Federal Court  Cour fédérale

Date: 20121024

Docket: T-1144-05

Citation: 2012 FC 1235

Toronto, Ontario, October 24, 2012

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

APOTEX INC.

Plaintiff

and

MERCK CANADA INC. and MERCK FROSST CANADA & CO.

Defendants

PUBLIC REASONS FOR JUDGMENT AND JUDGMENT

[1] This is a continuation of an action commenced by the Plaintiff Apotex in 2005 for compensation for any loss suffered by it as against the Defendants, collectively Merck, under the provisions of section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (*NOC Regulations*). The purpose of this present part of that action is to seek to quantify that loss. For the reasons that follow I have made findings as to the matters in controversy and ask that the accounting experts for each of the parties, on the basis of these findings, and including the matters agreed upon, collaborate to produce a final calculation as to the amount of

compensation. I have asked for submissions as to costs. Following receipt of the foregoing, final Judgment will be issued.

INDEXING

[2] For convenience, the matters considered in these Reasons can be found at the following paragraphs:

LITIGATION HISTORY

[3] I will repeat what I wrote in my earlier decision in this action cited as 2008 FC 1185 at paragraphs 3 to 7:

> *FACTUAL BACKGROUND*
>
> *3 Counsel for the parties are to be commended for co-operating in providing an agreement as to facts and documents (Exhibit 1). The Plaintiff, Apotex Inc., is what is known colloquially as a generic drug company which manufactures and markets primarily generic versions of pharmaceuticals in Canada. In the PMNOC Regulations, Apotex is referred to as a "second party". The two Merck Canadian companies Merck Frosst Canada Ltd. and Merck Frosst Canada & Co. (collectively referred to in these reasons as Merck) are the Canadian branch of a multinational organization which manufactures and markets are what are commonly referred to as "brand name" or "originator" or "innovator" pharmaceuticals and are what is referred to as "first person" under the PMNOC Regulations. Merck & Co. Inc., a United States company, was named as a party defendant in this action but shortly before trial, an Order was issued, on consent, discontinuing this action against that entity.*
>
> *4 The pharmaceutical of interest in this action is a drug commonly known as alendronate which is used primarily in the treatment of osteoporosis. Merck has an interest in a patent, Canadian Patent 2,294,595 ('595) which, among other things, includes claims directed to a particular dosage regimen for the use of that known drug, alendronate, in the treatment of osteoporosis, a known use. Merck listed the '595 patent with the Minister of Health under the provisions of the PMNOC Regulations which meant that any generic*

seeking approval to sell a generic version of alendronate in Canada for the patented dosage regimen for the treatment of osteoporosis and wanting to take advantage of simply referencing approvals already given to Merck for that drug could file an Abbreviated New Drug Submission (ANDS). In so doing a generic is required to send a notice to Merck alleging, among other things, that the '595 patent would not be infringed or was invalid, thereby permitting Merck to commence an application in this Court to prohibit the generic from marketing its generic version of alendronate in Canada in the dosage regimen claimed in the '595 patent.

5 Merck received an NOC approving for sale its version of alendronate in Canada on February 4, 2002. Apotex filed an ANDS for alendronate on February 7, 2003 and sent a Notice of Allegation to Merck on April 14, 2003 alleging that the '595 patent was invalid for a number of reasons. On May 29, 2003, Merck & Co. Inc. and Merck Frosst Canada & Co. commenced proceedings in this Court, T-884-03, to prohibit the Minister of Health from issuing a Notice of Compliance to Apotex which otherwise would permit Apotex to sell a generic version of the alendronate drug in Canada. On February 3, 2004 the Minister send a letter to Apotex advising it that its application was approved but would be held in abeyance subject to the Court proceedings. On May 26, 2005, Mosley J. of this Court gave Reasons and an Order in T-884-03, dismissing Merck's application, finding that Apotex's allegations as to invalidity, on some but not all grounds, were justified. These Reasons are cited as 2005 FC 755. No appeal was taken. On May 27, 2005, the Minister issued a Notice of Compliance to Apotex permitting it to sell its generic version of alendronate, Apo-alendronate, in Canada.

6 On July 5, 2005, Apotex instituted this action T-1144-05 claiming recovery against Merck under the provisions of section 8 of PMNOC Regulations for the period from February 3, 2004 to May 27, 2005.

7 By Orders of this Court dated January 24, 2006 and August 14, 2008, the quantification of any amounts found to be properly recoverable in this action is a matter to be determined at a subsequent trial. The two preliminary issues previously referred to are the subject of the present trial.

[4] I delivered the following Judgment after that trial:

JUDGMENT

For the Reasons provided herein:

THE COURT ADJUDGES that:

1. Section 8 of the Patented Medicines (Notice of Compliance) Regulations SOR/93-133 as amended (SOR/98-166) effective until 2006 is:

a. within the competence of the Federal Court to hear and determine an action brought thereunder;

b. enabled by the Patent Act, R.S.C. 1985, c. P-4 as amended S.C. 1993, c. 2, s. 4; and

c. intra vires the constitutional authority of the federal Parliament of Canada

2. In this action brought under the provisions of said section 8:

a. Apotex Inc. is not entitled to elect an account or the disgorgement of the profits of the Respondent, Merck Frosst Canada Ltd. or Merck Frosst Canada & Co.;

b. Apotex Inc. is entitled to claim damages or its lost profits for the period from February 3, 2004 to May 26, 2005; and

c. Apotex Inc. is entitled to claim damages for lost sales and lost permanent market share as claimed in paragraphs 1 (a)(ii) of its Further Amended Statement of Claim dated October 6, 2008 for a period beyond May 26, 2005 provided it is shown in evidence that such loss was not rectified and could not have been rectified before that date;

3. The quantification of the damages or lost profits referred to in paragraph 2 above shall be the subject of the further trial as set out in the Order of this Court dated August 14, 2008.

> *Any party is entitled to seek case management by the Prothonotary assigned to this action for directions as to the procedure to be followed in respect of said trial;*
>
> *4. No party is entitled to costs of this present portion of the trial of this action.*

[5] Merck appealed from my Judgment and the matter was heard by the Federal Court of Appeal; which Court delivered Reasons for Judgment, cited as 2009 FCA 187. Judgment was delivered by that Court as follows on June 4, 2009:

> ***JUDGMENT***
>
> *[1] The appeal is allowed in part, paragraph 2 (c) of the judgment rendered by the Federal Court Judge is set aside, and giving the judgment which ought to have been given, it is held that Apotex's claim for damages for lost sales and lost permanent market share must be confined to such losses which can be shown to have been incurred during the section 8 period. Costs computed at the mid-level of Column I of Tariff B are awarded in favour of the appellant.*
>
> *[2] Apotex's cross-appeal is dismissed with costs computed at the mid-level of Column III of Tariff B.*

[6] Thus, the present trial came before me commencing on September 17, 2012. The parameters of the task before me are contained in paragraphs 2(b) and 2(c) of my Judgment as modified by the Federal Court of Appeal and may be restated as follows:

> *2(b) Apotex Inc. is entitled to claim damages or lost profits for the period from February 3, 2004 to May 26, 2005 (the section 8 period); and*

> *2(c) Apotex Inc.'s claim for damages for lost sales and lost permanent market share must be confined to such losses which can be shown to have incurred during the section 8 period.*

[7] As to liability, the parties have entered into an Undertaking whereby each of the Defendants Merck Frosst Canada & Co. and Merck Frosst Canada Ltd. have agreed that any order or judgment for monetary relief against either of them in this action may be enforced by Apotex against either of them, subject to their right to appeal or seek a stay.

[8] It must also be noted that during trial I was advised that about a year and a half ago the Defendant previously called Merck Frosst Canada Ltd. changed its name to Merck Canada Inc. I made an Order changing the style of cause to reflect this change.

THE ISSUES

[9] Having regard to my Judgment, as modified by the Court of Appeal as set out above, my task is to arrive at a calculation of the "loss suffered by Apotex" during the period from February 3, 2004 to May 26, 2005, based on a hypothetical situation that Apotex had not been impeded from entering the Canadian marketplace with its 70 mg Apo-alendronate tablets by any NOC proceedings taken by Merck.

[10] I am obliged to my colleague Justice Snider, who, in two recent decisions, *Apotex Inc v Sanofi-Aventis*, 2012 FC 553, and *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2012 FC 552, has provided a clear and useful roadmap as to how to approach such a calculation. I propose to follow, by and large, that roadmap by addressing the following issues:

a. The "But For" World, who bears the burden

b. What is the relevant period?

c. What is the overall size of the alendronate market in that period?

d. What would have been the size of the generic share of the overall alendronate market in that period?

e. What would have been Apotex's share of that generic share in that period?

- When would Apotex have been alone in that market?
- When, if at all, would Cobalt have entered that market?
- When, if at all, would Novopharm have entered that market?

f. At what price would Apotex have sold in that market in that period?

- When the sole generic?
- When in competition with other generic(s)?
- Compensation for double ramp-up

g. What deductions, if any, should be made from the selling price?

- agreed deductions
- rebates
- free goods

- How is pre-judgment interest to be calculated?

[11] I will first review the evidence.

THE EVIDENCE

[12] At the trial before me in September 2012, the Plaintiff Apotex provided evidence from two expert witnesses and five witnesses as to fact. Portions of the transcript and exhibits from Apotex's discovery of Merck were entered into evidence, as well.

[13] Apotex called as expert witnesses the following two persons. Merck agreed that they could be called as experts and the parties jointly tendered in evidence their agreement as to their expert qualifications, which I repeat as follows:

a. Mr. Howard Rosen: A Senior Managing Director of FTI Consulting Inc. having offices in several places around the world. He is located in Toronto, Ontario. The parties have agreed as to his qualifications as follows:

> A Chartered Accountant, Chartered Business Valuator and Certified Fraud Examiner with expertise in investigative and forensic accounting, business

valuation and loss quantification in commercial and intellectual property disputes.

b. Ms. Rosemary Bacovsky: President, Integra Consulting Ltd. of Calgary, Alberta. The parties have agreed as to her qualifications as follows:

> A pharmaceutical industry consultant and pharmacist with expertise in formulary listings, market access, reimbursement policies and pricing regimes of the Canadian pharmaceutical marketplace.

[14] The Plaintiff Apotex called the following five persons as factual witnesses:

a. Ms. Marlie Yoshiki: Client services, Global Operations of IMS Brogan, an organization that collects and distributes to members of the pharmaceutical community, data; including data as to the sale of pharmaceutical products in Canada.

b. Mr. Darren Hall: Vice President, Supply Operations of Apotex Pharmaceuticals, a company related to the Plaintiff. He testified as to the manufacture and capacity to manufacture alendronate tablets by his company for Apotex.

c. Dr. Bernard Sherman: Chairman of the Board of the Plaintiff Apotex. He is responsible for the overall operations of Apotex and gave evidence as to those operations, including the manufacture and sale of the alendronate product at issue.

d. Mr. David Kohler: Vice President, National Sales of the Plaintiff Apotex. He gave evidence as to the sales of Apotex products in Canada, including the alendronate product at issue.

e. Mr. Gordon Fahner: Vice President of Business Operations and Finance of the Plaintiff Apotex. He gave evidence as to the manufacture and sales of Apotex products, including the Apotex product at issue. He testified as to rebates given to Apotex's customers.

[15] The Defendant Merck provided evidence from two expert witnesses and seven witnesses as to fact. Portions of the transcript and exhibits of Merck's discovery of Apotex were entered into evidence, as well.

[16] Merck called as expert witnesses the following two persons. Apotex agreed that they could be called as experts, and the parties tendered into evidence their expert qualifications, which I repeat below:

a. Mr. W. Neil Palmer: President and Principal Consultant of PDCI Market Access Inc. of Ottawa, Ontario. The parties have agreed to his qualifications as follows:

> Neil Palmer is a pharmaceutical industry consultant with expertise in formulary listing, market access, reimbursement policies and pricing regimes related to the Canadian pharmaceutical marketplace.

b. Mr. W. Ross Hamilton: A partner in the firm of Cohen Hamilton Steger of Toronto, Ontario. The parties have agreed to his qualifications as follows:

> Chartered Accountant with a specialist designation in investigative and forensic accounting and expertise in business valuation and damages quantification in commercial and intellectual property disputes.

[17] The Defendants Merck called the following seven persons as factual witnesses:

a. Mr. Gordon Fahner This is the Apotex executive who was a witness for Apotex. He was recalled by Merck under subpoena.

b. Mr. Jeff Spencer: Vice President, Women's Health and Diversified Brands of Merck Canada Inc. He testified as to Merck's marketing and litigation strategy.

c. Mr. David Boughner Director, Strategic Initiatives of Teva Canada Limited (formerly Novopharm). He testified as to Novopharm's marketing strategies.

d. Mr. Chris Ichiyen Director, Financial Management of Cobalt Pharmaceuticals Company. He testified as to Cobalt's marketing strategy.

e. Mr. Brent Fraser: Director, Drug Processing Services, Ontario Public Drug Program. He testified as to how drugs were put on to the Ontario drug formulary.

f. Ms. Kimberley Van Wart: Consultant, Mississauga, Ontario. She was previously the President of Cobalt Canada. She testified as to Cobalt marketing and legal strategies in the 2004-2005 period.

g. Ms. Virginia Cirocco: Consultant, Mississauga, Ontario. She was an Executive Vice President of Shoppers Drug. She testified as to the purchasing practices of that organization in the 2004-2005 period.

[18] In reply, the Plaintiff Apotex recalled:

a. Mr. Gordon Fahner: He testified as to the percentage of Apotex sales to Shoppers Drug in the 2004-2005 period.

[19] I have found all of the expert witnesses to be credible. Where they differed, they did so in respect of methodology and assumptions made. Where I have preferred the evidence of one of them over the other, I have not done so on the basis of credibility, or in any sense on the basis of superior credentials. I will endeavour to state, in respect of certain of their conclusions or opinions that I prefer, to say why I have done so.

[20] With respect to the factual witnesses, I find that all but one of them is credible. I have comments as to that person and two others.

[21] Two factual witnesses who I find to be credible nonetheless cause me concern. Ms.Yoshiki and Ms. Van Wart. Some background is necessary to explain my concern. This matter was case managed. In May of this year I issued a direction that Counsel were to exchange lists of witnesses including will-says for the factual witnesses. There was to be no surprise at trial. The trial of this matter was originally scheduled to be heard in June of this year. A few days before the trial was to begin, Counsel for Merck notified Counsel for Apotex that Merck was changing its position with respect to an important factual issue; namely, the date that Merck would be alleging that a second generic, Cobalt, entered the Canadian marketplace. After a pre-trial hearing with Counsel, I adjourned the trial, on terms, to permit Apotex to explore the factual basis that Merck had for the change of position and to provide new instructions to its expert witnesses (and the same would apply to Merck). With respect to Cobalt, Merck's Counsel provided certain information to Apotex's Counsel as to the factual basis for Merck's assertions as to the entry date of Cobalt into the Canadian market. That basis was the evidence to be given by Mr. Ichiyen, and certain documents were provided. Apotex conducted a discovery of Merck a few days before this trial began in September, and Merck's Counsel gave assurances that this was all there was in respect of this matter.

[22] Mr. Ichiyen appeared as a witness for Merck at the trial before me. He was examined and cross-examined. Suffice it to say that his evidence did not turn out as Merck might have expected. He said that Cobalt would not enter the marketplace as long as there was a patent around. He was Cobalt's auditor, but not a Cobalt executive or employee at the relevant time. I do not find anything in his evidence that would be sufficient to support Merck's assertion as to an early entry date by Cobalt into the Canadian market.

[23] As the evidence shows, one of Merck's Counsel, minutes after Mr. Ichiyen had given his evidence at the trial; obtained Ms. Van Wart's email address from Ms. Cirocco, another of Merck's witnesses who had not yet been called and contacted Ms. Van Wart to set up a meeting with her. It must be made very clear that Ms. Van Wart's name was not on Merck's witness list; nor was it disclosed at any time to Apotex, whether on discovery or otherwise, before the evening prior to the morning of trial when Ms. Van Wart gave her evidence. Apotex strongly objected to her appearing as a witness. I allowed her to appear, indicating that I would reserve as to admissibility of her evidence and, in any event, review the evidence with a very large measure of salt.

[24] As it turned out, Ms. Van Wart's testimony was largely directed to an attempt to contradict Mr. Ichiyen's evidence and to provide a picture much more favourable to Merck. Ms. Van Wart's evidence was based on her recollection as to what might have happened some eight years ago assisted by discussions that she had a few hours previous with persons not called as witnesses and a review of documents not tendered in evidence. It became clear during cross-examination that the Canadian Cobalt company's decisions such as whether and when to enter the Canadian marketplace, particularly when a patent might be involved, were made by those higher up the corporate ladder. The Canadian Cobalt company was a subsidiary of a European corporate structure. Ms. Van Wart had limited input into these decisions. I will admit her evidence, but will prefer that of Mr. Ichiyen. Ms. Van Wart's evidence is insufficient to persuade me as to Merck's position that Cobalt would have entered the Canadian market in or about November 2004, or at any time prior to the entry of Novopharm.

[25] I rebuked Merck's Counsel at trial. The direction as to disclosure of witness names and will says was ignored. A delay of several months in the date set for the hearing of the trial was provided but seemingly did not assist in the preparation of the case. Days before this trial began Merck's Counsel, on discovery, gave assurances that there would be nothing more presented at trial.

[26] I must add that my remarks in no way should be taken to reflect upon the character of Ms. Van Wart. She retired from Cobalt some time ago, and has a consulting business. She was contacted the night before she appeared. Her memory was refreshed by speaking to persons who did not appear as witnesses, and in reviewing documents not produced at trial. A contact was arranged through Ms. Cirocco, but nonetheless came out of the blue as far as Ms. Van Wart was concerned. She seemed to be perplexed and uncertain as well she might be, as to what was going on.

[27] I also have concerns about the evidence of Ms Yoshiki. Her name was not on Apotex's witness list, nor was a will-say provided. In this case however Merck did not object to her being called as a witness. She did not contradict the evidence of another witness. She provided information as to data was collected by an organization known as IMS Brogan, in particular Canadian Drug Store Hospital Audit known as CDH. The accounting experts for each of the parties referred to this data. Unlike Ms. Van Wart her evidence was not an endeavour to impeach a party's own witness. I accept her evidence and find it credible.

[28] The third factual witness, about whom I have concerns, is Ms. Cirocco. She graduated from university as a pharmacist. She joined Shoppers Drug Mart in 1995 and retired from a position as Senior Vice President of Pharmacy and Corporate Affairs in 2009 to do what she described as

volunteer community work and consulting. Although she was apparently subpoenaed, she was in fact retained by Merck's solicitors as a consultant. For instance, she was the person who quickly obtained Ms. Van Wart's email address.

[29] Ms. Cirocco testified principally as to the rebate programme instituted by Shoppers Drug Mart, whereby Shoppers would more or less insist wherever possible that generic drug suppliers such as Apotex provide by way of a rebate, a percentage of the money paid by Shoppers to purchase drugs from the drug supplier. Her evidence in this regard went well beyond her *will say* as provided by Merck's Counsel to Apotex's Counsel, particularly in a critical area as to the size of the rebate. Her evidence in this regard was unsupported by any document or other evidence.

[30] The evidence shows that Apotex's Counsel, when her name was disclosed to them by Merck's Counsel in June, attempted to contact Ms. Cirocco with a view to discussing her possible evidence in the case. This is quite proper; there is no property in a witness. Ms. Cirocco played a game of cat and mouse, through emails, with Apotex's Counsel. She insisted that they disclose a list of questions they might ask. They did so, by email. She did not communicate with them any further and never met with them. That is her prerogative; however, it indicates a lack of candour and a willingness to play games.

[31] Further, it appears that Ms. Cirocco was disciplined for professional misconduct in 2004 by the Ontario College of Pharmacists. She frankly admitted to this when asked in cross-examination. Merck's Counsel went through an extremely lengthy examination in chief as to Ms. Cirocco's

background and activities in the pharmaceutical field, and never touched on this aspect. He did so in reply but only because the matter had been raised in cross-examination.

[32] It appears that, according to Ms. Cirocco, Shoppers was accepting rebates as high as sixty percent (60%) in about the relevant period. The Ontario government had passed legislation in 2006/7 intended to curb rebates at twenty percent (20%). It appears from Ms. Cirocco's evidence that her company had what she described as "private business" in "various places" that apparently continued to receive those larger rebates.

[33] In all, I am quite sceptical as to Ms. Cirocco's evidence. It deals with the rather murky business of rebates. She provided no candid illumination in this area. She offered that Shoppers was getting rebates of up to sixty percent (60%) This statement, if true, is important. It was not disclosed by Merck in a pre-trial will say or otherwise. It is unsupported by any other evidence. This number was never put by Merck's Counsel in cross-examination of any Apotex witness, including Mr. Fahner, who appeared again as a witness in reply after Ms. Cirroco had given her evidence.

[34] I will not accept Ms. Cirocco's evidence on any point unless it is clearly supported by other credible evidence.

THE "BUT FOR" WORLD, WHO BEARS THE BURDEN

[35] The Court is required to consider what would likely have been the case had Apotex not been prevented from entering the Canadian marketplace with its generic 70 mg Apo-alendronate tablets. It was prevented from doing so because Merck had instituted and prosecuted through to a judgment unfavourable to it, proceedings under the *NOC Regulations*. Therefore, the Court is to determine, as best it can, a hypothetical question: What would have been the case "but for" those proceedings?

[36] In entering the "but for" world, the Court is to be mindful as to who bears what burden. Both parties have cited and relied on what I wrote at paragraph 35 of my decision in *Apotex Inc v AstraZeneca Canada Inc*, 2012 FC 559; therefore, I repeat it:

> *35 In brief, it may be said that the party who has led sufficient evidence to put an issue "in play", must, to succeed on that issue, put in sufficient evidence so that on the balance of probabilities, the relevant facts are accepted by the Court as having been proved. Thus Apotex must put in play and subseqtently prove on the balance of probabilities the facts that it needs to establish its case for compensation. AstraZeneca must put in play and subsequently prove those facts that it asserts disqualifies Apotex or reduces or negates Apotex's claim for compensation.*

[37] Also, both parties have cited and relied upon the decision of the Supreme Court of Canada in *Athey v Leonati*, [1996] 3 SCR 458, at paragraphs 26 and 27, which I repeat:

> *26 The respondents argued that the trial judge's assessment of probabilities in causation was similar to the assessment of probabilities routinely undertaken by courts in adjusting damages to reflect contingencies. This argument overlooks the fundamental distinction between the way in which courts deal with alleged past events and the way in which courts deal with potential future or hypothetical events.*

> *27 Hypothetical events (such as how the plaintiff's life would have proceeded without the tortious injury) or future events need not be proven on a balance of probabilities. Instead, they are simply given weight according to their relative likelihood: Mallett v. McMonagle, [1970] A.C. 166 (H.L.); Malec v. J. C. Hutton Proprietary Ltd. (1990), 169 C.L.R. 638 (Aust. H.C.); Janiak v. Ippolito, [1985] 1 S.C.R. 146. For example, if there is a 30 percent chance that the plaintiff's injuries will worsen, then the damage award may be increased by 30 percent of the anticipated extra damages to reflect that risk. A future or hypothetical possibility will be taken into consideration as long as it is a real and substantial possibility and not mere speculation: Schrump v. Koot (1977), 18 O.R. (2d) 337 (C.A.); Graham v. Rourke (1990), 74 D.L.R. (4th) 1 (Ont. C.A.).*

[38] I emphasize the last sentence of that decision; the hypothetical possibility must be real and substantial not mere speculation. Put another way, the possibility must be realistic and not simply hopeful.

WHAT IS THE RELEVANT PERIOD

[39] This period has already been determined by this Court and affirmed by the Federal Court of Appeal. It is from February 3, 2004 to May 26, 2005. The parties have agreed that the accountants should pro-rate the compensation over precisely those dates.

OVERALL SIZE OF THE ALENDRONATE MARKET

[40] The parties are agreed that the size of the total market for 70 mg alendronate tablets during the relevant period is to be the quantity as sold by Merck, the only authorized person in the real world who sold that product in that period.

[41] I should add that others, including Apotex, Novopharm and Cobalt, were selling alendronate tablets in other strengths, 5 mg and 10 mg tablets, during at least a portion of that period. To some extent, the experts have used sales of these tablets as models or proxies for their opinions. The difference between these tablets and the 70 mg tablets appears to be that the 70mg tablets are intended for "once a week" administration.

GENERIC SHARE OF THE OVERALL ALENDRONATE MARKET

[42] The parties have agreed that the share of the alendronate market that would have been occupied by the generics in the period in question; that is, the share in the "but for" world, is the same as the share occupied by the generics in the subsequent "real world" period.

APOTEX'S SHARE OF THE GENERIC MARKET

[43] To answer this question, two matters must be addressed. First, when would Apotex have entered the market in the "but for" world. Second, when would one or other of the two generics, Cobalt and Novopharm, have entered that market in the relevant period, if at all.

[44] The question as to when a generic would have entered the marketplace must be answered in several parts. First one has to establish when the generic would have received its Notice of Compliance (NOC). Another part is whether the generic had the capacity to manufacture or acquire the product in the relevant time. Another part is whether the generic was motivated or dissuaded from entering the marketplace during the relevant period. The final part is when, if at all, the product would have been accepted by the relevant branch of the provincial or territorial

governments for listing in a formulary; which listing would permit the product to be sold in that province in significant quantities.

1. Capacity

[45] I find on the evidence, particularly of Mr. Hall, that Apotex had the ability to manufacture 70 mg alendronate tablets in a quantity sufficient to fill the market in the relevant time period. This is supported by the fact that as soon as Apotex did receive its NOC in the "real world", sufficient quantities appeared on the market very quickly. This matter was not seriously contested by Merck.

[46] I find in considering the evidence of Mr. Ichiyen and Ms. Van Wart, that I do not have enough evidence to persuade me that Cobalt had sufficient resources available to it in the 'but for' period to make or obtain the product. Neither of them had first-hand knowledge that would support such a conclusion.

[47] As to Novopharm, I find on the evidence of Mr. Boughner that he did have first-hand knowledge of the relevant facts. He testified that Novopharm had the ability to acquire from a related company abroad, sufficient quantities of alendronate product to supply the market in the relevant time period.

2. Motivation

[48] I find that both Apotex and Novopharm would have entered the market during the "but for" time period had each of them received an NOC. Both Dr. Sherman and Mr. Boughner testified as to this. No serious challenge was raised in respect of this testimony.

[49] The matter is different with respect to Cobalt. Mr. Ichiyen testified that Cobalt would not have launched a product while a patent was in place. Ms. Van Wart's testimony related only to a situation where no patent was in place. I find that, in the relevant period, since Merck still had a patent in place, Cobalt would not likely have been motivated to launch a product.

3. Formulary Listing

[50] It is common ground that a pharmaceutical product such as tablets containing an active ingredient such as alendronate cannot be sold commercially in Canada until the distributor has received from the federal Minister of Health a Notice of Compliance (NOC). It is also common ground that, even though a distributor has received an NOC, the product generally cannot be sold in any reasonable commercial quantities in any province of Canada until it has been listed on what is called a formulary, by the relevant provincial Ministry. Thus, when considering when a product could have been sold in Canada, an important date is the date that the product would have been listed on the relevant provincial formulary.

[51] It is common ground that, in general, the first generic version of a drug listed on a provincial formulary during the period in question here, 2004 and 2005, would have been sold at a price established at seventy percent (70%) of the price established for the previously listed branded

product. In argument Apotex's Counsel urged that the price would have been greater. I will address this matter later. It is further agreed that when one or more generics subsequently enter the marketplace, the price of all generics will drop to sixty-three percent (63%) of the brand listed price. Therefore, it is important in this case to determine the period for which Apotex's 70 mg alendronate product would have been the exclusive generic, and the period for which it was no longer the exclusive generic.

[52] In discussing price in this context, I am not considering the issue of rebates which I will discuss elsewhere.

[53] Each of the parties provided expert evidence as to the dates, in the relevant period, when Apotex would, in their opinion, have been listed on the provincial formularies and when the products of competitor generics, Novopharm and Cobalt, would have been so listed.

[54] These experts, Ms. Bacovsky for Apotex, and Mr. Palmer for Merck; are agreed as to twenty-three of those dates, and disagree as to seven. I set out Table 1 of Mr. Palmer's Supplementary Report of September 10, 2012 at paragraph 33, which lists all of the dates and highlights those in disagreement.

Table 1. But-For Provincial Drug Plan Listing Dates

	Apo-Alendronate 70mg	Co-Alendronate 70mg	Novo-Alendronate 70 mg
"but-for" NOC Date	03-Feb-04	21-Oct-04	07-Jan-05
But-for Provincial listing Dates (Non-concurring Bacovsky dates)			
BC	2004-Aug-28	2004-Dec-08	2005-Mar-07
	(2004-Feb-10)	(2004-Dec-13)	(2005-Feb-28)
AB	2004-Mar-08	2005-Apr-01	2005-Jul-01
SK	2004-Apr-01	2005-Apr-01	2005-Jul-01
	(2004-Mar-01)		
MB	2004-Jun-15	2005-Jan-03	2005-May-07
ON	2004-Jul-20	2004-Dec-21	2005-Feb-24
	(2004-Apr-06)		(2005-Jan-25)
QC	2004-Oct-06	2005-Jun-01	2005-Oct-05
NB	2004-Mar-26	2004-Nov-30	2005-Apr-06
NS	2004-May-15	2004-Dec-01	2005-Jul-01
PE	2004-Aug-23	2005-Feb-28	2006-May-29
	(2004-Mar-01)		
NL	2004-Mar-16	2005-Jun-01	2005-Jun-01

[55] Ms. Bacovsky set out the dates which were in disagreement at Table 1 of her Responding Expert Report dated September 16, 2012, paragraph 3, as follows:

Table 1: Disagreement between Provincial Drug Plan Listing Dates in the Bacovsky Expert Reports and the Palmer Expert Reports

Province	Product	Bacovsky Estimate	Palmer Estimate
British Columbia	Apo-Alendronate	February 10, 2004	August 28, 2004
	Co-Alendronate	December13, 2004	December 8, 2004
	Novo-Alendronate	February 28, 2005	March 7, 2005
Saskatchewan	Apo-Alendronate	March 1, 2004	April 1, 2004
Ontario	Apo-Alendronate	April 6, 2004	July 20, 2004
	Novo-Alendronate	January 25, 2005	February 24, 2005
Prince Edward Island	Apo-Alendronate	March 1, 2004	August 23, 2004

[56] The accounting experts, Mr. Rosen for Apotex, and Mr. Hamilton for Merck, have used these listing dates in their calculations. Thus, it is necessary to resolve the disagreements.

[57] Fortunately, the parties have agreed that while several of these dates are in disagreement, the disagreement makes no material difference to the final calculation of a quantum. Further, the parties have agreed that "but for" sales in Canada's territories may be added in to the quantum.

[58] In the result, the "but for' entry date for Apotex's product remains in dispute in respect of two provinces only; Ontario and Saskatchewan.

a. <u>Ontario</u>

[59] Ms. Bacovsky's opinion is that Apotex's product would have been listed on the Ontario formulary on April 6, 2004. Mr. Palmer's opinion is that it would be listed on July 20, 2004. Much of the bases for the differences in these opinions lies in their respective views as to the Ontario "fast track" programme in place at about the relevant period and whether the Apotex product, had it received its NOC in early February 2004, would have been placed on that fast track.

[60] Merck called the evidence of Mr. Fraser, who was a senior official with the relevant Ontario ministry at the time. I accept his evidence as credible and authoritative as to what transpired in the Ontario Drug Benefit Program (ODB), the relevant department at the time.

[61] Mr. Fraser stated that, in general, the ODB had a continuous programme for the review of drugs sought to be listed on the formulary. Those that had received an NOC as approved generic

equivalents of drugs already approved on the formulary received faster treatment. Once approved by ODB, the matter was passed up for approval by cabinet. Delays could occur if cabinet was not meeting within the next while or if the matter could not be reached on the cabinet agenda. His department established internal cut-off dates, not generally known to the public, as to when material respecting various drugs would be bundled together to be forwarded for cabinet approval. In the period in question a cut-off date of December 31, 2003 was established so that any new drugs submitted for approval as of that date would be bundled and forwarded for cabinet approval in April 2004. He testified that any submission received after December 31, 2003, such as February 2004, would not have been eligible for inclusion in the April 2004 bundle previously sent to cabinet.

[62] Ms. Bacovsky's opinion leading to an approval date of April 6, 2004 was based on her reading of a recital of evidence given in Reasons for Judgment in a decision given by Justice O'Driscoll of the Ontario Superior Court of Justice in *Apotex Inc v Minister of Health*, Court File 157/04, et al, April 27, 2004, involving the drug citalopram. In that case, a submission for listing on the formulary made by another generic in December 2003 was included in the April 2004 bundle, but Apotex's submission made in January 2004 was not. This is consistent with Mr. Fraser's evidence that a submission filed after the end of December 2003, namely in February 2004, would not have been included in the bundle sent to cabinet for approval in April. It would have been put in a later bundle.

[63] When asked in cross-examination whether Mr. Fraser's evidence (which had not yet been given) that December 31, 2003 was a hard cut-off date would have changed her opinion, Ms. Backovsky paused and said only that Mr. Fraser was not senior enough in the decision making

process. I find that he was senior enough and that his factual evidence is to be preferred to Ms. Bacovsky's opinion evidence.

[64] Mr. Palmer's opinion is based on the assumption, borne out by Mr. Fraser's evidence, was that July 20, 2004 was the more likely date for listing of the Apotex product on the Ontario formulary. I agree with that opinion and so find that the relevant date for the listing of the Apotex 70 mg. tablets on the Ontario formulary in the but-for world is July 20, 2004.

b. <u>Saskatchewan</u>

[65] It is Ms. Bacovsky's opinion that Apotex's product would have been listed on the Saskatchewan formulary on March 1, 2004. Mr. Palmer's opinion if that the listing would have taken place April 1, 2004. Apparently, there is no middle ground; it is one date or the other.

[66] Ms. Bacovsky used ciprofloxacin as the criterion for the speed of listing a product in Saskatchewan. Here, her opinion was that listing could be achieved in less than a month.

[67] Mr. Palmer's opinion was that a drug submitted for listing in February 2004 would more likely be processed and listed in the month of April, not March. He stated that ciprofloxacin was a special case where listings were expedited because of a perceived fear of an anthrax outbreak. The time period for listing, in his opinion, is consistent with listings of other drugs such as ramapril.

[68] I accept Mr. Palmer's approach. It is more consistent with a realistic estimate as to a listing date than with the more hopeful approach of Ms. Bacovsky.

[69] The listing date for the Apotex product in Saskatchewan in the but for world would have been April 1, 2004.

FORMULARY LISTINGS FOR THE NOVOPHARM AND COBALT ALENDRONATE PRODUCTS

[70] I have already found that the evidence is insufficient to support Merck's assertion that Cobalt would have entered the marketplace in the relevant period. The evidence does not establish that Cobalt could make or obtain the product in that period or that it would have been motivated to release the product in that period. In any event, the only province for which the experts were apart as to listing dates for the Cobalt product is British Columbia, and it is agreed that for purposes of calculations, the difference is not relevant.

[71] As to Novopharm, there is a minor difference between the experts as to the listing dates in British Columbia, but that, as previously discussed, is irrelevant.

[72] There is also a difference between the experts as to Novopharm's listing date on the Ontario formulary in the "but for" world. In this case, Mr. Palmer's date, February 24, 2005, is more favourable to Apotex than Ms. Bacovsky's date of January 25, 2005.

[73] In argument, Merck accepted Mr. Palmer's date and I so find that the Novopharm listing date in the "but for" world in the Ontario formulary would have been February 24, 2005.

AT WHAT PRICE WOULD APOTEX HAVE SOLD ITS PRODUCT

[74] There are two scenarios to consider when endeavouring to establish the price that Apotex would have sold its 70 mg alendronate tablets in the "but for" world. They are the period when it was the only generic, and the period when another generic would have entered the market. In this case, that other generic would have been Novopharm. As I have found, there is insufficient evidence to establish that Cobalt would have entered the market at any time within in the relevant time period.

[75] Apotex's expert, Ms. Bacovsky, stated that the price would generally be set at 70% of the brand (Merck) when a generic such as Apotex was the sole generic in the marketplace, and 63% of the brand when other generics entered a particular provincial formulary. Apotex's expert, Mr. Rosen, accepted those figures to be consistent with his understanding of the real world, and provided his opinions based on those percentages.

[76] Merck's expert, Mr. Palmer, accepted those figures, as well. Merck's expert, Mr. Hamilton, provided various scenarios where those figures were used.

[77] It seems that it has been comfortably established that the 70% figure for exclusivity, and 63% for shared market, would be the basis for establishing a price.

[78] In closing argument, Apotex's Counsel scoured through various pieces of testimony and argued that there was, to use their words, a "realistic chance" that Apotex would have sought and secured a price greater than the 70% level during its period of exclusivity.

[79] While, undoubtedly, Apotex would have, in negotiating with its customers, sought as high a price as it dared; there may have been a chance that it could have obtained a price just below that of the brand; say, 95%. However, I am not persuaded that this is the most realistic expectation in the "but for" world.

[80] I find that the most realistic price that Apotex would obtain for its product in the "but for" world is 70% of the brand price during exclusivity, and 63% of that price when it was not exclusive.

DOUBLE RAMP-UP

[81] When an organization introduces a new drug product into the marketplace, there is an initial period during which the product has to be made or acquired, orders received from customers, and the product is to be shipped to customers. This is referred to in evidence as "ramp-up". In the real world, when Apotex did release its 70 mg alendronate tablets, it did incur a "ramp-up" before it reached a more or less steady state as to sales levels. The accounting experts differ as to what this "ramp-up" loss - that is, the lower level of sales before reaching a steady state - was in the real world. Mr. Hamilton's opinion is that Apotex suffered minimal losses due to ramp-up in the real world. Mr. Rosen's opinion is that they were larger.

[82] Both Mr. Hamilton and Mr. Rosen agree that in the "but for" world, Apotex would also have incurred a ramp-up in the period when its product was introduced. Further, and very importantly, they agree that, were it not for the view taken by the Federal Court of Appeal in its earlier decision in this case, 2008 FCA 189 at paragraphs 97 to 102, it would be proper accounting

practice to avoid a "double ramp-up". In other words, the loss encountered in the "real world" ramp-up should be added to the compensation for loss in the "but for" world.

[83] The jurisprudence on this issue bears repeating. When the argument was first raised before me in the earlier trial of this action, it was done so not in the context of ramp-up, but in the context of permanent loss of market share. For instance, if Apotex had entered the market in the "but for" period, it may have achieved, say, 60% of the market, but since it was delayed, it only achieved 50% in the "real world"; thus it suffered a continuing loss of 10% market share in the period after the "but for" period. I wrote at paragraphs 117 to 121 in 2008 FC 1185:

> *FUTURE LOSSES*
>
> *117 Merck characterizes a claim made by Apotex in respect of certain damages as a claim for "future losses". While perhaps not entirely accurate as catchwords, it is convenient to refer to that claim as such.*
>
> *118 Apotex's claim is set out in paragraph 1. (a)(ii) of its Further Amended Statement of Claim as follows:*
>
> > *1. The Plaintiff, Apotex Inc. ("Apotex"), claims:*
> >
> > *(a) damages suffered by Apotex in respect of the drug alendronate by reason of the commencement of a proceeding by the Defendants pursuant to the Patented Medicines (Notice of Compliance) Regulations (the "Patent Regulations"), in respect of:*
> >
> > ...
> >
> > > *(ii) lost sales and permanent market share due to the fact that launch by Apotex of its alendronate product was unjustly delayed with the result that two other generic manufacturers, Novopharm Limited ("Novopharm") and Cobalt Pharmaceuticals Inc. ("Cobalt"), launched their alendronate products essentially simultaneously, thus denying Apotex the*

> *opportunity to establish as permanent market share advantage in advance of any generic competitor.*
> *119 Excerpts from the discovery of Apotex were put in evidence at trial (Exhibit 4) in which there was the following exchange between counsel (Tab 1, pages 21 & 22), Markwell for Merck and Crowfoot for Apotex:*

Mr. Markwell: Sorry, to clarify your last statement. The damages that flow from those losses at law, what do you mean by that?

Mr. Crowfoot: Well, the damages that flow from that period because they were kept off the market during that period. The damages may incorporate things like lost market share which is a present value calculation.

Mr. Markwell: So it's not correct, then that your loss is restricted to the 16-month period, that it could be for the longer period of time?

Mr. Crowfoot: No, the losses in respect of the 16-month period being off the market. The calculation of that loss may involve the present value calculation of a lesser market share than Apotex otherwise would have had.

Mr. Markwell: During those 16 months or beyond those 16 months?

Mr. Crowfoot: The loss of market share occurs once they enter the market, and they only have an X percent market share instead of a Y percent market share. That loss is incurred as of the date that they entered the market because they cannot acquire the market share they should have. So the losses still occurred within the period, but calculating it may involve looking forward.

Mr. Markwell: So what would be the time frame for those future losses?

Mr. Crowfoot: The loss of market share would be perpetual, but it's the present value calculation that are the further out you get, the less financial impact it has. It's all a matter of expert evidence. I don't know how long it would be.

Mr. Markwell: So it's Apotex's position that there may, in fact, be a perpetual loss that would be calculated as of the date of the Notice of Compliance taking into account factors that will be subject of expert evidence?

Mr. Crowfoot: Yes.

120 As I understand Apotex's claim, it is saying that during the period from February 3, 2004 to May 26, 2005, the marketplace for this particular product became distorted because two other generics entered the marketplace in that period. Apotex claims that, were it not for Merck's NOC application against Apotex, Apotex could have been first in the marketplace or at least entered the marketplace at about the same time that the other generics did and that Apotex's market share would, thereby, have been larger that it now is. Apotex argues that such lesser market share is a matter that permanently endures and is a matter of permanent loss. The loss, says Apotex, may be quantified by experts at the later trial.

121 I analogize the situation to one of an injury that a person may have suffered by the tortious activity of another person. For instance, a person may be injured in the leg so that, for the rest of that person's life, that person suffers a leg disability. The leg may heal, the person perhaps ought to have sought, but did not, medical attention or remedial therapy. These are matters of quantification and not a matter of injury itself.

[84] The Court of Appeal in 2009 FCA 187 reversed me on this point, writing at paragraphs 97 to 102:

97 No one takes issue with the Federal Court Judge's characterization of the claim made by Apotex in its Further Amended Statement of Claim. The issue is therefore whether the claim as construed by the Federal Court Judge comes within the words of subsection 8(1). This again gives rise to a pure question of statutory interpretation which stands to be reviewed on a standard of correctness.

98 As has already been noted, section 8 in its original form was somewhat obscure (see para. 45 above). The RIAS which accompanied the 1998 amendment to section 8 indicates that the change was brought in order to provide a clearer indication as to the circumstances in which damages can be awarded. In this respect, the amended version of section 8 makes it clear that:

> *[T]he first person "is liable to the second person for any loss suffered during the period*

> *(a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the Court is satisfied on the evidence that another date is more appropriate; and*
>
> *(b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.*
>
> *[...] la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :*
>
> *a) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal estime d'après la preuve qu'une autre date est plus appropriée;*
>
> *b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.*
>
> *[My emphasis]*

99 According to the analysis of the Federal Court Judge, the losses claimed by Apotex were caused during the period since that is when Apotex was prevented from occupying the market and obtaining the market share which, based on its claim, it would otherwise have had. No one takes issue with this reasoning. The question is whether the decrease in sales which occurs in future years as a result of this decreased market share comes within section 8. The Federal Court Judge, by allowing the claim for losses "beyond May 26, 2005" to proceed, answered this question in the affirmative.

100 When regard is had to the broad grant of authority conferred by subsection 55.2(4) of the Patent Act, it seems clear that the measure of the compensation which can be awarded under the PM(NOC) Regulations is a matter within the discretion of the Governor-in-Council. It is also clear that in keeping with the purpose of the PM(NOC) Regulations and the balance which the Patent Act seeks to achieve, a range of compensation was open to the Governor-in-Council in the exercise of this discretion.

101 In this case, we have the advantage of knowing that in 1998 the Governor-in-Council focused on this very issue, and chose to

> *limit the measure of the losses which can be compensated by way of damages to those suffered during the period. No issue of principle flows from this. The Governor-in-Council could have extended the measure of the losses to include those caused during the period, regardless of when they are suffered. However, it did not do that.*
>
> *102 The Governor-in-Council's clearly expressed intent must be given effect to. This excludes compensation for losses occurring in future years since such losses cannot be said to have been suffered during the period. It follows, for instance, that Apotex's entitlement to damages for lost sales resulting from the alleged decrease in its market share must be confined to sales that can be shown to have been lost within the period. In order to be compensated, the losses must be shown to have been incurred during the period. I therefore conclude that the appeal should be allowed on this limited point.*

[85] It is to be noted that in paragraph 101, the Court of Appeal rests its findings on the use of the word "suffered" in section 8 of the *NOC Regulations*, and contrasts "suffered" with "caused". Yet, in paragraph 102, that Court uses neither word; it uses the word "incurred". Justice Snider in her decision released in May of this year, *Apotex Inc v Salofi-Aventis*, 2012 FC 553, supra, declined to award compensation for double ramp-up, based on her view of the Federal Court of Appeal decision, supra. She wrote at paragraphs 265 to 270:

> *265 Apotex claims that it should be entitled to recover an amount that it refers to as a second "ramp-up" or "ramp-up damages". Sanofi submits that Apotex is not entitled to any such recovery.*
>
> *266 In general terms, as I understand it, the term "ramp-up" refers to the period of time that it takes a drug manufacturer after initial approval of its drug to reach its final level of sales. It takes some time to negotiate agreements with pharmacies and distributors, to get formulary listings and to physically get product to drug stores. In the hypothetical world, Apotex would have experienced a ramp-up period for which it does not seek compensation. However, Apotex does seek compensation in respect of its "real world" or "duplicate" ramp-up which it argues was only incurred because of Sanofi's actions.*

267 Mr. Rostant described this "ramp up" during the "Subsequent Loss Period" (i.e. after December 12, 2006) as follows (Exhibit 26 at 33):

> *When Apotex launched Apo-Ramipril in December 2006, there was a "ramp up" period before it earned profits on a fully functional basis ("Ramp Up Period"). After receiving its NOC, Apotex commenced the marketing and sale of Apo-Ramipril, including obtaining formulary listings. Had Apotex commenced sale of Apo-Ramipril at the start of the Initial Loss Period, it would have only experienced the "ramp up" at that earlier date, such that, in the period in December 2006 and following, it would have made its sales on a fully functional basis.*
>
> *... [t]he lost profit associated with the ramp up period in the Subsequent Loss Period is the difference between what Apotex would have sold had it ramped up in the Initial Loss Period and what it sold in the Subsequent Loss Period when it ramped up.*

268 According to the calculations of Mr. Rostant, the lost profits suffered by Apotex during the subsequent ramp-up were $9,205,121. Mr. Hamilton calculated this amount as $7,211,327 (Exhibit 119, Schedule 9).

269 Although the value of the second or duplicate ramp-up period is obviously a loss to Apotex, it is a loss occurring after the Relevant Period. The scope of a claim under s. 8 of the PM (NOC) Regulations was addressed by the Court of Appeal in Alendronate (FCA), above. In that case, Apotex had pleaded that, under s. 8 of the Regulations, it was entitled to damages in respect of "lost sales and permanent market share" (see Alendronate (FC), above at para 118). Most relevant to the question before me, the Court of Appeal held that s. 8 does not include damages for "future losses", such as decreased market share due to delayed entry into the generic market. It is worthwhile repeating the determinative portion of the decision, at paragraphs 99 to 102:

> *[99] According to the analysis of the Federal Court Judge, the losses claimed by Apotex were caused during the period since that is when Apotex was prevented from occupying the market and obtaining the market share which, based on its claim, it would otherwise have had. No one takes issue with this reasoning. The question is whether the decrease in sales which occurs in future years as a result of this decreased*

market share comes within section 8. The Federal Court Judge, by allowing the claim for losses beyond "May 26, 2005" to proceed, answered this question in the affirmative.

[100] When regard is had to the broad grant of authority conferred by subsection 55.2(4) of the Patent Act, it seems clear that the measure of the compensation which can be awarded under the PM(NOC) Regulations is a matter within the discretion of the Governor-in-Council. It is also clear that in keeping with the purpose of the PM(NOC) Regulations and the balance which the Patent Act seeks to achieve, a range of compensation was open to the Governor-in-Council in the exercise of this discretion.

[101] In this case, we have the advantage of knowing that in 1998 the Governor-in-Council focused on this very issue, and chose to limit the measure of the losses which can be compensated by way of damages to those suffered during the period. No issue of principle flows from this. The Governor-in-Council could have extended the measure of the losses to include those caused during the period, regardless of when they are suffered. However, it did not do that.

[102] The Governor-in-Council's clearly expressed intent must be given effect to. This excludes compensation for losses occurring in future years since such losses cannot be said to have been suffered during the period. It follows, for instance, that Apotex's entitlement to damages for lost sales resulting from the alleged decrease in its market share must be confined to sales that can be shown to have been lost within the period. In order to be compensated, the losses must be shown to have been incurred during the period. I therefore conclude that the appeal should be allowed on this limited point.

[Emphasis in original]

270 Apotex argues that the decision of the Court of Appeal in Alendronate (FCA) did not extend to a claim for subsequent ramp-up. I do not agree. The holding of the Court of Appeal is directly applicable to this type of loss. Apotex is claiming for a loss that may have been caused during the Relevant Period but that was not incurred during that time. The claimed loss - however named - falls squarely within the exceptions set out in Alendronate (FCA) and, unfortunately, is not recoverable.

[86] I am not satisfied, particularly given the common view of the accounting experts that, normally, compensation would be made to prevent a double ramp-up loss, that the Court of Appeal had this situation in mind.

[87] However, in the interests of comity and in the expectation of an inevitable appeal regardless how I might decide, I will adopt the view of Justice Snider. I will not allow compensation for double ramp-up.

DEDUCTIONS

a. Agreed Deductions

[88] It is understood that certain deductions must be made from the price that Apotex otherwise would have received for the quantities of product it would have sold in the "but for" world. The parties have agreed to some of them, in particular:

- Prompt payment discount
- Sales returns
- Cost of sales
- Sales Commissions
- Freight and distribution

[89] The parties have arrived at the basis for accounting for these factors, and they require no further discussion in these Reasons.

[90] The parties have not agreed as to two categories of deductions:

- Rebates
- Free goods

[91] I will, therefore, discuss these matters.

b. Rebates

[92] Rebates, sometimes referred to as trade allowances or incentives, are amounts that are paid by the seller, such as a generic drug company, to its purchaser; generally after the goods have been invoiced by the seller to the purchaser. The purchaser would send an invoice to the seller, generally based on a percentage of the price of the goods sold. The purchaser would receive a cheque in the amount invoiced.

[93] While various explanations may be given for this practice, one must be blunt. It is a kick back. The Ontario government, for one, endeavoured in 2006 and later, to regulate this practice and limit the amount to twenty percent (20%).

[94] The practice seems to be a murky one. There seems to be no established figure for the rebates; nor does one particular rebate necessarily, but not inevitably, apply to one particular product and another to another. The rebates seem to be applied collectively to a range of products and vary over time. Much seems to depend on the negotiating strength of the supplier, such as Apotex, and the purchaser, such as a pharmacy chain or purchasing group. Product exclusivity gives

the supplier a stronger hand; non-exclusivity gives the purchaser a stronger hand. Even if there is exclusivity, a supplier may give a rebate in order to build goodwill or in expectation of favourable treatment in other areas. A purchaser who does not get a favourable rebate may seek to exact retribution elsewhere, or later. There is no science or exactitude that can be applied.

[95] In the present situation, several proxies were established. For instance, what were the rebates offered for the 5 mg and 10 mg alendronate tablets? What were the "real world" rebates once Apotex entered the market with its 70 mg tablets? What rebates were given for other drugs, both exclusive and non-exclusive in the "but for" period? In argument, the parties urged that rebates ranging from almost zero (Apotex) to sixty percent (60%) (Merck) were applicable. Here and there in the evidence one can find support for using rebates of five percent (5%) or forty percent (40%) and many other figures.

[96] There is no one correct figure. Undoubtedly, Apotex, in its period of exclusivity, would like to have given little or no rebate. However, other factors, such as customer goodwill or fear of retribution elsewhere, may have resulted in a rebate being given.

[97] Having considered all the evidence, I am satisfied that the most reasonable conclusion as to the level of rebate that Apotex would have given in its period of exclusivity is that level arrived at by Mr. Rosen in Schedule 16 of his Report of August 7, 2012. That figure is [redacted] It is arrived at using several other drugs as proxies. I appreciate that there may have been other drugs as well that could have been used as proxies, but those selected by him are reasonable.

[98] Mr. Hamilton uses Mr. Rosen's figure in some of his calculations, as well. He also uses 40% and 60%, but clearly stated in cross-examination that he did so only because he was instructed by Merck's Counsel to do so. He had no independent basis for selecting these figures.

[99] Turning to the period when Apotex was no longer the exclusive generic, the evidence shows that in the "real world", Apotex gave rebates of [redacted] including free goods. Mr. Rosen's Schedule 16, aforesaid, using proxy drugs, estimated the rebate during the non-exclusive period at [redacted].

[100] Thus, I am faced with a choice; "real world" at [redacted] or proxy drugs in the "but for" world at [redacted] In the exclusive period, I did choose Mr. Rosen's proxy model. It would seem that, in order to be consistent, I should do so again. I will not. I will choose the "real world" figure as being better established as being the most appropriate. Mr. Rosen's figure for the exclusivity period was the best evidence I had for that period. The "real world" figure for the non-exclusive period is the best evidence I have for that period.

[101] Thus, I conclude that the allowance for rebates in the period of Apotex exclusivity should be set at [redacted] of the selling price and at [redacted] of the selling price in the non-exclusive period.

c. Free Goods

[102] Mr. Rosen and Mr. Hamilton disagreed as to what, if any, deduction should be made for the provision of free goods. The figures of [redacted] and [redacted] as stated above, include a provision for free goods.

[103] The difference between these experts boils down to whether the data as provided by Ms. Yoshiki's organization (IMS CDH) did or did not include free goods. Her evidence was that it did not include free goods. For that reason, Mr. Rosen's approach is the correct one.

[104] The percentages set out previously, [redacted] and [redacted] take into account free goods. No further deduction will be taken for free goods.

INTEREST

[105] Apotex claims interest on the sums of money found to be payable to it by Merck in this action. Apotex's accounting expert, Mr. Rosen, calculated interest based on a simple interest rate of 2.8%. Merck's accounting expert, Mr. Hamilton, calculated interest based on the average annual Bank of Canada short-term lending rate.

[106] I was advised by Counsel that the parties had agreed as to the manner in which pre-trial interest is to be calculated. Exhibit P-65 sets out that manner. Pre-trial interest is to be calculated according to what is set out there. That interest shall run to the date of these Reasons

CONCLUSION AND COSTS

[107] I have endeavoured to set out in these Reasons those matters that have been agreed upon by the parties, and to resolve those matters that have remained at issue. The accounting experts for the parties are to collaborate and provide a final figure as to compensation, together with a brief report setting out the calculations made to support the result. While I trust that no matter has been overlooked in these Reasons, and that no matter will still be the subject of disagreement, I may be spoken to as soon as possible if that is not the case. I expect to receive the final figure and report as to calculations within fifteen (15) days.

[108] The parties have asked that I reserve as to the matter of costs. They should keep in mind my earlier Order adjourning the trial date, which addressed some aspects as to costs. There may be other Orders, as well, which made certain dispositions as to costs. The parties are to make brief (5 pages or less) submissions as to costs within ten (10) days following the submission of the report of the accounting experts aforesaid.

JUDGMENT

FOR THE REASONS PROVIDED:

THIS COURT'S JUDGMENT is that:

1. The accounting experts for the parties shall collaborate and produce within fifteen (15) days an agreed upon amount of compensation for Apotex having regard to those matters agreed upon and the findings made in these Reasons. They shall submit a brief Report setting out the basis for their figure. If any matter remains in dispute it shall be identified and I will set out a process for resolving it.

2. The parties shall make submissions as to costs (no more than five pages) within ten (10) days after the submission from the experts as above.

3. Final judgement is reserved until after receipt of the two foregoing matters.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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PLACE OF HEARING:	Toronto, Ontario
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REASONS FOR JUDGMENT AND JUDGMENT:	HUGHES J.
DATED:	OCTOBER 24, 2012

APPEARANCES:

Harry B. Radomski Jerry Topolski Ken Crofoot Ben Hackett	FOR THE PLAINTIFF
Patrick E. Kierans Allyson Whyte Nowak Adam Haller	FOR THE DEFENDANTS

SOLICITORS OF RECORD:

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Norton Rose Toronto, Ontario	FOR THE DEFENDANTS