided under the Supply Agreement given the wide ambit of the Licence Agreement. Thus, according to the evidence, the only item of value received by Glaxo Canada under the Supply Agreement was ranitidine.

## THE CANADIAN PHARMACEUTICAL INDUSTRY

### Regulation

[17] The prescription pharmaceutical market in Canada was regulated by the HPB of Health Canada during the period under appeal. Prescription pharmaceuticals could not be marketed in Canada without approval from the HPB. The HPB had the responsibility of evaluating the safety, effectiveness and quality of all drugs and medical devices before they could be marketed in Canada.

[18] During the period 1980 to 1993, the HPB was responsible for the review of New Drug Submissions ("NDS"). The HPB was ultimately responsible for ensuring that all drugs, including ranitidine products, were safe and effective for their intended use. A NDS was made by the appellant for ranitidine tablets. When a NDS is prepared for a new chemical entity, the data provided may be divided into information relating to the following sections:

a. Chemistry and Manufacturing of the Product: the drug substance (API) and dosage forms must meet appropriate standards and the drug must be manufactured in a manner that allows the product to exert its inherent pharmacologic effects.

b. Pharmacologic Properties of the Drug: This information provides the results of all studies performed in vitro or conducted in vivo in animals. The purpose of these experiments is to elucidate the basic pharmacologic effects of the drug.

c. Toxicities of the drug: Toxicological studies are undertaken in animals to determine the adverse effects of each new drug, with the purpose of predicting the possible toxicities the compound may show in humans.

d. Effects of the Drug in Humans: These clinical studies explore the absorption, distribution, metabolism and excretion of the drug in humans, as well as its ability to treat the disease of concern and its adverse effects.

Generic Drugs

[19] At all relevant times a compulsory licensing system existed in Canada which allowed the marketing and sale of a generic version of patented pharmaceutical products, including ranitidine products, in exchange for a royalty of four percent paid to the patent owner. Thus, a generic company could sell a generic version of a drug to the public notwithstanding that the patent for the drug was still in effect.

[20] Like innovator companies such as the appellant, generic companies were required to satisfy HPB's standards with regard to the proposed product's safety, efficacy and quality. However, unlike innovator companies, generic companies did not have to provide evidence of clinical testing. Instead, HPB would accept adequate published data on drug safety and accept published clinical data from well controlled trials.

[21] Generic manufacturers therefore sought to establish that their drug products were equivalent to those of innovator companies for which a Notice of Compliance had been issued. This was accomplished by submitting complete chemistry and manufacturing data establishing chemical equivalence, as well as bioavailability studies to demonstrate bioequivalence. A Notice of Compliance by HPB for a NDS constituted a declaration of equivalence, as the generic product had been determined

to be pharmaceutically equivalent and bioequivalent to the Canadian innovator product.[8]

[22] Two companies, Apotex Inc. and Novopharm Ltd., began selling generic ranitidine products in Canada in 1987 and 1989, respectively. Apotex and Novopharm purchased ranitidine from arm's length manufacturers. The sales of the generic ranitidine products had a negative impact on Zantac's market share; Zantac's share during the period under appeal dropped from 38 percent to 20 percent of unit sales of tablets. The appellant's market share as a percentage of total sales of all ranitidine products declined from 49 percent to 40 percent.

Formularies

[23] During the years in issue, the provinces operated government-funded drug plans in order to ensure that Canadians covered by provincial health insurance received the necessary pharmaceutical products and to maintain the affordability of these required drug products. For this purpose, each of the provinces established a drug formulary, which is a listing of those drugs for which the government pays some or all of the cost. If a drug is not listed on its formulary, the province's insurance plan does not pay for the drug and the consumer/patient must pay for the drug out of his or her own pocket. This negatively affects sales.

[24] Mr. Lorne Davis, a pharmacologist for the Saskatchewan Prescription Drug Plan, explained that each provincial government regulates admission of a drug to its formulary. Submission for approval to a formulary does not derogate from the requirement that each innovator or generic drug product must also be approved by HPB, but only those drugs approved by a provincial government will be listed on that province's formulary. Generally, the formulary is published and distributed to the province's doctors to make them aware of the drugs that are on the formulary. Such information would influence the doctors' decisions about what drugs to prescribe to their patients. For generic products, inclusion on the formulary means the generic drug has been approved as being interchangeable with the innovator product and that it can be substituted by a pharmacist when filling a prescription.

[25] Generic products were listed at a lower retail price than innovator drugs. And, even as between themselves, the generics competed to list on the formularies at a lower price. According to Mr. Fahner, Vice-President, Finance at Apotex, the first

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[8] "Chemical equivalence", "bioavailability" and "bioequivalence" are defined in the Glossary, Appendix IV.

generic product on a market typically sells at 80 to 85 percent of the price of the branded product. The next generic product that enters the market usually would be priced slightly under the first generic, and so on.

[26] Mr. Fahner explained that because of the provincial substitution programs, the generic companies directed their sales efforts towards pharmacists, as opposed to doctors. In addition to offering their products at prices that were less than the branded products, the generic companies sought to market their products by providing volume discounts, mostly to the large pharmacy chains, and delivering incentives to the smaller independently owned pharmacies. The goal was to have various pharmacies stock a wide range of the generic company's drug products, which would lead to greater sales. In some cases the provinces tendered contracts (mostly for hospitals sales) to the least expensive generic product distributor.

[27] One of the main purposes of provincial drug insurance plans is to reduce the cost of drugs in Canada. To that end, the drug plans allowed for the substitution of less expensive generic products where such products were available. For a time the provincial drug plans allowed the prescribing of the more expensive innovator products where the prescribing physician included the notation "no substitutions" on the form. Later, the provincial drug plans required mandatory substitution, that is, the drug plan would not pay any of the cost of the more expensive branded innovator product where there existed a less expensive generic product. Mr. Fahner testified that Saskatchewan stopped accepting no-substitution prescriptions in 1991.

MARKETING AND PRICING

[28] When ranitidine was discovered, Glaxo Group's then Chief Executive Paul Girolami (later Sir Paul and head of Glaxo Group)[9] was advised by his Research Director that Zantac was superior to Tagamet because of its greater selectivity, more favourable safety profile, higher efficacy and easier dosage regimen. As a result, Sir Paul decided that Zantac should be priced at a substantial price premium of approximately 20 percent to Tagamet to reflect that superiority, and that the global marketing platform for the product would be focused on the demonstrated advantages of Zantac over Tagamet.

[29] Once launched, Zantac achieved significant sales volume and overtook Tagamet as the premier anti-ulcer drug. It became, according to Paul Meade, who

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[9] Sir Paul Girolami was described by various witnesses as the "chairman", "CEO", "président" and "number one" at Glaxo Group.

worked in Glaxo's marketing group in both Canada and the United Kingdom, the "gold standard in ulcer therapy".

Marketing

[30] As was the case with other pharmaceutical products, the marketing of Zantac was restricted to claims supported by data and approved by regulatory authorities. Glaxo Group established a world-wide marketing strategy for Zantac which was implemented by each subsidiary at the local level. The British parent's "core marketing strategy" for Zantac was based on the medical uses of the drug product. Its main claim was that Zantac lessened or prevented gastric ulcers and esophagitis. Mr. Meade described the marketing plan as follows:

> Zantac will be positioned as a major evolutionary advance in the management of peptic ulcer and other acid pepsin-aggravated disorders of the upper gastrointestinal tract. Zantac contributes three important new parameters to ulcer therapy - simplicity of dosage, unsurpassed efficacy and a remarkable freedom from clinically significant side reactions.

[31] Glaxo Group made the decision to promote a particular product such as Zantac and did the initial research and product development and then provided this information to the local distributor. In Canada, the appellant added a "Canadian flavour", in the words of Mr. Woloschuk, who worked in marketing at Glaxo Canada from 1976 to 1996. He explained that the way a product is sold in England may not be the same way it is sold in Canada. The strategy, he declared, was "sell the product and [stress that] it's good for this indication, but we need to change that to make it more Canadian".

[32] Each local Glaxo World distributor, including the appellant, was required to apply the message in its local market. Glaxo Group provided written material to the distributors and sponsored marketing workshops which were attended by employees of its distributors. The local distributors then communicated the Glaxo message to their local markets. Marketing personnel in Canada delivered promotional directives and material to the local sales managers, who would then oversee the marketing efforts of a team of local sales representatives. The local sales representatives would visit local doctors and communicate to them the various marketing information about Zantac. The appellant's goal was to convince doctors to prescribe Zantac over other ulcer-relief products.

Anti-Generic Marketing Strategies

[33] When the generic companies were preparing to enter the ranitidine market in Canada in 1985, Glaxo Canada was very aggressive in attempting to abort or at least delay the generic companies' efforts. This is notwithstanding the appellant's position at trial that the generic companies were not its competitors. Five tactics to deal with the generics were set out in a document entitled "Report on the Genericization of Zantac in Canada" ("Report"): legal challenges, positioning, sales force, brand image, and investment in the brand, including the launch of an ultrageneric drug.

1) Legal Challenges

[34] According to the Report, "all legal avenues to have the generic removed from the market, or delisted from provincial formularies were pursued." In 1987, Mr. K.F. Read, the appellant's Director of Regulatory Affairs, attempted to convince HPB to refuse a generic company a Notice of Compliance for a ranitidine product by raising potential safety concerns. The appellant also tried to obtain an injunction against HPB, but failed. In his reasons for an order dismissing the application for an interim injunction Rouleau J., was of the view that the appellant's "sole motive . . . in bringing this application . . . [was] . . . to prevent competition in a market where it has . . . enjoyed a virtual monopoly".[10] An appeal to the Federal Court of Appeal was dismissed. Mr. Jacques Lapointe, who was the appellant's president during the years in appeal, agreed that the application was "one of the tactics" used by Glaxo Canada to fight the availability of generic ranitidine in Canada.

2) Positioning

[35] The appellant sought to establish Zantac as the standard of excellence in ulcer therapy. The superior profile of Zantac was compared and contrasted with the questionable quality of the generics to physicians, pharmacists and provincial formularies.

3) Sales Force

[36] Once generics entered the market, the appellant expanded on its sales force and created a Pharmacy Service Sales Force to deal exclusively with pharmacies.

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[10] *Glaxo Canada Inc. v. The Minister of Health and Welfare, the Attorney General of Canada and Apotex Inc. and Novopharm Limited*., Court No. T-449-87, September 22, 1987.

This allowed the Physician Sales Force to concentrate exclusively on physicians. The appellant launched an anti-generic campaign, which included the "no-substitution campaign". The Physician Sales Force sought to persuade doctors to include the phrase "without substitutions" or "no substitute" on Zantac prescriptions which meant that a pharmacist could not substitute a generic product in place of Zantac. The Pharmacy Service Sales Force encouraged pharmacists to stock and dispense Zantac instead of a generic drug for all customers, who were not covered under a provincial drug plan.

[37] In addition, the Glaxo Hospital Savings Plan was devised to enable Glaxo Canada to compete effectively with generic ranitidine in the Canadian hospitals. Under this plan, hospital pharmacists received an on-invoice discount and a volume discount based on the whole portfolio of the drugs purchases. The initial on-invoice discount for Zantac products was 25 percent. The rebate was increased to 40 percent and then to 45 percent. The discounts allowed the appellant to match the price of generic ranitidine products in hospitals.

4) Brand image

[38] Mr. Faheem Hasnain, a Glaxo official discovered by respondent's counsel, explained that Zantac's success in Canada was due to the brand's perception in the marketplace. "That was our ace in the hole." He added that "what it came down to is marketing . . . we had a pretty good marketing team, in fact we had a great marketing team". There was a perception in the marketplace that Zantac was a high-quality, superior agent. He acknowledged that every marketing campaign takes into account local nuance and local understanding of customer base. In Canada, for example, the advertising campaign played on the suggestion that there were quality problems with generics and that it was only with Zantac that the patient could be sure of the quality.

[39] In 1988, ACIC, a Toronto manufacturer of ranitidine, offered to sell its product to Glaxo Canada. The proposed price was a one time payment of $240,000 for research and thereafter $350 to $400 per kilogram. Jacques Lapointe testified that Glaxo Canada and Glaxo World had some concerns about the ramifications of entering into an agreement with this supplier. In a letter dated April 21, 1988 to Jeremy Strachan of Glaxo Holdings, Mr. Lapointe wrote:

> From a marketing point of view the longer we can keep Novopharm from entering the market with a second generic ranitidine the better we are able to defend our position against Apotex who are recognized in the marketplace to have a definite

> quality problem. **It would also be much more difficult to defend against generics if the generics' quality was equal to or superior to that offered by Zantac.**
>
> There could be significant financial implications as well. We have been challenged, as you know, by Revenue Canada on transfer pricing of ranitidine in view of the availability of raw material on the world market in the $350 price range. … In addition to the argument concerning the inclusion of development costs in Glaxo material, another possible defence would be the poor quality of this cheaper material from off-shore sources. ACIC's unnegotiated offering price for material of good quality is $400 and this from a Canadian source. If we were to enter into a purchase agreement at this price, however, the world-wide ramifications would need to be critically assessed. Such a precedent could jeopardize transfer pricing on a much larger scale.
>
> . . .
>
> Our planned course of action is to stall [ACIC] for as long as possible. We have requested a further sample of the initial batch which will be sent to John Padfield's laboratories for evaluation along with the report of our analysis as soon as available. Assuming that the quality of this material is confirmed, we may want to consider tying up this source of production indefinitely before the material becomes available in the marketplace.
>
> [Emphasis added.]

[40] Glaxo Canada ultimately decided not to purchase ranitidine from ACIC. Mr. Lapointe testified that the reason for this was because its marketing strategy involved the claim that Glaxo manufactured ranitidine was superior to the generic ranitidine and that the only way to be sure you were getting a quality product was to buy Zantac. In his view, if the appellant started sourcing its ranitidine from a supplier that could be available to the generics, it would lose credibility in the positioning of the product. Mr. Lapointe testified that this decision was not related to any concerns about the quality or purity of ACIC's ranitidine.

[41] Canada was unique in that it was one of the first markets in which generic drugs were available and it had provincial formularies with mandatory substitution. While Glaxo World may have one marketing plan for most drugs that also applied across Canada, Lapointe agreed that for certain products there would be different marketing plans for Quebec and even in some provinces where mandatory substitution of generics was at a different level. Mr. Meade also agreed that the appellant "did certain things differently" in Quebec. Language and cultural differences, he said, made that province different.

5) Investment

[42] In 1989, Glaxo World launched another ranitidine product in the Canadian market to compete directly with the generics on price. Glaxo Canada formulated its ranitidine into finished ranitidine products for sale to Kenral Inc. ("Kenral"), a corporation owned by the Upjohn Company of Canada. The product sold under the Kenral label was identical to Zantac, save for the brand name. According to Paul Lucas, Senior Vice-President, Corporate Mobility for the appellant, this was the first voluntary agreement Glaxo World had negotiated with a generic company and the royalty of six percent payable by Kenral "was a much better deal" than the four percent payable by the generic companies. Mr. J.W. Cuttle, Marketing Management Kenral, said Kenral was created to compete in the generic market as an ultrageneric. He defined an ultrageneric product as one that is manufactured by the originating brand-name pharmaceutical company but is sold in the generic market segment at generic prices.

[43] A business plan for the appellant for the five-year period 1991/92 to 1995/96 discussed various strategies to grow market share for Zantac while protecting it "from competitive inroads" at a time when Zantac's sales were declining due to the presence of the generics and the potential competition from Omeprazole, a new anti-ulcer product that had recently entered the market. Strategies included fragmenting the market with line extensions, continued promotional efforts for Zantac's long-term use on enhancing the company image and support to physicians, pharmacists and consumers.

[44] By 1993 Zantac had lost significant market share to the generics in Canada; the decision was made to cease promotion of Zantac rather than to fight a losing cause. This was a uniquely Canadian phenomenon. In the rest of the top ten markets, the central marketing strategy of investing heavily in Zantac to expand the market was still in effect as the patent had not expired.

Pricing and Third Party agreements

[45] As stated, Glaxo World's pricing strategy was to price their product at approximately a twenty percent premium to Tagamet. In Canada, the United Kingdom and the United States there were no government controls restricting the price and Glaxo World was free to determine the selling price of Zantac. However, in many countries the retail price ("in-market price") was set by the local government, often based on the cost of the API to the distributor or with reference to the in-market

price in other countries. In those countries, Glaxo World had to negotiate price with government authorities. As a result, Glaxo World had an interest in setting high transfer prices for the API because a higher transfer price paid by the local Glaxo World distributor to Adechsa would often result in a higher in-market price, both in that country and in others that may rely on it.

[46] In many of the European markets Glaxo World undertook to promote and distribute Zantac through third-party distributors in addition to its local subsidiaries. These third-party distributors were also referred to during the testimony as foreign licensees and co-marketers. Dr. Gregory Bell, an expert in the pharmaceutical industry and transfer pricing, explained that a co-marketer is someone who sells the same chemical entity as the innovator, but under a different brand name. The primary functions performed by the third-party distributors were marketing, detailing and distribution. As was the case with Glaxo Canada, third parties used marketing tools provided by Glaxo World in the United Kingdom to promote to physicians the clinical advantages of their ranitidine products over Tagamet.

[47] Glaxo World used what is referred to as a resale-price method[11] to determine the transfer price of the API. 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-market price for the finished ranitidine product;
>
> from that in-market price the parties agreed, assuming specified conditions were satisfied, a gross profit margin the 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.

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[11] See para. 63, below for the Organization for Economic Co-operation and Development's ("OECD") definition of "resale price method".

[48] Mr. Fisk made it clear that the price of the API had no connection to its manufacturing costs or to the costs of the generic products. He explained that "the driver was the in-market price and, obviously, you know, Group's guidelines in terms of what an appropriate level of gross margin would be". According to Mr. Hasnain, a 60 percent gross margin was chosen because they determined that it would give a sufficient return to the distributors to properly market the drug.

[49] According to Dr. J. Gregory Ballentine, an economist who was qualified as an expert in transfer pricing, this pricing method allows for consistency of returns for similar functions across similar markets, notwithstanding different in-market prices in different countries. However, the respondent contends that the process is circular in that Glaxo World determines the transfer price based on its target in-market price and the pricing authority determines the approved in-market or reimbursement price based on the cost of the API.

[50] Contractual arrangements varied from country to country. In some countries, there was a Licence Agreement with Glaxo Group; in others, with the local Glaxo subsidiary. In most countries intangibles, for example the right to use a Glaxo Group trademark and the right to marketing support, were included in the purchase price of the ranitidine and the royalty payment, if one was specified, was waived. This can be contrasted with Canada, where there was a royalty payable to Glaxo Group pursuant to the Licence Agreement. Under the terms of each Licence Agreement, all local Glaxo distributors were required to purchase granulated ranitidine from a Glaxo Group approved source and to sell the licensed product under a trademark owned or controlled by Glaxo Group. This is similar to the appellant's agreement.

[51] Dr. Ballentine explained that Glaxo entered into the co-marketing agreements for various strategic reasons, including achieving a higher in-market price, to obtain earlier product registration and to limit the entry of other competitors. For example, in France and Italy Glaxo's co-marketing agreements allowed it to negotiate a high reimbursement price from the government. In Spain and Portugal the government limited the number of brands or licenses for each product. Glaxo World's goal was to protect the market from "pirates" who buy ranitidine from non-approved sources by signing up the major players as co-marketers and thereby flood the market to limit the opportunities from other firms to buy from non-approved sources and compete.

[52] A good illustration of why co-marketing agreements were so important to Glaxo World is the marketing agreements with Menarini, an Italian company. In Italy, the first country in which Zantac was sold, all ranitidine products were

reimbursed at the same price, which was set by the government. The reasons for partnering with Menarini included the weakness of patent protection in Italy, to take advantage of the influence Menarini had with the Italian health authorities to obtain quick registration approval and the perceived advantage of using an Italian-based company in order to obtain a high in-market price. On cross-examination, Mr. Fisk agreed that the fundamental element in getting a high in-market price approved by the government was the high price of the API to the distributors. Had Menarini been purchasing ranitidine for a lower price, the approved in-market price for both its product and Glaxo's product would have been lower.

[53] In a witness statement David John Richard Farrant, Glaxo Group Developing Trade Areas Director from 1981 to 1988, explained that Glaxo believed that the Italian owned company would be more likely than Glaxo to negotiate a high price. As it turns out, this strategy worked "spectacularly well", and they obtained an Italian price which was at a 44 percent premium to the price of Tagamet, much higher than expected. Mr. Fisk testified that securing a high in-market price in Italy was particularly important because this was the first time the Glaxo World strategy of achieving a premium price over Tagamet was tested and it was important to send a signal to the rest of the operating companies that this was the strategy. The high in-market price in Italy had an effect on the in-market price set in other countries as well, since many countries in Europe set their prices by reference prices in the United Kingdom and in the first country where the product was launched.

[54] In addition to its co-marketing agreement in Italy, Glaxo World had agreements in France, Austria, Finland, Germany, Greece, Spain and Portugal. According to the appellant, during the years in appeal the co-marketers paid between $962.20 and $2,641.69 per kilogram of ranitidine.

[55] During the years in appeal, there were many differences between the Canadian market and the European markets. Unlike Canada, Glaxo had a monopoly in Austria, Finland, France, Germany and Italy that provided an opportunity to charge high prices for ranitidine sales to third parties. Unlike Canada, price controls based on ranitidine's selling price existed in these countries as well as in Greece, Spain and Portugal. Canada had generics on the market, whereas most of the European markets did not and two of those that did (Greece and Spain) provided for generic ranitidine products to be compensated for at the same price as the Glaxo products. In the European markets there was no encouragement for the use of generics through mandatory substitution rules.

[56] In 1993, a representative from Vitoria, one of the Spanish licensees, wrote to Adechsa asking for a reduction in the transfer price:

> As you know the price of the [ranitidine] supplied by Adechsa hasn't been reviewed for many years and, actually, that price […] represents nearly 12 to 13 times more than the current free market prices…
>
> We beg you to grant us a significant decrease of price for [ranitidine], in order to allow us to compete on equal basis with the – competition and so, try to change the negative trend of the market share, which we have been witnessing in the last years. For this purpose, please take in consideration the relation between your price . . . and the free market price above mentioned, where the competition gets their raw material.

[57] On cross-examination of Mr. Fisk, the respondent established that Glaxo World had sold ranitidine to an Indian company called Bio Tech Pharma for $225 (U.S.) per kilogram starting in 1986. As of 1992, Glaxo World was selling ranitidine to a Hungarian company called Biogal for $550 (U.S.) per kilogram and to an Egyptian company for $630 (U.S.) per kilogram. With respect to the price in Egypt, Mr. Fisk explained that there were generic materials available there and Glaxo Egypt had to compete with the lower-priced generics. When respondent's counsel asked Dr. Ballentine why Adechsa did not sell ranitidine to Glaxo Canada at the same price it was sold to the Indian company, he replied:

> Because it can sell it to Glaxo Canada for more than that…
>
> What they pay for it to sell it in India is completely irrelevant, because they are not selling it in India. They are selling it in Canada. The price in Canada is different than the price in India, and that is perfectly expected and understood.

[58] Mr. Fisk's cross-examination also revealed that the prices disclosed by the appellant did not all take into account various discounts and allowances given to the third party licensees by Glaxo and that the adjusted transfer price was much lower in many cases. For example, in the case of Austria, a promotional allowance was being paid by Glaxo World into a Singapore bank account with no documentation submitted to the Austrian government. This effectively reduced the transfer price and would have resulted in a reduced in-market price had the government been aware of it. The licensees in Italy, Portugal and Spain were all receiving various promotional allowances, discounts, free goods and lump sump payments as well. Mr. Fisk also admitted that he did not review the books and records of the French, Italian and Finish licensees; instead he relied on various invoices and data from a pharmaceutical data organization, IMS. IMS is an

organization that collects data such as prices and sales of particular drugs in various countries for use by pharmaceutical companies, primarily to assess market conditions. While IMS claims to have a high degree of accuracy in some countries, IMS will not warrant the accuracy of its information and Glaxo Canada will not confirm or contest its accuracy. IMS does not check its information with the drug manufacturer, but instead relies on pharmacies or wholesalers to report their sales information. IMS data does not include any discounts offered to manufacturers, any discounts, promotions or free goods offered to pharmacists or wholesalers and IMS does not always collect data from hospitals.

OECD CONVENTION AND COMMENTARY

[59] Subsection 69(2) of the *Act* is analogous to Article 9(1) of the *OECD Model Double Taxation Convention on Income and Capital*. The OECD issued a commentary on transfer pricing analysis in 1979.[12] The Canada Revenue Agency ("CRA") relies on OECD Commentaries in assessing: Information Circular 87-2, *International Transfer Pricing and Other International Transactions*, dated February 2, 1987. Information Circular 87-2 was replaced by IC 87-2R, *International Transfer Planning* on September 27, 1999. The Federal Court of Appeal has said that it is "common ground that the [OECD Commentary] inform or should inform the interpretation and application of subsection 69(2)".[13]

[60] The OECD Commentary on Article 9(1) relies on the arm's length principle to determine the prices that multinational enterprises ("MNEs") would charge for goods and services sold from one jurisdiction to another. The arm's length principle recognizes that independent enterprises would charge prices according to market forces when dealing with each other. The Commentary recognizes that transfers between MNEs do not necessarily represent the result of free market forces, but may instead have been adopted for the convenience of the MNE. Consequently, prices set by an MNE may differ significantly from the prices agreed upon between unrelated parties engaged in the same or similar transactions under the same or similar conditions.

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[12] *Transfer Pricing and Multinational Enterprises: Report of the OECD Committee on Fiscal Affairs* (Paris: Organization for Economic Co-operation and Development, 1979) [The "OECD Commentary"]. The OECD Commentary were updated in 1995 [the "1995 Commentary"], but in terms of broad propositions to be considered in this case, the differences between editions may be disregarded.

[13] *SmithKline Beecham Animal Health Inc. v. Canada*, 2002 FCA 229, [2002] F.C.J. No. 37 (Q.L.), 291 N.R. 113.

[61] According to the OECD Commentary MNEs may adopt transfer prices for reasons other than to minimize tax, but, regardless of the reason, intra-group transfers which are not carried out at arm's length prices will likely result in profits shifted from one country to another. The Commentary also recognizes that in some MNEs the members have enough autonomy so that they can bargain with each other in a manner similar to that of independent entities.

[62] A hierarchy of methods that can be used to determine transfer price is set out in the OECD Commentary. There are three "traditional transaction methods": comparable uncontrolled price method, cost plus, and resale price. The 1995 Commentary provides for two additional methods: the profit-split method[14] and the transaction net margin method, which are to be used if none of the other three methods are not appropriate.

[63] The methods are defined by the OECD Commentary:

> (a) The **comparable uncontrolled price ("CUP") method** offers the most direct way to determining an arm's length price. The transfer price is set by reference to comparable transactions between a buyer and a seller who are not associated enterprises. Uncontrolled sales may include sales by a member of an MNE to an unrelated party and sales to a member of an MNE by an unrelated party as well as sales in which the parties are not related to each other or to the MNE (though they may themselves be members of other MNEs). Uncontrolled sales are, in short, sales in which at least one party to the transaction is not a member of the taxpayer's affiliated group, but they would include only bona fide transactions and not sales unrepresentative of the market, for example made in a limited quantity at unrealistic prices to an unrelated buyer, for the purpose of establishing an arm's length price on a larger transaction. The method requires the uncontrolled transactions to be carefully reviewed for comparability with controlled transactions.[15]
>
> (b) The **cost-plus method** of estimating an arm's length price is based on the supplier's cost to which an appropriate profit-mark-up is added. It is a method that raised problems both as regards assessing costs and the appropriate mark-up for profit and its likely to be appropriate as a deterring criterion mostly in specific situations, though it may also be useful as a means of verifying provisionally acceptable prices after other methods have

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14 This method was not relied on by either party and is not considered in these reasons.

15 OECD Commentary, para. 48.

> been applied.[16] This method may be helpful in estimating an arm's length price, when semi-finished products are sold…[17]
>
> (c) The **resale price method ("RPM")** begins with the price at which a product which has been purchased from a related seller is resold to an independent purchaser. This price is then reduced by an appropriate mark-up representing the amount out of which the reseller would seek to cover [its] costs and make a profit. What is left after subtracting the mark-up can be regarded as an arm's length price of the original sale. This method is probably most useful where it is applied to marketing operations.[18]
>
> (d) The **transactional net margin method ("TNMM")** examines the net profit margin relative to an appropriate base (e.g. costs, sales, assets) that a taxpayer realizes from a controlled transaction…[19]

[64] Both parties called an expert witness to explain transfer pricing and to testify as to the appropriate method of establishing the transfer price between the appellant and Adechsa. Dr. J. Gregory Ballentine testified for the appellant. Dr. Jack Mintz testified for the respondent. Both experts agreed that the CUP method is the preferred method for determining transfer prices.

[65] Only in the absence of useful evidence of an uncontrolled transaction will it be necessary to use another method.[20] For example, because no comparable transaction exists or because there are differences in the transactions that cannot be taken into account. The other methods are also useful in that they can be used as a check on each other.

PARTIES' POSITIONS

[66] Again, the issue in these appeals is whether the prices paid by Glaxo Canada to Adechsa for ranitidine would have been reasonable in the circumstances if the Glaxo Canada and Adechsa had been dealing at arm's length.

[67] The respondent's position is that the generic companies' purchases of ranitidine from arm's length manufacturers are comparable transactions. She submits that the arm's length price the appellant would have paid Adechsa is the

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16 *Ibid*. para. 63.
17 *Ibid*. para. 65.
18 *Ibid*. para. 56.
19 1995 Commentary, para. 3.26.
20 OECD Commentary, para. 12.

same as the prices paid by Apotex and Novopharm to their suppliers. To support its CUP analysis the respondent relies on the cost-plus method.

[68] The appellant's position is that the generics are not an appropriate comparator for two reasons: a) the appellant contends that its actual business circumstances were wholly different from those of Apotex and Novopharm, such that the transactions are not comparable within the meanings of subsection 69(2) of the *Act* and the CUP method; and b) the ranitidine purchased by the appellant from Adechsa was manufactured under Glaxo World's standards of good manufacturing practices ("GMP"), granulated to Glaxo World standards, and produced in accordance with Glaxo World's health, safety and environmental standards ("HSE"). The appellant contends that the ranitidine purchased by the generic companies is not a comparable good because it is not manufactured to Glaxo World's standards.

[69] The appellant submits that the independent third party licensees in Europe are the best comparator because they purchased the same ranitidine under the same set of business circumstances as the appellant. The appellant relies on the resale price method to confirm its CUP analysis.

ANALYSIS

[70] There are three key differences among the parties. These are (1) whether the Supply Agreement and the Licence Agreement should be considered together to determine a reasonable transfer price; (2) the meaning of the phrase "reasonable in the circumstances" in subsection 69(2) of the *Act*; and (3) the impact of the differences in GMPs and HSEs on the comparability of the ranitidine purchased by the appellant with that purchased by the generic companies.

[71] The CUP method is the preferred method to use to establish the arm's length transfer price. However, before any analysis of CUP, each of the differences described in the preceding paragraph should be considered.

Relevance of the Licence Agreement

[72] A major difference in the parties' approaches to calculating the transfer price is whether the total cost of ranitidine to the appellant, including royalties, should be considered or only the transaction between Adechsa and the appellant for the purchase of ranitidine. The appellant argued both the Supply Agreement with

Adechsa and the Licence Agreement with Glaxo Group should be considered. The respondent argues that the two agreements are to be looked at separately and that the only transaction relevant to these appeals is the Supply Agreement with Adechsa. The respondent relied on *Singleton v. Canada*[21] for the proposition that one must look at the transaction in issue and not the surrounding circumstances, other transactions or other realities because in order to give effect to the legal relations, one has to view the agreements independently. The respondent points out that the two agreements covered distinct subject matters, with all benefits or goods being provided by the respective owner and that there was no tie-in between the Licence Agreement and the Supply Agreement. In some of the contracts with the European licensees the Supply Agreement referenced the Licence Agreement.

[73] The respondent also led evidence to establish that the appellant acquired another API, salbutamol, from a third party. Salbutamol is a product used in inhalers to help people with asthma. Pursuant to the Licence Agreement with Glaxo Group, the appellant paid a royalty to Glaxo Group and received all the intangible benefits pertaining to the drug as set out in paragraph 14, above. There was a separate Supply Agreement between the appellant and the third party for the purchase of the API. There was no connection whatsoever between the two agreements. The respondent submits that this is further evidence that the two agreements were independent from one another.

[74] The appellant relies on two cases, *Koffler Stores Ltd v. M.N.R.*[22] and *GSW Appliances Limited v. M.N.R.*,[23] to support its argument. Both these cases were decided prior to *Singleton*, *supra*, and neither is particularly relevant. *Koffler Stores* involved the purchase of two pharmacies and the consequent surrender of the leases to the purchaser by the vendor. The Court determined that one contract was the "genesis contract" (or principal contract) and the others were contracts in implementation of the genesis contract and were "ancillary and incidental" to it. The Court concluded that one should look at the contracts together to determine the nature of the payments under one of them. I have made no similar finding of fact. Both the Licence Agreement and the Supply Agreement can stand alone; neither is ancillary to the other. *GSW Appliances* involved the issue of inventory allowance where a particular company had ceased to carry on business. The problem in that case was that there were two agreements both purporting to transfer inventory on the same date, one to the taxpayer's parent and another to a third party. The Court

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21 [2001] 2 S.C.R. 1046.

22 76 DTC 6194 (FCTD), aff'd 76 DTC 6195 (FCA) ("*Koffler Stores*").

23 85 DTC 378 (TCC) ("*GSW Appliances*").

found the two agreements were inconsistent with each other and it applied what is referred to as the law of repugnancy and concluded that if you apply the law of repugnancy, it is appropriate to look at one contract to understand the other. But there was no suggestion in this current case that there is a repugnancy between the license and the supply agreements.

[75] Appellant's counsel argued that the benefits available under the Licence Agreement between it and Glaxo Group ". . . [were] relevant in determining the proper price at which an arm's length party would have been prepared to purchase ranitidine from Adechsa in the circumstances." Dr. Ballentine characterized the issue as "what would be the cost of selling ranitidine products in Canada?" and, in doing so, he combined the royalty paid pursuant to the Licence Agreement with the purchase price for ranitidine hydrochloride paid to Adechsa to arrive at a bundle of goods and benefits received from the Glaxo World as a whole.

[76] Dr. Bell testified that both Glaxo Canada and Glaxo Group were concerned about the "net transfer price", taking into account both the cost of the API and the royalty. During his testimony he suggested that we "abstract from issues of taxation" and focus on the profit. He testified that as long as the innovator gets his 40 percent profit, how it is earned does not matter, and it makes no difference whether the profit is through a combination of the purchase price and a royalty or through the purchase price or royalty alone. In his closing submissions appellant's counsel referred to Dr. Bell's testimony and argued that the Court should respect the legal structure designed by Glaxo World.

[77] By suggesting that the taxation issue be minimized, Dr. Bell has demonstrated that he has a flawed understanding of a transfer pricing inquiry. The purpose behind this exercise is to determine a reasonable purchase price for the API and ultimately to determine the tax liability of the appellant. Royalty payments in Canada are subject to withholding tax and the profit will accrue to Glaxo Group and be taxed in the United Kingdom. The purchase price for ranitidine is not subject to any withholding tax and the profit accrues in Switzerland, and ultimately in Singapore. To suggest that Glaxo Group does not care whether its profits are in the form of royalty payments or purchase price belittles the issue in these appeals.

[78] I agree with the respondent that the Supply Agreement with Adechsa and the Licence Agreement with Glaxo Group cover separate matters and that they are to be considered independently as required by *Singleton*.[24] The United States Tax Court

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[24] *Supra*.

came to a similar conclusion in a transfer pricing case, *Bausch & Lomb, Inc. v. Commissioner*.[25] It may very well be that a 40 percent total profit to Glaxo Group is reasonable; however, the issue before me is whether the purchase price of the ranitidine was reasonable. One cannot combine the two transactions and ignore the distinct tax treatments that follow from each.

CONSIDERATION OF SUBSECTION 69(2)

[79] The appellant submits that the circumstances under which the appellant acquired ranitidine and the circumstances under which the generic companies acquired ranitidine are not comparable. The appellant argues that the price it paid to Adechsa for ranitidine was "reasonable in the circumstances", within the meaning of subsection 69(2) of the *Act*. The OECD Commentary explains that for the prices of goods to be comparable, it is necessary to have economic comparability, comparability of goods and for the goods to be sold at the same point in the chain from produce to consumer. The 1995 Commentary adds the following factors to the list of considerations: comparability of functions of the enterprises, comparability of contractual terms and comparability of business strategies.

[80] The appellant relies on the 1995 Commentary and submits that its "actual business circumstances were wholly different from those of the . . . [generic companies], but similar to those of the Glaxo Group's independent licensees in a number of countries." In fact, this argument is key to the appellant's argument, as was pointed out several times during the trial. In appellant counsel's submissions, he lists the conditions or business circumstances that in his view distinguish the appellant's transactions from those of the generic companies:

> (a) Glaxo Canada bought ranitidine from Adechsa using RPM, as did the independent licensees. Apotex and Novopharm did not.
>
> (b) Glaxo Canada had to buy ranitidine from sources approved by Glaxo Group and could not freely determine its own sources. Glaxo Group's independent licensees were similarly constrained. Apotex and Novopharm were not.
>
> (c) Glaxo Canada was required to conduct its business in accordance with Glaxo Group's standards. In addition to having to purchase its ranitidine from Glaxo-approved sources, these standards required that Zantac be manufactured under Glaxo Group's standards of good manufacturing practices, granulated to Glaxo

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[25] 92 T.C. 525, 1989 U.S. Tax Court.

Group standards, and produced in accordance with Glaxo Group's health, safety and environmental standards; and

(d) Glaxo Canada received regulatory approval and marketing assistance from Glaxo Group, as did the independent licensees. Apotex and Novopharm did not.

(e) Glaxo Canada sold Glaxo Group ranitidine products under trademarks owned by Glaxo Group, as did the independent licensees. Apotex and Novopharm sold under their own trade marks.

(f) Glaxo Canada marketed and detailed to doctors using standard pharmaceutical industry tools, as did the independent licensee. Apotex and Novopharm did not market or detail to doctors.

(g) Glaxo Canada sold its ranitidine products at a price premium to Tagamet, as did the independent licensee's. Apotex and Novopharm sold their ranitidine products at a discount to Zantac.

(h) In marketing and detailing to doctors, Glaxo Canada's primary focus was to promote the clinical advantages of Zantac (its ranitidine product) over Tagamet (the brand name cimetidine product). The independent licensees had a similar focus. By contrast, Apotex and Novopharm sold generic versions of both ranitidine and cimetidine. Their primary focus was competing with each other for pharmacy shelf space.

(i) The Glaxo Group manufacturer approved for Glaxo Canada during the period under appeal, Glaxochem (Pte) Singapore, met Glaxo Group's standards of GMP, granulation and environment. The generic suppliers to Apotex and Novopharm did not.

[81] The appellant has also submitted that the evidence of Dr. Mintz should be rejected, *inter alia*, because he ignored the unique circumstances stemming from Glaxo Canada's business model when completing his transfer pricing analysis.

[82] The respondent's position is that since the 1995 Commentary came out after the period in appeal it ought not to be relied upon. This is notwithstanding that respondent's counsel cited the 1995 Commentary in her written submissions. Counsel also argued that the different business circumstances are not relevant considerations in the transfer pricing analysis.

[83] The 1995 Commentary can assist me in considering transfer pricing issues before me. Neither party pointed to any inconsistencies between the 1995 and earlier Commentary. The 1995 Commentary is more detailed and provides more

examples than the earlier version. The preface to the 1995 Commentary sets out that they are "intended to be a revision and compilation of previous reports by the [OECD] addressing transfer pricing . . . The principal report is [the 1979 OECD Commentary]".[26] Both the 1979 and the 1995 Commentaries have a role in the CUP analysis.

[84] Several examples of relevant business strategies are suggested in the 1995 Commentary, including: "innovation and new product development, degree of diversification, risk aversion, assessment of political changes, input of existing and planned labour laws, [. . .] other factors bearing upon the daily conduct of business…[and] market penetration schemes".[27] These are examples that one would want to consider in any event absent the 1995 Commentary.

[85] The circumstance set out in paragraph 80(a) above, that Glaxo Canada bought ranitidine from Adechsa using RPM is not relevant to the issue of comparability. No one is really disputing the method that Glaxo World used to arrive at the price of its ranitidine. The issue is whether that price was reasonable.

[86] Several of the circumstances listed by the appellant stem from contractual obligations in its 1988 Licence Agreement with Glaxo Group or from Glaxo World's marketing and pricing strategies. For example, it was by virtue of the Licence Agreement that the appellant was required to purchase its ranitidine from Glaxo approved sources and adhere to Glaxo standards.

[87] The appellant's position is that the only authorized sellers of Glaxo ranitidine were Adechsa and Glaxochem and if the appellant wanted to sell Zantac it had to purchase from one of these suppliers. Because Glaxo Group set the price, it could sell for whatever it wanted. This was the testimony of Dr. Bell who said that the reason the appellant did not purchase ranitidine for $225 (U.S.) like Glaxo India did was because Glaxo Group would not allow it. Dr. Bell testified that what was scarce was the right to sell Zantac and because of this scarcity, Glaxo Group could set the price it charged for its ranitidine.

[88] The respondent does not argue that the appellant ought to have purchased ranitidine from a different supplier. She says that the price was not reasonable. The Crown looks at the prices the generic companies paid for ranitidine to determine whether the price paid by the appellant was reasonable.

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[26] 1995 Commentary, para. 13, p. P-4.

[27] *Ibid*. paras. 1.31 – 1.32.

[89] If the legislature intended that the phrase "reasonable in the circumstances" in subsection 69(2) should include all contractual terms there would be no purpose to subsection 69(2); any MNE would be able to claim that its parent company would not allow it to purchase from another supplier. No MNE would ever have its transfer prices measured against arm's length prices, because all MNEs would allege that they could purchase only from sources approved by the parent company. The controlling corporation in a MNE would structure its relationships with its related companies, and as between its related companies, in this manner or in some similar manner. There is no question that the appellant was required to purchase Glaxo approved ranitidine. The issue is whether a person in Canada dealing at arm's length with its supplier would have accepted the conditions and paid the price the appellant did.

[90] The circumstances set out in (f), (g) and (h) in paragraph 80 relate to the fact that Zantac was priced at a premium to Tagamet and that the appellant focused its marketing on selling to doctors. Again, there is no dispute that the appellant's marketing and pricing strategies differed from most, if not all, of the generic companies' strategies. However, the issue at hand is the reasonable price to be paid for the purchase of ranitidine, not Zantac. The evidence has established that it was the marketing efforts of Glaxo Canada and the value of the Zantac brand name that resulted in the price premium for Zantac. The evidence of Dr. Bell and Mr. Hasnain was that the perception of the consumer was very important to Zantac's success. There was no evidence that the price or value of the API had any effect on the price of the finished product. In fact, Glaxo World did its pricing the other way around, taking the price of the finished product and determining the price of the API from what it would eventually fetch for the final product. Any difference in business strategy between the appellant and the generic companies relates to the end selling price of the finished product, not the purchase price of the API.

[91] Finally, in (d) and (e) in paragraph 80, the appellant says that it received regulatory approval and marketing assistance from Glaxo World and that it sold its ranitidine product under trademarks owned by Glaxo World. This is irrelevant because intangibles come from the Licence Agreement, which is to be considered separately from the Supply Agreement.

[92] The 1995 Commentary states that business strategies must be looked at to determine comparability. However in the appeals at bar, the business circumstances and strategies that the appellant submits distinguish it from the generic companies have no bearing on the transfer pricing issue.

GOOD MANUFACTURING PRACTICE

[93] A point in dispute is the impact of Glaxo's GMP. The appellant submits that the Glaxo ranitidine and that purchased by generic companies are not comparable because of the differences in GMP and HSE standards. The respondent agrees that there may be differences in GMP and HSE but states that those differences are of no significance to either safety or efficacy and therefore should have no bearing on the purchase price of ranitidine.

[94] GMP is a term used for the control and management of manufacturing and quality control testing of foods and pharmaceutical products. The appellant's expert, Mr. William Ment, a senior regulatory compliance consultant who was a branch director of the U.S. Food and Drug Administration ("FDA") until 1999, described GMP as:

> policies, practices, written procedures that companies establish to ensure that the whole production process, which includes manufacturing, testing and release, reduces as much as possible the risk to that product having – being adulterated, having harmful impurities, et cetera, in it.

[95] In the view of Clive Rogers, Glaxochem Limited's purchasing manager between 1988 and 1994, GMP:

> …means that you are running your site efficiently with good housekeeping. You have trained personnel operating it. You are keeping full and comprehensive records of all your manufacture, all your batch records. You are doing proper chemical analysis on all the materials that you buy in, that you use in process. You segregate materials that are rejected that you bought in and only use good ones, and you can track a manufacturer right the way through from beginning to end and you know who has done what to it at what time and did it comply with a manufacturing process that was registered.

[96] A total of five science experts were called, all of whom attempted to put their testimony in layman's terms, to varying degrees of success. With respect to these issues the following facts are clear:

(a) During the years in appeal, Canada did not conduct inspections of or have GMP requirements for API manufacturers. The responsibility for ensuring the quality of the API was placed on the dosage form manufactures.

(b) Canada required the dosage form (secondary) manufacturers to manufacture their finished products in accordance with GMP;

(c) Generic ranitidine was chemically equivalent and bioequivalent to Glaxo's ranitidine and was approved for sale by HPB; and

(d) Glaxo Group had GMPs for the primary manufacture of the API; the generic suppliers did not.

[97] The appellant argued that Glaxo's standards differed from those of the generic API manufacturers in that Glaxo World required that its ranitidine be (1) manufactured under Glaxo's GMP standards (2) produced in accordance with HSE and (3) granulated to Glaxo World standards.[28] The suppliers to the generic companies did not manufacture ranitidine according to Glaxo standards.

[98] When Mr. Ment was asked "[t]o what extent can test methods be developed to detect adventitious contamination, cross-contamination or all and any kind of chemical that may be found in a batch?" he replied, "[i]t would be extremely difficult, if not impossible, to do that with a battery of tests that companies typically run for batch release testing. They are not designed to detect and to identify adventitious contamination, except to a very limited extent."[29]

[99] A similar sentiment was expressed by Dr. Ian Keith Winterborn, the appellant's science nominee at discovery who also testified at the trial of these appeals. He said "[i]t is impossible to design – well, it is not impossible, but it

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[28] Glaxo Canada purchased granulated ranitidine from Adechsa. Apotex and Novopharm purchased non-granulated ranitidine from their suppliers. The cost of granulating a kilogram of ranitidine is described in Exhibit R-0105. Glaxochem Ltd was charged £10 per kilogram to undertake granulation. Adechsa was charging $1,629 per kilogram for non-granulated ranitidine and $1,652 for granulated ranitidine, according to Mr. Winterborn. He stated that the granulation process was not a requirement of the manufacturing process, but was a process created by Glaxo Group. For purposes of these appeals, I conclude the granulated ranitidine has a value of $25.00 per kilogram more than non-granulated ranitidine.

[29] There are three basic types of contamination - adventitious, related and cross-contamination. Adventitious contaminants come from external sources and include such things as dust and insects. Mr. Ment recounted an example of adventitious contamination that occurred not long ago when flaking paint and flaking metallic corroded metal dropped into an excipient manufacturer’s open vats. Cross-contaminants typically come from other APIs or raw materials that are manufactured or used in the same multi-product facility. Related contaminants come from the manufacturing process itself and they can be either known, if their structure has been determined, or unknown, if their structure has yet to be determined.

would be onerous to try to design analytical tests which could detect and quantify any and all potential contaminants that might occur during manufacture, if the conditions under which the material is manufactured are not known and not understood."

[100] Mr. Ment said laboratory testing was aimed at detecting the most likely contaminants (based on the process used) and cross-contaminants (based on the other chemicals present in a multi-product facility) but even with such testing, he said that some contaminants might still slip through undetected.[30]

[101] Appellant's counsel has not argued that his client's ranitidine was superior to the ranitidine used by the generic companies. He argued that Glaxo GMPs were superior and that this reduced the risk of contamination during manufacture. The respondent's expert, Dr. Leslie Benet, saw things differently. Dr. Benet, a professor of biopharmaceutical sciences at the University of California, San Francisco, was qualified as an expert in pharmaceutical sciences, pharmacology, bioequivalency, chemical equivalence and other scientific aspects of drug-related issues. He emphasized that the real issue is not contamination *per se* (which goes to quality) but harmful contamination (which goes to safety). According to Dr. Benet, for example, cross-contamination with Atenolol, a beta-blocker used for lowering blood pressure, would not be a concern because it has a very wide therapeutic index. Cross-contamination with penicillin, on the other hand, would be a concern because people have allergic reactions to penicillin.[31] He testified that any differences in GMP and HSE are irrelevant. In his view companies may establish whatever internal standards they like but drug products are approved based on the regulatory standards in each country. The only issue, according to Dr. Benet, is whether the API met the Canadian standard. The appellant has admitted that the

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30 Mr. Ment's testimony on this point was highly technical. He stated that contaminants could pass through testing undetected:

(1) if they were not present at sufficient levels;

(2) if inexperienced or overworked laboratory personnel failed to properly follow-up on unusual or atypical results;

(3) if they passed through the column of a high-performance liquid chromatograph (a sensitive analytical instrument often called simply an HPLC) in the void volume. (The void volume contains diluent substances not retained in the column and those that come off the column from a previous injection. It is basically ignored by the analyst); or

(4) if they co-eluted with (meaning they exited the HPLC's column at the same time as) other expected compounds and, in so doing, hid behind the expected compound's peak on the chromatogram.

31 There is no evidence that penicillin was being manufactured at a facility of a supplier of ranitidine to the generic companies during the years in appeal.

generic ranitidine was bioequivalent and chemically equivalent to Glaxo's ranitidine. This is the standard used by HPB to determine whether a Notice of Compliance for a New Drug Submission will be granted. In Dr. Benet's view this is enough to end the inquiry.

[102] The appellant has suggested that both the Zantac brand and Glaxo's reputation would be impacted if harmful contaminants were ingested by the ultimate consumer. The appellant's view, therefore, is that Glaxo World has an incentive to do more than just meet the basic regulatory requirements. To reduce the risk of contamination it was not unreasonable for the appellant, for its comfort and that of the Glaxo World, to purchase ranitidine produced under good manufacturing practices for a marginally higher price than one would pay for ranitidine that lacked GMP.

[103] The Therapeutic Products Directorate of the Health Products and Food Branch of Health Canada is the Canadian authority that regulates pharmaceuticals and medical devices for human use. The respondent's witness, Mr. Sultan Ghani, became the director of the Bureau of Pharmaceutical Sciences of the TPD in 2002. He was qualified as an expert in good manufacturing practices of the pharmaceutical industry in general, the drug approval process, quality assurance and GMP in the pharmaceutical industry in Canada.

[104] Mr. Ghani explained that, during the years in issue and right up to the time of his testimony, Canadian regulations placed the responsibility for the quality of the active pharmaceutical ingredient on the dosage form (or secondary) manufacturer, and that this was where Health Canada considered the responsibility to rest as well. However, this practice will soon change due to international efforts to bring GMP standards to API manufacturers.

[105] Mr. Ghani also said the number of GMP problems associated with API manufacturing was very, very small compared with the number of GMP problems associated with dosage form or secondary manufacturing and this was why Health Canada did not concern itself with API manufacturers. He also admitted that cross-contamination is a concern everywhere, including the API manufacturers, if proper cleaning and other precautions are not taken. In re-examination, Mr. Ghani

acknowledged that there are limits to end-product testing and that GMPs do reduce the risk of contamination as much as possible.[32]

[106] During the years in appeal, the FDA was the only government regulator in the world to inspect API manufacturers. Routine FDA re-inspections of Glaxo's Singapore site were conducted on April 17-18, 1989 and February 21-23, 1994. The FDA found only minor deficiencies and concluded the facility was in general compliance with then current GMPs. Uquifa[33] was also found to be an 'approvable' source of ranitidine hydrochloride for the U.S. market during, but not necessarily throughout, the period in question. This is evidenced by the FDA's Center for Drug Evaluation and Research ("CDER") acronym 'AE' (meaning approvable) found on the FDA reporting forms for the inspections of Uquifa conducted in 1987, 1990 and 1993. Deficiencies were identified in each of the inspections but those deficiencies were all later rectified.

[107] Of particular significance is the fact that the FDA reporting form for the August 22, 1995 inspection of Uquifa still used the CDER acronym AE, for approvable, and the associated endorsement page signed on November 11, 1995 and December 8, 1995 clearly says: "FOLLOW-UP Recommend approval of both applications". Thus, although Uquifa may have been an 'approvable' source of ranitidine hydrochloride, it was not yet an FDA 'approved' source.

[108] The subtle difference between the words 'approved' and 'approvable' seems to have caused problems for witnesses of both parties. The following exchange occurred on cross-examination of Dr. Benet:

> Q. Have you seen any approval, final approval? [referring to the FDA approval of Uquifa]
>
> A. Yes. It is in this document. Let's go on to the next couple of pages.
>
> Q. At the date of this audit, it was not approved; right?
>
> A. It was approved in January -- when they reviewed this data. Can we go on to the next pages?

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32 While GMPs reduce the risk of contamination as much as possible, the risks cannot be eliminated. Both parties brought up examples of product recalls and manufacturing problems at Glaxo and the generic facilities. This evidence assists neither party.

33 Uquifa was a manufacturer in Spain who supplied ranitidine to the generic companies. Other generic companies who were approved suppliers of ranitidine by HPB were Lek, Medichem, Delmar and Maprimed.

. . .

Q. If you turn to page 13, it says: "No response has been received from the firm. Recommend firm be considered an acceptable source." That is February 1991?

A. Right.

Q. That is a recommendation. Have you seen the approval?

A. Yes. It is down in the bottom of the document I have, but you don't see it there. The document I have has the approval on it, which we got from the FDA by Treaty.

. . .

this was the FDA approval of the product, and it is ranked – you can get the document that shows it is approved, approvable.

MR. RHEAULT:

Q. Approved or approvable?

A. "Approvable" is the word they use. See, this document only has the reporting district. You need to see the document that is the next page that says what the action is, and that is not on this document. Maybe it is not in your document, but I was shown -- my counsel, when I asked to see 505438, was able to show me that. That is it, "District decision, AE." That is approvable.

[109] Dr. Benet appears to have equated 'approvable' with 'approved'. On cross-examination, he stated that Uquifa was GMP approved by the FDA in 1990, when in fact, it appears that it was not. I do not know to what extent this assumption impacted Dr. Benet's conclusion that Glaxo's GMPs did not lead to any differences in quality, safety or efficacy of Glaxo's API compared to the generic API.

[110] Dr. Chris Baker, who became a director of logistics within Glaxo's pharmaceutical arm around 1990 and 1991, also seems to have equated 'approvable' with 'approved'. In response to questioning, he said that he was aware that Uquifa had been approved by the FDA, but that the deficiencies listed in the FDA Form 483s showed that they were still having problems as late as 1995.

[111] It appears that the non-active ingredients in a dosage form (pill, tablet. . .) may not have been manufactured according to GMP. The appellant's science nominee, Dr. Winterborn, said in examination in chief:

> Glaxo had other requirements in addition to simply testing a sample to a specification. One of those main requirements was that all actives [meaning active pharmaceutical ingredients or APIs] had to be made in accordance with good manufacturing practices.

I infer from this that Glaxo did not require its non-active ingredients to be manufactured in accordance with GMPs.[34]

[112] Furthermore, the respondent's expert, Mr. Ghani, said:

> …recently, even there has been some discussion of having GMP for the excipients [the 'glue' that holds the tablet together], which means non-active pharmaceuticals, because they think that [the] majority of your tablets or capsules, the amount of the excipient is higher. You have a 25-milligram tablet, you have a 25-milligram active drug, but you may add [to] it about more than a gram of non-active [ingredients] into that one. There are organizations, right now, that have developed the GMP quality standards for excipients, but I am sure that [over the] next few years this will become a topic for regulatory bodies to address…

[113] I accept Mr. Ghani's testimony that GMP standards for excipients are a relatively recent phenomenon. As such, it is perhaps not surprising that the appellant did not have GMPs for the excipients; nevertheless, it is open to question why the appellant would go to such lengths to avoid contaminants entering the final product via non-GMP APIs when they were willing to accept the risk of contaminants entering the final product via non-GMP excipients.

[114] With respect to HSEs, the appellant also argued that the ranitidine purchased by the generic companies was not manufactured in dedicated (i.e. single product) facilities, the reason being that multi-product facilities have a greater risk of cross-contamination. What is interesting about this argument it that Glaxo manufactured ranitidine hydrochloride in two facilities, Singapore (a single product facility) and Montrose U.K. (a multi product facility). The appellant never suggested that the API manufactured in Singapore was superior to the API manufactured in Montrose. In fact, Dr. Chris Baker described the Glaxo Group

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[34] Glaxo did not manufacture its own excipients. The Glaxo Group product standard signed on September 10, 1990 lists Avicel PH102 as the only excipient material approved for use in solvent film coated 150mg ranitidine hydrochloride tablets. Avicel is a registered trademark of FMC Corporation, an arm’s length diversified chemical company.

Primary Production Policies and Procedures as internal standards intended to ensure that the safety and security of Glaxo's processes and products were consistently maintained around the world. Consistency, he said, "implies how you manufacture and, therefore, if you manufacture, you have to manufacture in the same way, in the same process, in the same locations around the world. . . . Because allowing variations from market to market means the patient could, in consequence, get a different quality of product." Therefore, as far as the appellant is concerned, an API that comes out of a Glaxo multi-product facility is no different from an API manufactured in a dedicated facility; Glaxo standards are the same. There was no evidence to support the appellant's claim that a multi-product facility of a generic supplier, by its very nature, is inferior to a dedicated facility.

[115] Mr. Tomas Barrera was qualified to give evidence on behalf of the appellant on whether Uquifa met Spanish environmental regulatory standards with respect to waste water discharges, hazardous waste and air emissions in the years in question. He was also qualified to give opinion evidence as to whether Uquifa met Glaxo's waste water discharge standards in the same period, but he was not qualified to speak to marketing issues.

[116] I place little, if any, reliance on Mr. Barrera's evidence because:

(a) he used information from Spanish regulatory authorities to assess Uquifa but relied on information provided by Glaxo to assess the Singapore site. (The environmental record of Glaxo Spain is wholly irrelevant because APIs were not produced there.);

(b) he admitted that Uquifa and the Singapore plant both exceeded waste water limits with the permission of their respective regulatory authorities; and,

(c) he admitted that he did not know whether Uquifa's 1988 to 1990 exemption with respect to waste water limits had been extended.

[117] Any difference between Uquifa's and Singapore's environmental compliance is not significant for the purpose of these appeals. Dr. Chris Baker said "the normal policy in Glaxo was to hold quite significant stocks of API, because the value of carrying the stock is relatively small [compared] to the impact of not being able to supply the market." This would have mitigated any security of supply concerns the appellant might have had about buying APIs from Uquifa, especially since there were a number of potential suppliers available. And since Apotex and

Novopharm also purchased product from Uquifa, none of them would have been in a position to secure a competitive advantage if environmental problems had surfaced at Uquifa.

[118] Appellant's counsel argued that Glaxo's adherence to GMPs meant that its ranitidine was not comparable to that used by the generic companies. I do not accept this argument. Glaxo's GMP and HSE standards do not change the nature of the good. As Mr. Winterborn stated, "Ranitidine is ranitidine is ranitidine". Bernard Sherman, the Chairman of Apotex, insisted that the Glaxo ranitidine molecule and the generic ranitidine molecule are identical. The appellant has admitted that the generic ranatinde was chemically equivalent and bioequivalent as required by HPB. Thus, were it not for the Licence Agreement and Glaxo World's self-imposed standards, the appellant could have purchased ranitidine from the generic suppliers, packaged it as Zantac and sold it for the same price it was selling the Zantac which contained Glaxo-manufactured ranitidine. However, I do accept that GMPs may confer a certain degree of comfort that the good has minimal impurities and is manufactured in a responsible manner. Granted, this has some value but it does not affect its comparability with the ranitidine used by the generic companies.

COMPARABLE UNCONTROLLED PRICE METHOD ("CUP")

[119] The 1979 and 1995 OECD Commentaries apply the following criteria in analyzing the CUP method: economic comparability, comparability of goods, comparability of point in the chain where goods are sold, comparability of functions of the enterprises, comparability of contractual terms and comparability of business strategies[35]. I shall review each.

I. Economic Comparability

[120] The OECD Commentary explains that geographically different markets differ so that it is rarely possible to directly determine an arm's length price in one country on the basis of market prices in another country. Geographically different markets therefore can be satisfactorily compared only if the economic conditions are the same or differences in conditions can be easily eliminated.[36] The 1995 Commentary elaborates on this point by noting several other circumstances that

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35 This strategy has already been addressed at paras. 79 to 92 of these reasons and are not repeated here.

36 OECD Commentary, para. 49.

may be relevant to determining market comparability. These include, *inter alia*, the size of the markets, the extent of competition in the markets and the relative competitive positions of the buyers and sellers, the availability of substitute goods and services, and the nature and extent of government regulation of the market.[37]

[121] There is no question that the generics and the appellant were operating in the same geographic market. They both sold their ranitidine products throughout Canada during the period in appeal. Similarly, both the generics and the appellant were operating in the same market, taking into account the additional circumstances set out in the 1995 Commentary. All three companies were engaged in the sale of prescription pharmaceutical products in Canada. The three companies were comparable in size, were subject to the same government regulations and were competing with each other and other ulcer medications for market share.

[122] In his report Dr. Ballentine concluded that there were at least two markets for ranitidine in Canada: the branded pharmaceutical market and the generic pharmaceutical market. He based this conclusion on the fact that the appellant and the generics sold their finished ranitidine products at different prices. He also noted that the generics had different marketing strategies, economic circumstances and business strategies than the appellant. Throughout the trial, the appellant's witnesses maintained that the appellant did not view the generic companies as their competitors. In its view, its competition was Tagamet and other brand name ulcer medications.

[123] The respondent's expert in pharmaceutical marketing, Dr. Charles King III addressed Dr. Ballentine's argument in his rebuttal expert report. Dr. King concluded that there is only one ranitidine market in Canada. He explained that economists define markets based on the analysis of substitutability and that products do not need to be identical in order to be substitutes. In his testimony Dr. King gave the example of butter and margarine, which are not identical goods but which operate in the same market. He noted that generic ranitidine is a substitute for Zantac and that the market for Zantac was not independent of the market for generic ranitidine. After generic ranitidine was introduced at a lower price than Zantac, many consumers changed from Zantac to a generic product. The fact that Glaxo Canada did not lower the price of Zantac does not mean that the generics were not competitors in the same market.

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[37] 1995 Commentary, para. 1.30

[124] At trial, Dr. Ballentine noted that his "use of the term 'markets' has caused some controversy. It doesn't matter to me what term is used. I will use, in my discussion here; there are two segments to the ranitidine tablet market in Canada." At trial, Dr. King agreed that it was acceptable to refer to two segments that carry different prices, so long as it was understood that both segments were competing in one economic market.

[125] There is no question in my mind that the generic corporations and the appellant were competing in the same economic market. The appellant itself acknowledged that it was losing market share to the generics and it came up with a marketing strategy specifically to fight the generic companies. The fact that the appellant and the generic companies charged different prices for their respective ranitidine products is not relevant to this question.

II. Comparability of goods

[126] In order for goods to be comparable, they should be as nearly as possible physically identical but if the differences are important a useful comparison may still be possible so long as appropriate adjustments can reasonably be made to the uncontrolled price to take account of the differences. The OECD Commentary notes that even in seemingly homogeneous products, such as steel for example, quality differences are an important determinant of price and this has to be taken into account. Nevertheless, in general it is fair to say that the less standardized the goods the less easy it will be to find comparable uncontrolled prices.[38]

[127] The appellant has argued that the ranitidine it purchased from Adechsa was not comparable to the ranitidine purchased by the generics because the ranitidine purchased by the appellant was manufactured under Glaxo World's standards of GMP, granulated to Glaxo World standards, and produced in accordance with Glaxo World's HSE standards, while the ranitidine purchased by the generics was not. I have previously concluded that Glaxo World's GMP and HSE standards do not change the nature of the ranitidine. If there is a difference, it is in only in possible reduction of contaminants; there is no difference in substance.

III. Comparability of point in the chain where goods are sold

[128] For prices to be readily comparable it is necessary to compare goods sold at the same point in the chain from producer to consumer or to be able to quantify

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38 OECD Commentary, para. 58.

easily the different points in the chain. The appellant and the generic companies both purchased ranitidine at the wholesale level. The parties agreed that this factor is comparable.

IV. Functional Analysis

[129] The 1995 Commentary states that comparison of the functions taken on by the parties is necessary as it seeks to identify and compare the economically significant activities and responsibilities undertaken by the independent and associate enterprises.[39] Functions identified include design, manufacture, advertising, marketing, and distribution, among others. It is also necessary to consider the risks assumed by the respective parties. Adjustments should be made for any material differences.

[130] The appellant and the generic companies performed similar functions, namely secondary manufacture, sales and distribution, and research and development. All three companies had regulatory affairs divisions whose purpose was to obtain approval for their respective drugs from the HPB. All three companies have, as the ultimate purchasers of their drugs, Canadian consumers. More specifically, with respect to ranitidine, the appellant and the generic companies all performed very similar functions in terms of purchasing bulk ranitidine from primary manufacturers, conducting secondary manufacturing in Canada and undertaking marketing activities and distribution. That the generic companies had a different strategy when it came to marketing their products does not mean that they had different functions than the appellant.

V. Comparability of contractual terms

[131] The contracts between the generic companies and their suppliers were not put into evidence. Dr. Sherman testified that Apotex's contract with its suppliers was for ranitidine only and did not include any assistance with marketing or secondary manufacturing, nor did it include exclusivity or the right to purchase future drugs. There is no evidence that the appellant's Supply Agreement with Adechsa was any different from the generic companies' agreements with their suppliers; the contract was for the simple purchase and sale of ranitidine.

VI. Are the European licensees comparators using the CUP method?

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[39] 1995 Commentary, para. 1.20.

[132] The appellant relies on the testimony and expert report of Dr. Ballentine to support its argument that the prices paid by Glaxo's European licensees are appropriate comparators. The appellant submits that the European licensees were similar to Glaxo Canada in that they were selling ranitidine products in the local markets under license from the Glaxo World on the basis of the price premium to Tagamet. The licensees were subject to the same types of restrictions as Glaxo Canada, including restrictions as to the use of the trademark owned or controlled by the Glaxo Group and the requirement to buy ranitidine from a Glaxo approved source.

[133] The respondent disagrees with the appellant's submissions and argues that the European licensees are not appropriate comparators for six reasons. First, Glaxo World's trading arrangements were set up specifically because it was not possible to compare prices between markets. Second, it is not possible to make adjustments to compensate for the differences between the different markets. Third, the transactions with the foreign licensees differ from the transactions between Glaxo Canada and Adechsa in material respects that cannot be quantified (intangibles, different functions). Fourth, the purchase prices of the licensees were arrived at as a result of a negotiation for gross profit margin and not on price. Fifth, Glaxo Canada has not established the transfer price to the European licensees. Last, Glaxo Canada ignores other potential comparators for no valid reasons.

[134] I do not intend to review each of the respondent's submissions. Suffice to say that I agree with the respondent that the European licensees are not good comparators. The European markets and the European transactions differed significantly from the Canadian market and the Canadian transactions and it is not possible to compensate for those differences. The evidence was that in marketing and selling a product one takes into account that each country is different and even parts of the same country may differ. I also reject the appellant's argument because it has not satisfactorily established the transfer price to the European licensees and has ignored other potential comparators which had lower transfer prices.

VII. Economic circumstance not comparable

[135] The OECD Commentary cautions against using comparators in different jurisdictions:

> . . . The progressive liberalization of international trade which has taken place during the last decades has certainly facilitated access to new markets, but it has not led, even in the countries where this liberalization is the most extensive, to the

> constitution of one single market where transactions would be made always and everywhere under the same conditions. **Only in very few cases is it possible to determine directly an arm's length price in one country on the basis of market prices in another country. Geographically different markets therefore can be satisfactorily compared only if the economic conditions are the same or differences in conditions can be easily eliminated.** The variety of economic and social structures, of geographical situations and of consumers' habits means that supply and demand of the same product may vary considerably from one country to another. In practice, market prices do vary from one country to another or even within one country and in addition different country policies in many spheres (for example, value of currency, taxes, competition policy, price or exchange control, size and efficiency of market and degree of concentration) are likely to influence price levels. **On the other hand, an enterprise enjoying a monopoly or other dominant position in the market can, and often will charge uniform prices to all its unrelated customers or to all of them in particular areas, or uniform prices modified only by identifiable market specific factors such as import duties**.[40]
>
> [Emphasis added.]

[136] During the years in appeal, there were significant differences between the Canadian markets and the European markets as set out in paragraph 55 of these reasons. Dr. Ballentine attempted to partially adjust for the selling price differentials by making certain changes to the transfer prices of the licensees. He stated that the purpose of the adjustments was:

> [to incorporate] the effects of compulsory licensing in Canada, maybe reference pricing in France, whatever pricing mechanism was followed in Spain. In my view, it doesn't matter what legislative, regulatory or administrative process is used to influence tablet prices. Those factors may have a material effect on tablet prices . . . that is what [Table 7] shows. I incorporate the various differences that have a material impact on tablet prices in their impact on ranitidine by making that adjustment.

[137] Dr. Mintz stated that it was very difficult to make adjustments and generally not possible to take into account the differences in markets; also, he did not understand the logic behind Dr. Ballentine's adjustments. Dr. Ballentine did not adjust for the monopoly situations in Europe as opposed to the competition amongst vendors to Canada or the price competition amongst the Canadian ranitidine sellers.

VIII. Contractual terms not comparable

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[40] OECD Commentary, para. 49.

[138] The transactions between Glaxo Canada and Adechsa were for a kilogram of ranitidine with no intangibles included in the purchase price. The transactions with the European licensees between 1990 and 1993 generally included the ranitidine and a variety of intangibles for a single consideration. This makes the Glaxo Canada transaction fundamentally different from the transactions involving the European licensees and makes comparisons between the two inappropriate. Transfer pricing policies differed between Glaxo Canada and European distributors as well. Special incentives like promotional goods were applied to European distributors, unlike Glaxo Canada.

[139] Dr. Ballentine attempted to adjust for the differences in the contracts by re-characterizing the issue to be one of what Glaxo Canada was required to pay to sell Zantac in Canada. In so doing, he bundled the royalty payment that the appellant paid to Glaxo Group with the transfer price it paid to Adechsa; this permitted him to attempt to compare the two Glaxo Canada transactions undertaken by the European licensees. Again, the issue in these appeals is not what is a reasonable price for Glaxo Canada to pay to sell Zantac in Canada; it is what is a reasonable price for Glaxo Canada to have paid for a kilogram of ranitidine. Dr. Ballentine's CUP analysis does not address the latter issue.

IX. Other differences: functional analysis

[140] Furthermore, if one accepts Dr. Ballentine's characterization of the issue as being broader than simply identifying a reasonable transfer price for a kilogram of ranitidine, then one should consider all the functions that Glaxo Canada has to undertake on behalf of its parent company – including research and development, registration of materials with the local health authorities, secondary manufacturing for arm's length parties (Kenral), financing activities and assistance with marketing strategies – and look for comparables with similar functions. As Dr. Mintz indicated, Dr. Ballentine was selective in choosing what to bundle and what to ignore. None of the European licensees undertook any of the foregoing activities, making them inappropriate comparators. Certain European licensees, including France, Portugal and Spain, had much less risk than Glaxo Canada. The licensees in those countries were guaranteed a gross profit margin of approximately 60 percent. Glaxo Canada had no similar profit guarantee. This is also something that would require adjustment; if possible.

[141] A better example of a CUP for Glaxo ranitidine is the sale by Adechsa to Biotech Pharma in India. Biotech Pharma was a third party that acquired only ranitidine for onward sale to a Glaxo-related company. There were no intangibles

associated with the ranitidine, making it a near perfect comparator to transactions with the appellant. The sale price was $225 (U.S.) per kilogram in 1986. Another example not considered by Dr. Ballentine was the sale to Glaxo Egypt, then owned by a third party, for $630 (U.S.) in 1992. The price at which Glaxo Group sold ranitidine to Glaxo Egypt was stated to be due to the need to compete with generic ranitidine. The circumstances of these countries were more similar to the circumstances of Glaxo Canada.

[142] Even if one accepts the appellant's submission that the European co-marketers are the most appropriate comparators, the appellant has not established to my satisfaction the transfer price they paid. As stated earlier in these reasons, the appellant did not disclose various promotional allowances paid by Glaxo World to the third party licensees. These payments effectively reduced the transfer price. Without complete records from the licensees, it is not possible to accurately estimate the net transfer price.

X. Is the Kenral transaction a comparator using the CUP method?

[143] Dr. Ballentine agreed that the Kenral transaction was not a good comparator, albeit for different reasons than the respondent. Kenral was competing in the same geographic market as the appellant and, like the appellant, used Glaxo approved ranitidine in its tablets. However, the transactions differed significantly taking into account functions, risk and contractual terms. Kenral purchased completed packages of ranitidine tablets from Glaxo Canada. Kenral received a guaranteed 25 percent gross profit and consequently bore little risk, unlike the appellant who bore all the costs and risks for product approval by HPB, secondary manufacturing, post launch research and development and marketing. Finally, Kenral received intangibles and other benefits in consideration for the purchase price: the ability to have HPB access the Glaxo Canada registration materials rather than prepare its own, secondary manufacturing, marketing assistance, including free goods, and Glaxo Canada paid the royalty of six percent to Glaxo Group in respect of ranitidine sales to Kenral. There is no evidence to establish what Kenral would have paid only for a kilogram of ranitidine without all the intangibles and other benefits.

[144] The appellant argued that if there was no comparator under the CUP method, the resale price method using the European licensees as comparators should apply. The appellant relied on the transactional net margin method ("TNMM") and the respondent relied on the cost plus method to confirm the reasonableness of their respective methods. However, all agree that the cost-plus

and resale price methods are secondary methods to be used when the CUP method is not appropriate and that the TNMM is another alternative when cost plus and RPM are not appropriate.

XI. The Resale Price Method

[145] The RPM compares gross margins, which is computed as net sales less cost of goods sold divided by net sales. RPM is most reliable when it measures the return of only one function, is isolated to a particular product and there is a high degree of similarity in functions and risks between the companies being compared. The OECD Commentary states that RPM is particularly useful where it is applied to marketing functions. Like the CUP method, it is difficult to compare transactions in different geographic locations using RPM. As Dr. Mintz explained, this is because expenses below the gross profit margin line will vary considerably depending on geography. Dr. Mintz gave the examples of taxes and marketing expenses. A licensee in a country with low marketing expenses or low taxes may be willing to accept a lower gross profit margin than a licensee in a high marketing expense or high tax jurisdictions. Thus, what may be a reasonable gross profit margin in one country will not be a reasonable gross profit margin in another.

[146] Dr. Ballentine compared the gross margins earned by the European licensees with the resale margins earned by Glaxo Canada on the sales of their respective ranitidine tablets. Dr. Ballentine calculated cost of goods sold in two steps. First he calculated the transfer price for ranitidine including the royalty, if any. Second, he calculated the secondary manufacturing costs. In calculating the cost of goods sold to the European licensees, Dr. Ballentine used the secondary manufacturing cost to Glaxo Canada. He acknowledged that there may be some differences in local labour costs and in the amount of overhead, but he concluded that the differences would be relatively small. His conclusions showed that in the period from 1990 to 1993, gross margins earned by the European distributors were between 45.8 percent and 82.4 percent, with nine of the 13 licensees having gross margins between 61.5 percent and 64.4 percent and the median gross margin earned was 62.0 percent, while Glaxo Canada's gross margin for the period was 61.7 percent. He concluded that the prices paid by Glaxo Canada for the purchase of ranitidine were not in excess of arm's length prices.

[147] The respondent questioned Dr. Ballentine's analysis. First, the respondent argued that Dr. Ballentine did not use accurate financial data. Instead of using financial data from the licensees themselves, which apparently were not provided to him, Dr. Ballentine relied on IMS data. Second, the respondent submits that Dr.

Ballentine should not have estimated secondary manufacturing costs based on Glaxo Canada's standard costs.[41] Dr. Ballentine also relied on the transfer price figures provided to him by Glaxo Canada which were changed several times and did not reflect a variety of other incentives. The appellant has not established the costs to the licensees needed to calculate gross margins.

[148] Even if one accepts the gross profit margins Dr. Ballentine estimated, there are a number of reasons that the results are not helpful. Dr. Ballentine's figures establish that the gross profit margins varied between 45.8 percent and 82.4 percent, with the two Portuguese licensees having the largest gross profit and the Austrian licensee at the bottom. The four Spanish licensees all had average gross profits of 61.5 to 62.0 percent. The two Finnish licensees had average gross profits of 61.8 to 62.0 percent. According to Dr. Mintz, this wide range undermines the reliability of the analysis. From the data, Dr. Mintz concluded that local conditions greatly influenced the gross profit margins that the licensees were earning; it was no accident that the gross profit margins earned by licensees located in the same country were similar and the gross profits earned by the licensees located in different countries are different. He concluded that there are other factors that influence the pricing of ranitidine that need to be taken into account, such as the kind of pressures that would be faced in a particular market, or the kind of functions that would be undertaken by the third-party distributor, or even the effort that is taken at advertising and marketing in each of the countries.

[149] Dr. Ballentine also excluded the results from co-marketers in Japan and Korea, which both showed higher margins than the median 62 percent, on the basis that they were related parties. However, Glaxo Canada had admitted that all three entities were owned 50 percent by third parties and that was the same criteria that Dr. Ballentine used to include the data from Cascan, a German company. He provided no reason for excluding the Glaxo Korea gross profit margin of 75

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[41] The actual secondary manufacturing costs are known for Fournier, the French co-marketer, and the charge to Glaxo Austria for undertaking secondary manufacture for Gebro, the Austrian co-marketer, is also known. While the Fournier cost is close to the estimate, the Gebro cost is not close to the estimate – it is nearly twice as high. In Germany and Italy, where secondary manufacture was undertaken by Glaxo subsidiaries, Dr. Ballentine originally used estimates, although he later corrected the numbers for the co-marketer in Germany. The average price charged to Fournier for secondary manufacturing was $184.14 per kilogram, as opposed to the average used by Dr. Ballentine of $233.80. Gebro also charged Glaxo Austria $513.39 and $586.81 (depending on package size) for secondary manufacturing, a much higher price than the average $233.80 used by Dr. Ballentine.

percent, although that too was an admitted fact. He also dismissed the gross profit margins earned by the two Portuguese licensees of 76.8 percent and 80.0 percent as anomalies. Dr. Mintz explained that when one is only dealing with 13 comparators, two data points cannot be ignored. Two of thirteen is statistically relevant. When the Glaxo Korea data is factored in, this makes three of fourteen. Therefore, Dr. Mintz disagreed with Dr. Ballentine characterizing the Portuguese licensees as anomalies and said he would want to look at what was causing the difference. Two of the known differences between Portugal and the other European countries are that non-Glaxo ranitidine was available for sale in Portugal at one twelfth of the Glaxo price. Also, while Glaxo Portugal and the two Glaxo licensees' ranitidine products all sold at about a single price, generic ranitidine in Portugal was selling at a discount. The circumstances in Canada were similar, which might suggest that the appellant should have a similar gross profit to that of the Portuguese licensees.

[150] For many of the same reasons that the European licensees were not good comparators for the CUP analysis, they are also not good comparators for the RPM. Glaxo Canada performed many more functions and assumed more obligations than the European licensees. These factors should have justified a lower transfer price or a higher gross profit margin to Glaxo Canada. With respect to the differences in functions, the fact that the European licensees were targeted to receive 60 percent gross profit margin for the marketing function may suggest that this is what the marketing function alone was worth. If this is so, then Glaxo Canada, performing many more functions, should have received a much higher gross profit margin than 60 percent, one that would compensate it for all the additional activities it undertook and one that recognized that Glaxo Canada incurred more risk than the European licensees because it lacked a guarantee.

[151] The appellant submits that *Ford Motor Co. of Canada v. Ontario Municipal Employees Retirement Board*[42] is authority for the reasonableness of RPM. However, respondent's counsel pointed out that she was not disputing that RPM was a valid method; her argument was that RPM is a secondary method which is appropriate to use when the CUP method is not suitable. The circumstances in *Ford* were such that there were no comparable transactions under the CUP method. Moreover, *Ford* can be further distinguished on the basis that the dealers in *Ford* were buying and selling the finished car. Their only functions were marketing and distribution. This can be contrasted with the appellant who performed more functions, again suggesting that RPM is not an appropriate method.

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[42] 41 B.L.R. (3d) 74, 2004 DTC 6224 (Ont. S.C.J.) [*Ford*] rev'd in part on other grounds 2006, 70 O.R. (3d) 81.

XII. Transactional Net Margin Method

[152] Dr. Ballentine used the TNMM as a reasonableness check on the price the appellant paid for ranitidine. This method compares net profits between companies. To apply this method, Dr. Ballentine compared the appellant's rate of return after research and development costs with those of independent companies involved in preparing and selling pharmaceutical products. Dr. Ballentine eliminated any companies that (1) that did not have sales in all four years from 1990 – 1993, (2) had less than $50 (U.S.) million in annual sales and (3), had an average research and development to sales ratio greater than three percent, because these latter companies might own significant technological intangible assets.

[153] The appellant spent more than three percent of sales on research and development during the years in question[43] but Dr. Ballentine thought it was appropriate to use the three percent comparison because the appellant had spent substantially less than that for many years prior to the years in question:

> Since the process of taking a drug from discovery and development through marketing approval can take 10 to 12 years, if not longer, current spending on pharmaceutical research and development, even if it is ultimately successful, may not be expected to result in a commercialized product until perhaps 10 or 12 years later. Even though Glaxo Canada's research and development spending in 1990 through 1993 was greater than 3 percent, that spending could not have resulted in sales of new drugs during 1990 - 1993. As a result, it is appropriate to compare Glaxo Canada to firms that spent less than 3 percent.

[154] Thus, Dr. Ballentine concluded that the appellant's profitability was higher than the profitability of the independent companies.

[155] In his rebuttal expert report, Dr. Mintz declared that:

> [I]t is far from clear that these are suitable companies for comparison without taking into account research and development costs, manufacturing, marketing practices, investment policies and other attributes that would affect margins. I cannot reach a conclusion that the comparisons made are valid at all.

[156] I cannot accept Dr. Ballentine's analysis on this issue. His reasoning for excluding the companies with higher research and development to sales ratios is

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[43] From Figure 6 in Dr. Balletine's report, it appears that the appellant had a research and development to sales ratio of close to 10 percent.

not reasonable. There is insufficient evidence of other functions undertaken by the comparators.

XIII. Cost plus method

[157] The respondent relies on the cost plus to support the reasonableness of its CUP analysis. In applying the cost-plus method, Dr. Mintz looked at the cost of manufacturing ranitidine and added to it a suitable profit margin. He ignored Adechsa and considered only the Singapore manufacturer because Adechsa actually incurred losses on its sales of ranitidine to the appellant once transfer prices and royalties paid to Glaxo Group are considered.

[158] During the years in appeal, the Singapore manufacturer had cost-plus margins ranging between 766 and 1059 percent. This can be contrasted with Glaxochem UK (Montrose) which had cost-plus margins between four and 16 percent during the same period and CKD Korea, which manufactured ranitidine due to an import ban in Korea, which had a mark-up of 25 percent by agreement with Glaxo Group Dr. Mintz then calculated the Singapore manufacturer's cost-plus margin using the transfer prices substituted by the Minister and found them to range from 62 to 159 percent, which is still much larger than the other manufacturers' margins.

[159] Dr. Mintz concluded that a reasonable mark-up would be 25 percent for the Singapore manufacturer and four percent for Adechsa (as agreed upon with the Swiss government). Using the cost-plus method to calculate the transfer price, Dr. Mintz found that the total reassessments of Glaxo Canada's profits would be 93 percent of the actual reassessments. He concluded that after the CUP adjustments for research and development, granulation costs and other factors, the total reassessments would be virtually identical to the CRA reassessments.

[160] The appellant did not call a witness to rebut Dr. Mintz's conclusions regarding the cost-plus method and his conclusions went largely unchallenged on cross-examination. At no point did the appellant challenge Dr. Mintz's figures, calculations or conclusions on this issue. The appellant's thrust was that Dr. Mintz was not experienced in the pharmaceutical industry. The appellant did establish that Glaxo Group had not used the cost-plus method to set the price of ranitidine. As I have stated several times, the method that Glaxo used to set its prices is not relevant to the issue of whether the price is reasonable.

Part I Assessments: Conclusion

[161] CUP is the preferred method and the generic companies in Canada are an appropriate comparator using the CUP method. The appellant acquired granulated ranitidine from Adechsa at an amount in excess of the fair market value of ranitidine, and pursuant to subsection 69(2) of the *Act* the appellant is deemed to acquire it at a reasonable amount. The price that would have been reasonable in the circumstances for Glaxo Canada to pay Adechsa for a kilogram of ranitidine is the highest price the generic companies paid for a kilogram of ranitidine. However, to this amount I would add $25 per kilogram as this was the approximate cost to Singapore for granulation. The ranitidine purchased by the generic companies was not granulated. The GMP performed by a Singapore may have increased the value of its ranitidine but only to the extent that, as stated earlier in these reasons, it gave some degree of comfort to the appellant that the product would probably have less impurities and contaminants than that of its generic competition. No submissions were made as to what this extra consideration should be. There is no evidence before me to consider what increase I might add to the generic price per kilogram of ranitidine on account of GMP. It would appear to be modest in any event. The evidence does not suggest any addition to the price of the ranitidine due to any HSE by Singapore. The appellant, in computing its income for a particular year, may not deduct the excess amount it paid to Adechsa. For example, if the appellant paid Adechsa $1,300 per kilogram for ranitidine and the highest price the generic companies paid for ranitidine was $380 per kilogram, the appellant would be permitted to deduct the amount of $380 per kilogram plus $25 per kilogram for granulation, a total of $405. The excess amount, $895, is not deductible in computing the appellant's income.

PART XIII ASSESSMENTS

[162] The excess amount, in the example, $895, has been paid by or transferred from Glaxo Canada to Adechsa. The Minister also has assessed the appellant for tax under Part XIII of the *Act* on the basis that its parent corporation, Glaxo Group in the United Kingdom, directed or concurred with the payment or transfer of the excess amount to Adechsa as a benefit that Glaxo Group desired to confer on Adechsa. According to subsection 56(2) of the *Act*:

| | |
|---|---|
| A payment or transfer of property made pursuant to the direction of, or with the concurrence of, a taxpayer to some other person for the benefit of the taxpayer or as a benefit that the taxpayer desired to have | Tout paiement ou transfert de biens fait, suivant les instructions ou avec l'accord d'un contribuable, à toute autre personne au profit du contribuable ou à titre d'avantage que le contribuable désirait voir accorder |

| | |
|---|---|
| conferred on the other person (other than by an assignment of any portion of a retirement pension pursuant to section 65.1 of the *Canada Pension Plan* or a comparable provision of a provincial pension plan as defined in section 3 of that Act or of a prescribed provincial pension plan) shall be included in computing the taxpayer's income to the extent that it would be if the payment or transfer had been made to the taxpayer. | à l'autre personne – sauf la cession d'une partie d'une pension de retraite conformément à l'article 65.1 du *Régime de pensions du Canada* ou à une disposition comparable d'un régime provincial de pensions au sens de l'article 3 de cette loi ou d'un régime provincial de pensions visé par règlement – doit être inclus dans le calcul du revenu du contribuable dans la mesure où il le serait si ce paiement ou transfert avait été fait au contribuable. |

[163] In her Reply to the Notice of Appeal the respondent stated that in assessing, the Minister assumed that Glaxo Group directed, or concurred with, the payment or transfer of the excess amount for its benefit. In her Amended Reply to the Amended Notice of Appeal, the respondent alleged that the transfer was for the benefit of Adechsa and it is on this basis that these appeals were heard. As a result of the Crown altering the basis of the assessments, the Crown had the onus of proof that the intended beneficiary of the excess payments was Adechsa. This onus was satisfied.

[164] For the purposes of subsection 56(2) of the *Act*, the respondent submits that Glaxo Group is the taxpayer, Adechsa was the person upon whom the benefit was conferred and the appellant was the source of the benefit. In *McClurg v. M.N.R*, Dickson C.J explained that the purpose of subsection 56(2) was to "ensure that payments which otherwise would have been received by the taxpayer are not diverted to a third party as an anti-avoidance technique."[44] An amount will be included in the income of a taxpayer who has not received the income directly when the following four conditions are met:

1. There is a payment or transfer of property to a person other than the taxpayer;

2. The payment or transfer is pursuant to the direction of or with the concurrence of the taxpayer;

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[44] [1990] 3 S.C.R. 1020 at 1052-1053 [*McClurg*].

3. The payment or transfer must be for the taxpayer's own benefit or for the benefit of some other person on whom the taxpayer desired to have the benefit conferred; and

4. The payment or transfer would have been included in computing the taxpayer's income if it had received it directly.[45]

[165] Conditions one and two are met. Glaxo Canada overpaid Adechsa for the purchase of the ranitidine and Glaxo Group concurred with the transfer price. With respect to condition three, the appellant argued that there was no intent to confer a benefit on Adechsa. Alternatively, the appellant argued that there was no benefit because a benefit cannot exceed the net profit earned by Adechsa in respect of the sales. Appellant's counsel explained that because Adechsa took a loss on the sale of ranitidine to the appellant, there can be no benefit. He also stated that condition four is not satisfied because Glaxo Group had no entitlement to any of the payments made to Adechsa.

[166] Counsel for the appellant stressed that one of the essential conditions for the application of subsection 56(2) is that the taxpayer must have desired to confer a benefit on the other party. Counsel argued that this condition, which has been recognized in numerous judgments,[46] was not met in the circumstances of this case. I cannot agree with counsel's assessment of the evidence in this regard. By 1990 Glaxo Group knew that the appellant was purchasing ranitidine for about five times more than what other companies in Canada were paying. Glaxo Group did not have a mistaken belief that the price the appellant was paying for ranitidine was reasonable. As set out in paragraph 13 of these reasons, Glaxo Group's taxation strategy was to minimize tax by shifting its profits to Singapore via Switzerland. Part of the strategy included using Adechsa as a distributor and funneling the excess amounts through it. The corporate structure of Glaxo World was, in part, designed to minimize income in high tax jurisdictions by diverting income to low tax jurisdiction.

[167] I also reject the appellant's alternative argument. Appellant's counsel has mistakenly equated benefit with profit; they are not the same. Had the appellant purchased ranitidine from Adechsa at the same prices the generic companies were paying, Adechsa would have taken a much larger loss. In short, Adechsa got

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45 *Ibid*, p. 1074.

46 Counsel for the appellant referred in particular to the decisions in *Smith v. The Queen*, 93 DTC 5351 p. 5356 (FCA); *Jones v. The Queen*, 96 DTC 6015 (FCA).

something for nothing. This is still a benefit even if it involves a smaller loss and not a profit.

[168] Finally, appellant's counsel argued that condition four was not met because Glaxo Group had no entitlement to any of the payments made to Adechsa. Appellant's counsel relies on *Smith v. The Queen*,[47] wherein Mahoney J.A. cited with approval from *Winter et al. v. The Queen*:[48]

> . . . [*Winter*] has added another precondition to the application of subsection 56(2), which seems to me to be relevant in the circumstances.
>
> It was held in *Winter*, at p. 6684,
>
> > that the validity of an assessment under subsection 56(2) of the Act when the taxpayer had himself no entitlement to the payment made or the property transferred is subject to an implied condition, namely that the payee not be subject to tax on the benefit he received.

Mahoney J.A. concluded that "Being 'subject to tax on the benefit received' means that the value of the benefit is required to be included in the calculation of the recipient's taxable income."[49]

[169] *Neuman v. Canada*,[50] a decision of the Supreme Court of Canada also considered subsection 56(2) of the *Act.* The excerpt cited from *Winter* in *Smith* is *obiter* based on the Federal Court of Appeal decision in *McClurg v. Canada (F.C.A.)*,[51] which was affirmed by the Supreme Court of Canada after *Winter* was decided. *McClurg* stands for the proposition that subsection 56(2) generally does not apply to dividend income because the reassessed taxpayer would not have received that money had it not been paid to the shareholder. *Winter* is summarized at paragraphs 51-53 of *Neuman*:

> In *Winter*, the majority shareholder in an investment company caused the corporation to sell some of its shares to his son-in-law, who was also a shareholder in the corporation, for a price of $100 per share. The Minister calculated the fair market value of the shares at approximately $1,000 per share and reassessed the

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47 *Ibid.*
48 90 DTC 6681 p. 6684 (FCA) [*Neuman*].
49 *Smith*, p. 5356.
50 [1998] 1 S.C.R. 770.
51 [1988] 2 F.C. 356 (F.C.A.), aff'd [1990] 3 S.C.R. 1020.

> majority shareholder under s. 56(2) by adding as income the difference between what the son-in-law paid for the shares and their market value.
>
> Marceau J.A., writing for the court, held that the fact that the taxpayer had no direct entitlement to the shares did not preclude attribution since there was no indication that s. 56(2) was intended to be so confined. Marceau J.A. concluded (at p. 593) that:
>
> > when the doctrine of "constructive receipt" is not clearly involved, because the taxpayer had no entitlement to the payment being made or the property being transferred, it is fair to infer that subsection 56(2) may receive application only if the benefit conferred is not directly taxable in the hands of the transferee.
>
> Marceau J.A. distinguished the Federal Court of Appeal's ruling in *McClurg* where Urie J. held that s. 56(2) does not apply to dividend income, which holding was affirmed by this Court, as follows (at pp. 591-92):
>
> > the *McClurg* decision was concerned with a declaration of dividend in accordance (in the views of the majority) with the powers conferred by the share structure of the corporation, **and I do not see it as having authority beyond the particular type of situation with which it was dealing.**
>
> I agree with Marceau J.A.: Winter concerned the conferral of a benefit which was not in the form of dividend income. The application of s. 56(2) to non-dividend income was not before this Court in *McClurg* and it is not before this Court in the present case. But the entitlement requirement implicitly read into the fourth precondition of s. 56(2) in *McClurg* clearly applies to dividend income.
>
> [Emphasis added.]

[170] *Neuman* was heard after *Smith* but did not refer to *Smith*. The benefit to Adechsa was not in the form of dividend income; the entitlement requirement does not apply to the appeals at bar.

[171] That the entitlement requirement does not apply to these facts is found in the interplay between subsection 56(2) and paragraph 214(3)(*a*) of the *Act*. The latter provision deems an indirect payment to be a dividend in situations involving a non-resident taxpayer. The *Act* provides a complete scheme for the treatment of the excess amounts transferred to Adechsa and no recourse to the entitlement requirement is necessary.

[172] In transfer pricing cases, the goal of the MNE is to divert profits to a low tax jurisdiction. The amounts will be included in calculating the income of the recipient to whom they were diverted (in this case Adechsa), with the result being a lower rate

of tax and more profits left for distribution to the parent company. The goal of the entitlement requirement, as set out in *Winter*, is to prevent the tax authority from choosing between potential taxpayers. In the case at bar, there is only one potential taxpayer and consequently the entitlement requirement cannot apply. Indeed, in a transfer pricing case the application of the entitlement requirement may allow a multinational enterprise to avoid tax altogether on income earned in a jurisdiction.

[173] Even if the entitlement requirement did apply to the case at bar, it was satisfied based on the facts. Pursuant to subsection 69(2) the reasonable amounts for the appellant to have paid Adechsa for the purchase of ranitidine are the highest amounts paid at the time for ranitidine by the generic companies. The amounts in excess of the reasonable amount(s) ($895 per kilogram in our example) that were transferred to Adechsa were not paid in consideration for ranitidine. Adechsa did not provide any other goods or services to the appellant and as such was not entitled to the excess amounts. The question is whether Glaxo Group was entitled to the excess amounts.

[174] Appellant's counsel did not offer an explanation as to whom he believed was entitled to the excess amounts. He stated it was not Glaxo Group. If not Glaxo Group, then who? It was Glaxo Group who was entitled to the excess amounts. But for the direction of Glaxo Holdings and the concurrence of Glaxo Group in setting the transfer price, the appellant would not have transferred the excess amounts to Adechsa. The excess amounts would have remained in the hands of the appellant and at some point in time all or part would have been distributed to Glaxo Group in the form of dividends. Glaxo World's tax strategy was to divert profits to Singapore before being paid to Glaxo Group as dividends. Ultimately, the amounts were indeed received by Glaxo Group.

[175] Subsection 212(2) of the *Act* imposes a 25 percent withholding tax on dividends paid to non-residents. This amount is reduced to ten percent under Article 10(1)(*a*) of the *Canada-United Kingdom Tax Convention(1978)*. Glaxo Canada was required to withhold the ten percent by virtue of subsection 215(1) and is liable for tax for failing to withhold the amounts under subsection 215(6).

[176] The Part XIII assessments are essentially correct. However, the deemed dividend and, consequently, the withholding tax assessed are to be reduced in recognition of the increase in the value of a kilogram of ranitidine by $25 for granulation.

CONCLUSION

[177] The appeals from the assessments made under the *Income Tax Act* for the 1990, 1991, 1992 and 1993 taxation years and assessments made under Part XIII of the *Act* with respect to the alleged failure of the appellant to withhold tax on dividends deemed to be paid to a shareholder in 1990, 1991, 1991 and 1993 are allowed and the matters are referred back to the Minister of National Revenue for reconsideration and reassessments only to decrease the excess amounts paid by the appellant for ranitidine by $25 per kilogram and to adjust the amounts of withholding tax accordingly.

[178] Costs shall be paid by the appellant; the parties may make representations as to the quantum of costs.

Signed at Ottawa, Canada, this 30th day of May 2008.

"Gerald J. Rip"

Rip J.

APPENDIX I

## APPELLANT'S MOTION: SUBSECTION 100(3)

[1] In the course of the respondent counsel reading, for the record, portions of examinations for discovery ("read-ins") for the record of the appeals, the appellant's counsel made an application under subsection 100(3) of the *Tax Court of Canada Rules (General Procedure)* to include other portions of the relevant examinations. I have compiled a table below summarizing which portions of the relevant examinations the appellant wishes to add ("add-ons") to the "read-ins" that I allow and do not allow.

[2] Subsection 100(3) provides that, "[w]here only part of the evidence given on an examination for discovery is read into or used in evidence, at the request of an adverse party the judge may direct the introduction of any other part of the evidence that qualifies or explains the part first introduced." This subsection is similar to section 289 of the *Federal Courts Rules*, headed "qualifying answers", and permits evidence to be read-in if "the Court considers is so related that it ought not to be omitted".

[3] The purpose of the Federal Court rule is "to ensure that evidence from a transcript of examination for discovery which is read in as evidence at trial is placed in proper context so that it is seen and read fairly, without prejudice to another party that might arise if only a portion of the content relevant at to a fair understanding of the evidence read in is given."[1] Although the wording of the Tax Court rule is not identical to that of the Federal Court rule, the purpose is the same.

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[1] *Canada (Minister of Citizenship and Immigration) v. Odynsky*, [1999] F.C.J. No. 1389 (QL).

[4] Thus, "qualifies or explains" refers to ensuring that the portions read in by the adverse party do not mislead the Court by leaving out a relevant portion of the evidence. In determining whether to allow the evidence, I considered the following:

- continuity of thought or subject-matter;
- the purpose of introducing the evidence in the first instance and whether it can stand on its own; and
- fairness in the sense that the evidence should, so far as possible, represent the complete answer of the witness on the subject-matter of the inquiry so far as the witness has expressed it in the answers he has given on his examination for discovery.

[5] Qualifying or explaining does not mean that any adjacent question will be admitted, nor does it mean that contradictory answers must be admitted. In *Canada v. Fast*,[2] Pelletier J. suggested that:

> "One must bear in mind that the process of reading in questions and answers is one of putting the opposite party's admissions on the record. That party always has the option of taking the stand to explain away or qualify those admissions. But it is not the rule that those qualifications must go as part of the examining party's case."[3]

[6] So, in dealing with requests for inclusions of clarifying or explanatory questions and answers, I generally considered whether the material is truly connected to the respondent's read-ins or whether it amounts to evidence which should have been entered in the appellant's witnesses' testimony.

[7] The proposed add-ons below appear in the order used by the appellant in its Notice of Motion:

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2 2002 FCT 542.

3 *Ibid*. para. 1.

| | Read-ins | | Appellant's add-ons | | | Allow | Reason |
|---|---|---|---|---|---|---|---|
| | Witness | Q's | Witness (if different) | Q's | Page | Y/N | |
| 1. | Fisk 2001-07-11 | 475 ~ 485 | | 474 | 1 | N | The Crown's read-in relates to the CUP method. The Appellant's add-on relates to resale/price method. These are different topics. Not qualifying. |
| 2. | Hasnain 2001-02-14 | 1393 -1394 | Fisk p.104 2001-07-12 | 975 | 2 | N | Add-ons don't explain Hasnain's responses re: analysis done to determine rate of return. |
| 3. | Fisk 2002-04-30 | 1537 | | 1534 ~ 1539 | 5 | Y | There is a connection here as all questions relate to the French market and Fournier. |
| 4. | Hasnain 2001-02-13 | 818-819 | Fisk/ Woloschuk 2005-05-12 | 4886-4897 | | | n/a – not included in Affidavit of Amanda Pollicino |
| 5. | Winterborn 2001-04-20 2002-05-13 2005-05-17 | 12-14 436-438 71-75 | Fisk 2003-10-16 | 1393 | 6 | N | Read-in relates to purpose of testing and the quality of ranitidine base from two Indian companies called Shasun and Cheminor. Add-on relates to whether Glaxo Canada tested its own product for chloroform. Not qualifying. |
| 6. | Winterborn 2001-04-17 | 69-74 | | 75-77 | 8 | N | Does not qualify. |
| 7. | Winterborn 2001-05-10 | 2082-2084 | | 2085 | 10 | Y | Question is directly related to the preceding one. Both deal with the amended supply |

| | Read-ins | | Appellant's add-ons | | | Allow | Reason |
|---|---|---|---|---|---|---|---|
| | Witness | Q's | Witness (if different) | Q's | Page | Y/N | |
| | | | | | | | agreement. Add-on explains that the agreement was not signed. |
| 8. | Winterborn 2002-05-15 | 1571-1575 | | 432-433 | 11 | N | Read-in relates to who are Glaxo approved sources for base. Add-on deals with polices and procedures for obtaining supplies from non-Glaxo sources. |
| 9. | Winterborn 2002-05-16 | 1928-1939 | | 1931-1932 | 12 | N | Read-in relates to whether Uquifa was unsafe/ineffective. Add-on unrelated. Does not qualify. |
| 10. | Winterborn 2002-06-06 | 3843-3846 | | 3874-3875 | | N | Read-in relates to one document; add-ons to another. Does not qualify. |
| 11. | Winterborn 2005-05-17 | 54 ~ 385 | | 87-135 | 15-46 | N | Read-in stands alone. |
| | | | | 258-267 | | Y | Add-on qualifies and explains evidence on following pages relating to particle size and suitability of the Uquifa sample. |
| 12. | Wolsochuk 2002-07-17 Hasnain 2001-03-20 | 1231-1235 p.216-217 | Wolsochuk 2002-07-17 | 1236 | 47 | N | Read-ins stands alone. They relate to Kenral's pricing and promotion and whether Glaxo charged Kenral for sharing information with it. Add-on relates only to who developed an advertising slogan. It does not qualify or explain the read-in. |
| 13. | Hasnain 2001-02-12 | 324-235 | | 326-328 | 49 | Y | Add-on qualifies read-in by clarifying that Glaxo World approved the Canadian pricing |

| | Read-ins | | Appellant's add-ons | | | Allow | Reason |
|---|---|---|---|---|---|---|---|
| | Witness | Q's | Witness (if different) | Q's | Page | Y/N | |
| | | | | | | | strategy. |
| 14. | Hasnain 2001-02-12 - 2001-02-13 | 618-620 | | 717-727 | 50 | N | Read-in asks for key issues facing Glaxo Canada. Add-ons deal specifically with the issue of who were Zantac's main competitors. This is not qualifying or explaining. Read-in stands alone. |
| | | | | 733 | | N | |
| | | 867 | | 870-871 | 52 | N | More elaborating. Read-in answer (867) identifies that Glaxo's market share was dropping, but their strategy was to grow the entire market. Add-on discusses what Glaxo was doing to increase the size of the market. |
| | | 1060 | | 1061 | 54 | N | Read-in stands alone. |
| 15. | Hasnain 2001-02-15 | 1635-1638 | | 1639-1640 | | Y | Read-in identifies issues of line extensions, brand positioning and the end of compulsory licensing. Portion of the add-ons which explain compulsory licensing is allowed because this was partially addressed in the Respondent's questions. |
| | | | | 1641-1655 | 55 | N | Portion of the add-ons elaborating on line extensions is not allowed. Not qualifying or explaining any part of the read-ins. |
| | | | | 1662-1663 | 58 | N | Add-on describes Glaxo's approach to promotion and competition from Tagamet. This does not qualify the read- |

| | Read-ins | | Appellant's add-ons | | | Allow | Reason |
|---|---|---|---|---|---|---|---|
| | Witness | Q's | Witness (if different) | Q's | Page | Y/N | |
| | | | | | | | ins. |
| | | | | 1696- | 60 | N | Add-on discusses whether compulsory licensing was an issue in other counties. This does not qualify the read-in which deals with domestic issues. |
| | | | | 1715 | 62 | Y | Add-on explains why compulsory licensing was as issue. |
| 16. | Hasnain 2001-03-19 | P.43 Lines 15-21 | | p.42-43 Lines 24-25, 1-14 | 64 | N | Read-in deals only with the issue of why price increases were in Canadian dollars. The add-on deals with changes to the whole-sale price. The add-on does not qualify or explain the read-in. |
| 17. | Hasnain 2001-03-20 | P. 236 Lines 8-18 | | P. 236 - 237 Lines 19-25, 1-3 | 65 | N | Read-in establishes that Kenral did not penetrate the market with respect to Ranitidine. Add-on relates to which Kenral products were more successful. Does not qualify or explain. |
| 18. | Hasnain 2001-03-29 | 1231-1234 | | 1220 | 66 | Y | Add-on identifies the document referred to in the read-in. |
| | | 1433 | | 1434 | 67 | N | Read-in relates to problems with Novopharm's ranitidine; add-on, to Apotex's problems. Does not qualify or explain. |
| | | 1466-1468 | | 1465 | 68 | N | Read-in stands alone. |

| | Read-ins | | Appellant's add-ons | | | Allow | Reason |
|---|---|---|---|---|---|---|---|
| | Witness | Q's | Witness (if different) | Q's | Page | Y/N | |
| 19. | Deposition of Paul Girolami Vol 1, July 9, 2002 | 162, 164 | | | 163 | Y | Add-on completes read-in. |
| 20. | Deposition of Paul Girolami Vol 2, July 10, 2002 | 9-10 | | | 8 | Y | Qualifies or explains as to why Sir Paul views the modification of the marketing group as being important. |
| | | 10, 12 | | | 11 | Y | completes Sir Paul's answer |
| 21. | IRS Statement of Girolami | 65 | | | 63-64, | N | Not necessary; read-in stands alone. |
| | | | | | 66 | Y | Adds context to para. 67 by identifying the point being discussed. |
| 22. | Depositon of John Coombe | 17 | | Lines 21-15 | 16 | Y | Qualifies or explains response on Singapore intellectual property. |
| | | 20, 21 | | Lines 1-15 | 22 | Y | Includes follow-up question re: price increases |
| | | 33 | | Lines 21-25 | 32 | Y | Continuation of question |
| 23. | Deposition of Michael S. Stone | 92, 93 | | Line 9<br>Line 16 | 91<br>94 | Y<br>Y | qualifies or explains by including time-frame follow-up/clarifying question |
| 24. | Charles B. Newcomb | 19, 21 | | Para. 20 | | N | Read-stands alone. |
| 25. | Michael S. Stone | 46, 47 | | Paras. 44-45 | | Y | Adds context by identifying agreements being discussed. |

| | Read-ins | | Appellant's add-ons | | | Allow | Reason |
|---|---|---|---|---|---|---|---|
| | Witness | Q's | Witness (if different) | Q's | Page | Y/N | |
| 26. | David J.R. Farrant | 59, 60 | | Paras. 53-58 | | Y | Qualifies answer in para. 59 by showing reasons to choose Singapore other than tax advantages. |
| | Hugh McCo.. John D. E. | 15 | | Para 10 | | N | Does not add to read-in. |
| | Nelson | 26-43 | | Paras 18-23, | | N | Explanation of different transfer pricing methods does not clarify or explain read-in. |
| | | | | 44-47 | | Y | Clarifies read-ins by identifying assumptions that calculations were based on. |

**APPENDIX II**

**LIST OF WITNESSES**
(in order of testimony)

**FOR THE APPELLANT**

1. **Bernard Majoie** - former president of Fournier, a French pharmaceutical company which entered into a licence and a supply agreement for the sale of Raniplex, a ranitidine product. He testified as to the relationship of Fournier as a co-marketer of Glaxo products.
2. **Michael McTeague** - was with Glaxo Canada from 1987 to 1999. He was hired as manager, legal services and promoted to general counsel and then director of human resources.
3. **Jacques Lapointe** - former CEO and president of the appellant during the period under appeal.
4. **Jose Colledefors** - legal director of Glaxo Spain.
5. **Clive Rogers** – company purchasing manager for Glaxochem Limited in the U.K., the primary production part of the Glaxo World of Companies, for the period 1988 to 1994.
6. **Chris Baker** – worked at the Central production services division of Glaxochem Limited in the U.K. He testified with respect to Glaxo manufacturing standards and good manufacturing practices.
7. **Jose Maria Seijas** – employed by Faes, one of the Spanish licensees (co-marketers) who described Faes' relationship with Glaxo.
8. **Graham Fisk** – Accountant who was employed by Glaxo Holdings P.L.C. from 1986 to 1994. He testified on trading arrangements within the World and with third parties; financial results of World and subsidiaries; relationship with Glaxo World and third parties and affiliates.

9. **Paul Meade** – employed by Glaxo Canada from 1989 to 1991 as a product manager for Zantac, then in the international marketing division of Glaxo World in the U.K. for three-and-a-half years, later worked for Glaxo Inc. in the U.S. He worked in marketing. He testified as to Glaxo World's marketing strategy and to the marketing assistance provided by Glaxo World to Glaxo Canada.
10. **Angela Palmer** – a property patent litigation adviser with Glaxo World. She was called to enter in a report drafted by her supervisor Graham Brereton with respect to Uquifa (Spain) inspections by the FDA.
11. **James Cuttle** – was employed by Upjohn Canada as product manager for Kenral during the years under appeal. He testified as to the role of Kenral, which sold the “ultra-generic” form of Zantac in Canada.
12. **Ian Keith Winterborn** – the appellant's science nominee.
13. **Stefan Ziegele** – employed by IMS, a market research company which collects data on the pharmaceutical industry. He produced a product report on international sales of Zantac.
14. **Gregory Bell** – an expert on the pharmaceutical industry and transfer pricing.
15. **John Gregory Ballentine** - expert witness in transfer pricing.
16. **William Ment** - expert in Good Manufacturing Practices ("GMP") with an emphasis in chemistry (as opposed to manufacturing). He testified as to laboratory GMP manufacturing operations.
17. **Tomas Barrera** - Environmental consulting engineer with over 20 years experience employed as General Manager for Covitecma in Spain. He was called as an expert with respect to waster water discharges and hazardous waste. He testified as to whether Uquifa, a Spanish manufacturer of generic ranitidine, met Glaxo standards and local regulatory standards for waste water discharges, hazardous waste management and air emissions.

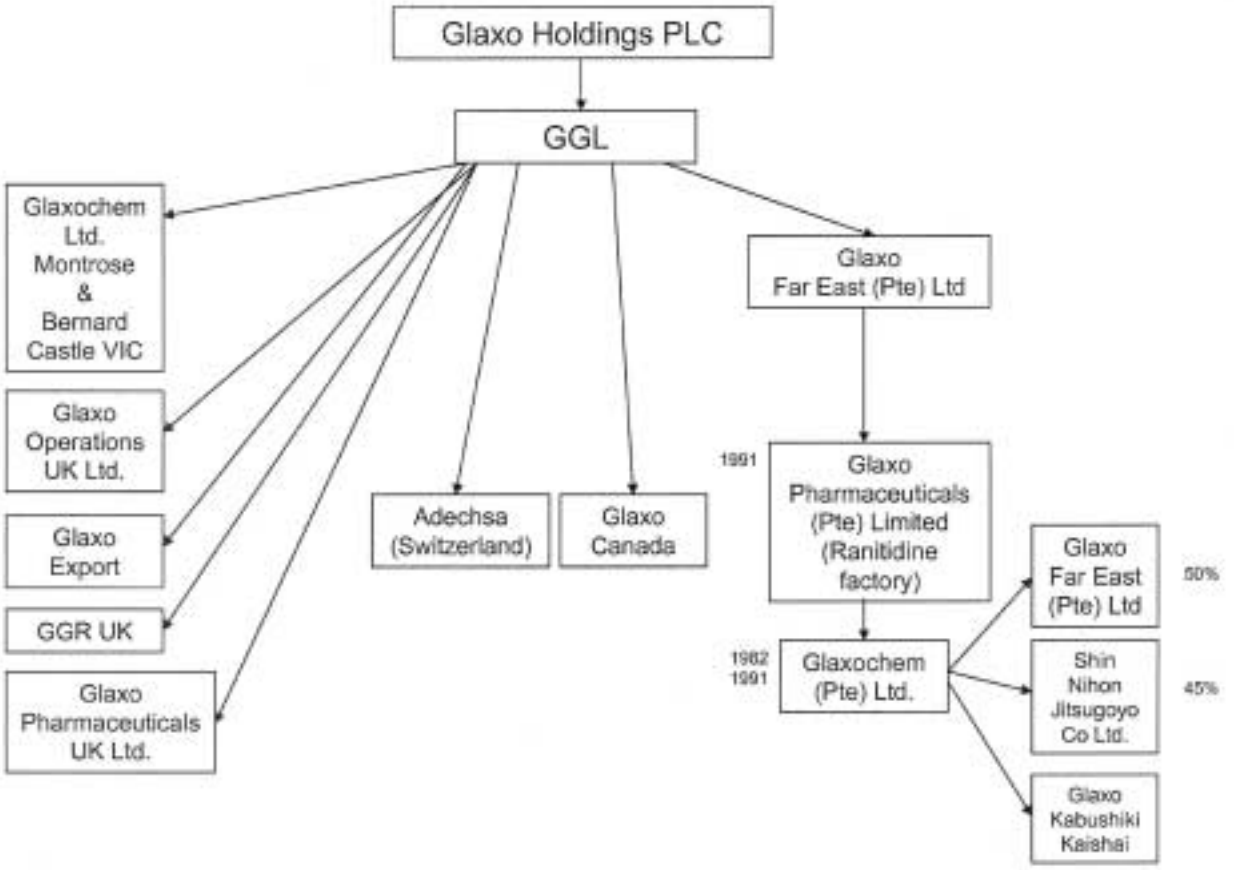
**FOR THE RESPONDENT**

1. **Douglas Welsh** – an accountant and Chartered Business Valuator employed by Clark Valuation Services. He summarized Glaxo financial data and reviewed profits various entities in Glaxo World earned both on the sale of ranitidine locally and globally.
2. **Lorne Davis** - pharmacologist with the Saskatchewan formulary. He was qualified as an expert in bioequivalence and bioavailability. He testified how a formulary determines that products are interchangeable.
3. **Gordon Fahner** – V.P. Finance at Apotex Inc., a generic pharmaceutical company.
4. **Bernard Sherman** – President of Apotex Inc.
5. **Daniel Youtoff** – Chartered accountant with Price Waterhouse Coopers ("PWC"). During the years under appeal, Novopharm was an audit client of PWC and the witness prepared its annual audits, annual financial statements and tax returns.
6. **Tamas Szederkenyi** – Senior Director of Analytical Research and Development with Novopharm.
7. **Dr. Sultan Ghani** - an employee of the Health Protection Branch. Qualified as an expert in the pharmaceutical industry in Canada, drug approval process, quality assurance and GMP in the pharmaceutical industry in Canada. He testified as to the drug submissions filed with Health Canada in order to get approval to market ranitidine hydrochloride drug formulations in Canada.
8. **Dr. Jack Mintz** – qualified as an expert in transfer pricing, but not specifically to the pharmaceutical industry.
9. **Dr. Leslie Benet** – qualified as an expert in pharmaceutical sciences, pharmacology, bioequivalence, chemical equivalence and other scientific

aspects of drug-related issues. He testified why a GMP inspection is not necessarily an indicator of good quality.

10. **Murray Puhacz** – Vice-President, Quality Operations with Novopharm during the years under appeal.
11. **Luciano Calenti** – President of ACIC Fine Chemicals Inc.
12. **Charles King III** – Qualified as an expert in pharmaceutical marketing. He testified about the marketing efforts that Glaxo Canada undertook; how much were Glaxo Canada's initiatives versus how much were provided by Glaxo World. He also testified that Glaxo Canada's focus, in terms of marketing, differed considerably from all of the other subsidiaries or licensees who were selling ranitidine.
13. **Sheryl Dore** –a team leader with Health Canada's Generic Drugs Quality Division of the Bureau of Pharmaceutical Sciences. She was involved in the review of the ranitidine hydrochloride drug submissions of Apotex.
14. **Eric Ormsby** – a biostatistician with Health Canada called to testify about the review of bioequivalence and bioavailability data provided to Health Canada in submissions by dosage form manufacturers in order to market their drug dosage forms in Canada.
15. **Tom Burkimsher** – auditor with the Canada Revenue Agency.
16. **Raymond Willis** – tax manager of Glaxo Canada during the audit from 1994 to 1995. He was cross-examined by the Crown under section 146 of the *Tax Court of Canada Rules (General Procedure)*.
17. **John Hems** – Director of Regulatory Affairs at Apotex Inc.
18. **Bohdan Woloschuk** - former employee of Glaxo Canada and one of their nominees at the discovery. He was responsible for marketing Zantac and he also administered the Kenral contract.

APPENDIX III




GGL is short for Glaxo Group Ltd.

The arrows indicate ownership. There should not be an arrow between Glaxo Pharmaceuticals (Pte) Limited and Glxochem (Pte) Ltd. The three arrows from Glaxochem (Pte) Ltd. to three other companies should be pointing in the opposite direction. Glaxochem (Pte) Ltd. was owned by the three other companies.

APPENDIX IV

## GLOSSARY OF TERMS

| Term | Abbreviation | Short Definition |
|---|---|---|
| Active Pharmaceutical Ingredient | API | The drug substance of a pharmaceutical product. |
| Bioavailability & Bioequivalence | | Bioavailability refers to the rate and extent to which a drug substance enters the blood stream and begins to have its effects on the patient, over time.<br>Bioequivalence refers to the comparative bioavailability of the generic drug products with the brand name product. Bioequivalence is the major basis for determining interchangeability under Provincial Drug Plans (formularies). |
| Chemical Equivalence | | Chemical equivalence is a term used in the HPB's guidelines for New Generic Drug Product Requirements. The tests designed to assure "chemical equivalence" were those that were developed to detect "related" impurities, looking at the synthesis and processes described in the supplier's Drug Master File. |
| Detailing | | The process by which pharmaceutical company representatives ("reps") interact with doctors, and describe the therapeutic properties of a pharmaceutical product. |
| Distribution | | The organization of the physical distribution of the pharmaceutical products to the wholesalers, pharmacies and hospitals. |
| Drug Master File | DMF | A Drug Master File is a document containing confidential information related to the manufacturing processes of the API. The generic manufacturer of a dosage form or finished product has provided |

| | | |
|---|---|---|
| | | information on the API in the DMF. The DMF is normally submitted by someone other than the drug product sponsor, to the HPB. |
| U.S. Food and Drug Administration | FDA | The federal department in the U.S. responsible for regulating food, pharmaceuticals, medical devices, cosmetics, nutritional supplements, radiological health. |
| Generic Company | | A company that sells copies of patented and branded pharmaceutical products under a compulsory license or after the patent has expired, under a generally descriptive name rather the original brand name. |
| Good Manufacturing Practices | GMP | GMP is a system of policies, practices, procedures, and documentation of activities and operations established and implemented by pharmaceutical companies to ensure that the APIs and/or dosage products that they produce have the quality, strength, identity, and purity that they purport or are represented to possess. This includes quality management; personnel training and qualification; sanitation and maintenance of buildings and facilities; design, cleaning, and maintenance of production equipment and analytical instruments; control of components and product containers and closures (etc.) |
| Health Protection Branch | HPB | A division of the Health Canada, the federal ministry responsible in Canada (during the period under appeal) for the review and recommendation for approval of a New Drug Submissions. |
| Health Safety and Environment | HSE | The standards regulating waste water discharge limits, emissions to the atmosphere and hazardous waste management as well as the health and safety of staff in the facility. |

| | | |
|---|---|---|
| Ultrageneric | | An "ultrageneric" product is one that is manufactured by the originating brand-name pharmaceutical company but is sold in the generic market segment of the market at generic prices. |

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| CITATION: | 2008TCC324 |
| COURT FILE NO.: | 98-712(IT)G |
| STYLE OF CAUSE: | GLAXOSMITHKLINE INC. v. HER MAJESTY THE QUEEN |
| PLACE OF HEARING: | Toronto, Ontario |
| DATES OF HEARING: | February 27, 28, March 1, 2, 5, 6, 7, 8, 9, 20, 21, 22, 23, 27, 28, 29, 30, April 3, 4, 5, 6, 11, 12, 24, 25, 26, 27, May 1, 2, 3, 4, 15, 16, 17, 18, 29, 30, 31, June 1, 5, 6, 7, 12, 13, July 17, 18 and 19, 2006. |
| REASONS FOR JUDGMENT BY: | The Honourable Associate Chief Justice Gerald J. Rip |
| DATE OF JUDGMENT: | May 30, 2008 |

APPEARANCES:

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| Counsel for the Appellant: | Pierre Barsalou, Sébastien Rheault, Eleni Kouros, McShane Jones and Ben Tomlin |
| Counsel for the Respondent: | Naomi Goldstein, Myra Yuzak and Karen Janke |

COUNSEL OF RECORD:

For the Appellant:

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|---|---|
| Name: | Pierre Barsalou, Sébastien Rheault, Eleni Kouros, McShane Jones and Ben Tomlin |
| Firm: | Barsalou Lawson |

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| For the Respondent: | John H. Sims, Q.C.<br>Deputy Attorney General of Canada<br>Ottawa, Canada |