Federal Court  Cour fédérale

Date: 20130716

Docket: T-1272-97

Citation: 2013 FC 751

BETWEEN:

MERCK & CO., INC. AND
MERCK CANADA INC.

Plaintiffs
(Defendants by
Counterclaim)

and

APOTEX INC. AND
APOTEX FERMENTATION INC.

Defendants
(Plaintiffs by
Counterclaim)

PUBLIC REASONS FOR JUDGMENT
(Confidential Reasons for Judgment released July 5, 2013)

SNIDER J.

I. Introduction

[1] In an action commenced on June 12, 1997, the Plaintiffs sought a declaration that Canadian Patent No. 1,161,380 ('380 Patent) was valid and infringed by the Defendants. On November 14, 2003, the action was bifurcated, meaning that the appropriate damages or accounting of profits would only be determined after the liability phase (Order of Prothonotary

Aronovitch dated November 14, 2003, as amended on November 20, 2003). The liability trial commenced on February 1, 2010 before me and concluded on May 21, 2010. In *Merck & Co v Apotex Inc*, 2010 FC 1265, 91 CPR (4th) 1 [*Liability Reasons*] aff'd 2011 FCA 363, 102 CPR (4th) 321, I found that the '380 Patent was valid and had been infringed by the Defendants and that the Plaintiffs were entitled to their damages rather than to an accounting of profits (*Liability Reasons*, above at para 624). The damages phase of this matter began on April 8, 2013 and concluded on May 3, 2013. During this phase of the proceedings, I heard evidence from four fact witnesses and one expert witness, followed by three days of final argument. These Reasons for Judgment deal with the quantum of damages to be paid to the Plaintiffs.

[2] In brief and for the reasons that follow, I have concluded that the Plaintiffs are entitled to a total damages award of $119,054,327, plus pre-judgment and post-judgment interest, comprised of:

- $62,925,126 as lost profits of Merck Canada Inc. (Merck Canada), in respect of Pre-Expiry Replacement Sales (defined below);

- $51,290,364 as lost profits of Merck & Co. Inc. (Merck US), in respect of Pre-Expiry Replacement Sales;

- [**Redacted**], based on a reasonable royalty calculation, for post-expiry infringing domestic sales; and

- [**Redacted**], based on a reasonable royalty calculation, for infringing export sales.

[3] In addition, I have made the following determinations:

- Merck should not be awarded its lost profits (if any) or a reasonable royalty in respect of Post-Expiry Ramp-up Sales;

- Merck is not entitled to “lost royalties” that would have been earned by Merck and Company, Incorporated (MACI) on additional sales of MEVACOR tablets;

- Apotex’s argument that its non-infringing alternative should be taken into account in assessing damages is rejected; and

- Pre-judgment interest should be calculated at a rate equal to the 1997 Bank Rate plus 1% and post-judgment interest at a rate of 5%.

[4] In these Reasons, unless otherwise expressed, all monetary figures are expressed as Canadian dollars.

II. Table of Contents

[5] For the convenience of the reader, I am including a Table of Contents. The references for each section are to the beginning paragraph numbers.

III. Background

[6] This litigation has a complex context and history. I refer the reader to paragraphs 10 to 16 and 18 to 39 of the *Liability Reasons*, for a more detailed description of the history. By way of short background, Merck US, one of the Plaintiffs in the action, is the named patentee of the '380 Patent, which patent was issued January 31, 1984 and expired on January 31, 2001. The '380 Patent is a product-by-process patent for the anti-cholesterol drug, lovastatin, when made with a micro-organism known as *Aspergillus terreus*. Merck Canada, the successor in interest to Merck Frosst Canada Ltd. and the other Plaintiff in this action, sold lovastatin under the trade name MEVACOR in Canada beginning in 1988, under licence from Merck US. Merck Canada purchased bulk lovastatin (API) from Merck US. Collectively, I refer to Merck Canada and Merck US as “Merck” or the “Plaintiffs”.

[7] In March 1997, Apotex Inc., one of the Defendants in this action, began selling its brand of lovastatin tablets in Canada (Apo-lovastatin). The API for Apo-lovastatin was made either by

Apotex Fermentation Inc. (AFI), the other Defendant in this action, in Winnipeg, Manitoba, or by Qingyuan Blue Treasure Pharmaceuticals Co. Ltd. (Blue Treasure), in China. In these reasons, I will refer to Apotex Inc. and AFI, collectively, as "Apotex" or the "Defendants".

[8] A highly relevant twist to this action is the capability of AFI to manufacture lovastatin API using a non-infringing process (referred to as AFI-4), a process which uses the micro-organism *Coniothyrium fuckelii* rather than *Aspergillus terreus*. In the liability phase of this action, I found that some – but not all – lovastatin API was made using a process (referred to as AFI-1) which infringed the '380 Patent. Specifically, I concluded (see, *Liability Decision*, above at para 638) that the following lots of lovastatin infringed the '380 Patent:

1. all Apo-lovastatin product that was produced by AFI from AFI batch CR0157 (CR0157) manufactured in AFI's facilities in Winnipeg and delivered to Apotex Inc. on December 2, 1996; and

2. all 294 batches of lovastatin produced by Blue Treasure after March 1998 and imported into Canada.

[9] In the end result, Apotex's infringement was significant. Approximately 60% of Apotex's sales made between March 1997 and the expiry of the '380 Patent were sales of infringing lovastatin. Viewed on a volume basis, approximately 71% of the total amount of lovastatin API supplied to Apotex Inc. by AFI was infringing material.

IV. Summary of Parties' Positions

[10] Very helpfully, on the eve of trial, the parties resolved a number of matters which, otherwise, would have required evidence during the trial. The resolved matters were memorialized in the "Streamlining Agreement Re: Certain Facts and Figures" (TX 175 or the Streamlining Agreement) dated March 27, 2013. Some of the key areas of agreement were on the subjects of: (a) the number and timing of sales of infringing and non-infringing Apo-lovastatin; (b) hypothetical profits of Merck US and Merck Canada; (c) the hypothetical MACI Royalty; and (d) the profitability of the AFI-4 process. As required, the specific items of agreement will be referred to in the relevant sections of these reasons.

[11] Merck claims lost profits with respect to three categories of sales:

1. MEVACOR tablets that would have been sold domestically by Merck Canada to replace each and every infringing Apo-lovastatin tablet sold domestically prior to January 31, 2001 (the Pre-Expiry Replacement Tablets or Sales);

2. Lost profits from the sale of lovastatin API that would have been sold by Merck US to Merck Canada to produce the Pre-Expiry Replacement Tablets; and

3. MEVACOR tablets (and related lovastatin API) that would have been sold domestically to replace each and every Apo-lovastatin tablet sold after the '380

Patent expiry during the hypothetical ramp-up period (the Post-Expiry Ramp-up Tablets or Sales).

[12] Merck also claims a royalty in respect of infringing sales that it would not have made, specifically:

1. Infringing Apo-lovastatin tablets sold into the export market prior to and after the '380 Patent expiry (Export Tablets); and

2. Infringing Apo-lovastatin tablets sold domestically after the '380 Patent expired (the Post-Expiry Replacement Tablets).

[13] Merck Canada further requests that its award of lost profits include an amount to reflect an 8.5% royalty payable to MACI. Merck also seeks pre-judgment interest at a rate of at least 5% per annum and its costs.

[14] The total damages claimed by Merck are $156,320,737, plus interest.

[15] In response, Apotex's position can be summarized as follows:

1. In respect of the Pre-Expiry Replacement Tablets, Merck Canada is entitled to:

    a. its lost profits for the CR0157 infringement; and

    b. only a reasonable royalty for the Blue Treasure infringing batches, on the basis that Apotex had available to it a non-infringing alternative;

2. Merck US is entitled to a nominal damages award only, since Merck US had assigned all of its rights to damages to MACI;

3. Merck is entitled to neither lost profits nor a reasonable royalty for the Post-Expiry Ramp-Up Tablets;

4. Apotex agrees with the payment of a reasonable royalty on the Export Tablets, but proposes a lower royalty rate than Merck;

5. Merck is not entitled to an additional recovery in respect of the MACI Royalty; and

6. Pre-judgment interest should be calculated at the Bank Rate in the first quarter of 1997.

[16] Apotex argues that the Merck's total damages should be $9,554,288 (plus a "nominal", unquantified amount to Merck US), together with pre-judgment interest at a rate of about 3.3% and post-judgment interest at a rate of 5%.

V. Issues

[17] Although the parties reached agreement on some of the underlying facts and relevant evidence from the liability phase was incorporated into this phase, a number of issues have endured.

1. In calculating Merck Canada's damages, are the Defendants able to raise the defence that they had a non-infringing alternative; that is, from March 1997, Apotex could have used the AFI-4 process to manufacture sufficient quantities of lovastatin to supply the Canadian market and, therefore, Merck Canada is only entitled to a reasonable royalty with respect to the Pre-Expiry Replacement Tablets?

2. If I agree that Apotex is able to raise its non-infringing alternative (NIA) defence and a reasonable royalty only is payable with respect to sales lost by Merck, what should that reasonable royalty be?

3. If I find that Apotex cannot rely on its NIA defence and the Plaintiffs are entitled to an award of lost profits (rather than a reasonable royalty):

    a. Is Merck entitled to lost profits for the Post-Expiry Ramp-Up Sales, due to the fact that Apotex did not require a “ramp-up” period to reach its ultimate market share?

    b. Using a differential accounting method of lost profits, should Merck Canada’s lost profits be reduced to account for the MACI Royalty?

4. In a calculation of Merck US’s lost profits:

    a. Is Merck US entitled to anything other than nominal damages because of its assignment of certain rights in the '380 Patent to MACI?

    b. If Merck US is entitled to recover its lost profits for sale of API to Merck Canada, should those damages be reduced in view of sales of API that would have been made to Merck Canada by Merck Sharpe & Dohme Quimica (Quimica) and, if so, at what level?

5. Since Merck agrees that they would not have captured export sales of lovastatin during the infringement and post-expiry sales made with infringing, stockpiled

API, what "reasonable royalty" would be applicable to those infringing sales made by Apotex?

6. At what level should Merck be awarded pre-judgment interest and post-judgment interest?

7. What principles should apply to any award of costs?

VI. Witnesses

[18] As mentioned above, only four fact witnesses and one expert witness testified at the trial.

A. *Merck Witnesses*

[19] Merck presented the following three witnesses.

[20] Mr. Kirk Duguid is presently the Vice President of Finance for Merck Canada (2T112-113). In November-December of 1996, Mr. Duguid was Director of Financial Planning and Analysis, responsible for financial planning and assisting with sales forecasts (2T113-114). Mr. Duguid testified about Merck's long-range marketing plan for MEVACOR in 1996. He also reviewed invoices relating to purchases of API by Merck Canada from Merck US and Quimica. Lastly, Mr. Duguid described the payment of royalties to MACI.

[21] Mr. Barry O'Sullivan is an Executive Director with the Corporate Tax Department of Merck US (2T212-213). He is responsible for worldwide physical and financial supply chain planning, inter-company licensing, funding of research and development, international inter-company transfer pricing and coordination of tax planning in Canada and Mexico. Mr. O'Sullivan testified about the physical supply chain for MEVACOR API and discussed the MACI Royalty.

[22] Mr. Joseph Promo is the assistant treasurer responsible for international treasury services for non-US subsidiaries of Merck US (3T443-444). Mr. Promo testified about Merck's weighted average cost of capital (WACC) and the use of WACC to decide whether a transaction is beneficial for the company. Mr. Promo also discussed Merck's long-term debt.

[23] Merck also presented one expert, Dr. Christine S. Meyer. Dr. Meyer was qualified as an expert to opine on "economic issues related to the determination of a reasonable royalty as a result of a hypothetical royalty negotiation" (2T238-241). The Court also accepted that this expertise includes applicable bargaining theory (2T241-243).

[24] Dr. Meyer explained economic principles relating to a hypothetical royalty negotiation, including potential costs and benefits to both Merck and Apotex. She set the hypothetical negotiation in November 1996, assuming that the patent was valid and infringed and that the parties provide each other with accurate information.

B. *Apotex Witness*

[25] Apotex presented only one fact witness (and no experts) to the Court. Specifically, Dr. Bernard Sherman was presented as a fact witness. Dr. Sherman is the Chairman of Apotex (5T506-507). He testified about the acquisition by Apotex of the company that later became AFI and the decision to outsource lovastatin production to Blue Treasure. Dr. Sherman also discussed his knowledge of infringement by AFI and Blue Treasure and what he would have done had he known about the infringement taking place. He also testified about the NOC proceedings and the AFI-4 process.

VII. Lost Profits of Merck Canada

[26] As I determined at the liability phase of the trial, Merck is limited to a claim of damages under s. 55(1) of the *Patent Act*, RSC 1985, c P-4 [*Patent Act*]. Section 55(1) provides that:

55. (1) A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.	55. (1) Quiconque contrefait un brevet est responsable envers le breveté et toute personne se réclamant de celui-ci du dommage que cette contrefaçon leur a fait subir après l'octroi du brevet

I will deal first with the claim of Merck Canada.

[27] Merck Canada claims that the infringement by Apotex led to lost profits that Merck Canada would have earned from the sale of MEVACOR tablets in the amount of $73,303,319.

This amount consists of $62,925,126 for the lost profits that Merck Canada would have earned if it had replaced each and every infringing Apo-lovastatin tablet sold domestically prior to January 31, 2001 (the Pre-Expiry Replacement Tablets). Merck Canada also claims that its damages award should include an additional amount of $10,378,193 to reflect the MACI Royalty.

[28] The parties have agreed that the profits that Merck Canada would have earned if it had sold the Pre-Expiry Replacement Tablets, incorporating a deduction for the MACI Royalty, are $62,925,126 (Streamlining Agreement at para 6). Underlying this final figure is an acknowledgment by the Defendants that they will not contest a host of questions with respect to the "but for" world. Settlement has been reached on the following issues: the volume of sales that would have been made by Merck Canada; the capacity of Merck Canada to manufacture the required MEVACOR tablets; and the appropriate accounting treatment of hypothetical gross sales revenues.

[29] There are two points of disagreement:

(a) whether the availability of Apotex's AFI-4 process (a non-infringing alternative or NIA) results in a finding that Merck Canada is only entitled to a reasonable royalty on the lost sales rather than its lost profits; and

(b) how or whether to account for the MACI Royalty agreed to be in the amount of $10,378,193 (Streamlining Agreement at para 8).

[30] In this section of the Reasons, I will consider only Merck's claim to $62,925,126 and Apotex's defence of a non-infringing alternative. The question of Merck's entitlement to the MACI Royalty amount is dealt with in Section VIII of these Reasons.

[31] In dealing with this issue, I have organized my analysis with regard to the following questions:

1. What are Apotex's submissions with respect to the NIA defence?

2. What are Merck's submissions with respect to the NIA defence?

3. What are the general principles of damages?

4. What are the key differences between "damages" and an "accounting of profits"?

5. What was the "causation" of Merck Canada's losses?

6. What is the state of the law of Canada on the NIA defence? This analysis requires me to examine the law of the United Kingdom upon which, at least thus far, Canadian law appears to be based.

7. Has Canadian law on the NIA defence changed or should it change because:

   a. The Supreme Court of Canada, in *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902 [*Monsanto/Schmeiser*], changed the law of damages;

   b. Courts in the United States have long recognized consideration of all competition the patentee would have faced but for infringement, including competition from the infringer;

   c. Recent legal commentary by Professor Norman Siebrasse has urged the adoption of the NIA defence; or

   d. The NIA defence has been accepted by the Federal Court in the context of damages assessed pursuant to s. 8 of the *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133 [*PM (NOC) Regulations*]?

8. Are there policy reasons to reject (or accept) the NIA defence in the context of Merck Canada's claim for lost profits?

A. *Apotex's Submission*

[32] Apotex submits that Merck Canada should not be awarded its lost profits with respect to the Pre-Expiry Replacement Tablets. Rather, Apotex urges the Court to conclude that, except for those tablets that formed part of the infringing batch CR0157, Merck Canada is only entitled to a reasonable royalty because Merck Canada cannot show that its damage was sustained "by reason of the infringement".

[33] The basis of this argument is that, commencing in March 1997, the "but for" analysis should take into account that Apotex had available to it a non-infringing alternative or NIA in the form of the AFI-4 process. Apotex used the NIA for about 40% of its sales in Canada during the period of infringement. From March 26, 1997 – the date that Apotex received its NOC – Apotex had the regulatory approval, the capacity and the physical capability to produce all of the tablets that it sold in Canada by the non-infringing AFI-4 process. It follows, submits Apotex, that Merck Canada has not demonstrated that its loss was caused by the use of the AFI-1 process by Apotex and is limited to a reasonable royalty on the Pre-Expiry Replacement Sales. This royalty should be assessed as an equal sharing of the difference in the cost of producing tablets with the infringing AFI-1 process and the non-infringing AFI-4 process. Rather than the $62,925,126 of lost profits claimed by Merck Canada, Apotex believes that the appropriate damages award should be (a) lost profits of $521,641 on the CR0157 tablets; and (b) a reasonable royalty of $6,997,270 on the balance of the Pre-Expiry Replacement Tablets.

B. *Merck's Position*

[34] Merck asserts that the NIA defence is only available to Apotex if the answers to all of the following questions are in Apotex's favour (Merck's Final Written Argument at para 68):

> 1. Is it more likely than not that the Defendants would have made and sold non-infringing Apo-lovastatin tablets in place of the infringing tablets?
>
> 2. Having breached its undertaking not to infringe, can the Defendants ask to have damages assessed as if they had honoured the undertaking, or is there some consequence – even a grave consequence – associated with the breach that bars the defence?
>
> 3. Even if the Defendants would have used AFI-4 in a hypothetical world, and even if grave consequences or breach of undertaking do not prevent the defence from being raised in this case, does the NIA defence exist as a matter [of] law?
>
> 4. Even if the law is changed to permit the NIA defence, was Apotex's non-infringing alternative "available" in fact?
>
> (Emphasis omitted.)

[35] The response to question 3 – the existence of the NIA as a matter of Canadian law – is determinative and, on that basis, Apotex's argument should be rejected. I do not need to consider the other arguments of Merck.

[36] However, if I had to decide those other questions, in my view, all three would be answered in the affirmative.

[37] The complete response to questions 1 and 4 is that the matter has been settled by the Streamlining Agreement. The agreement clearly states at paragraph 19 that the Defendants had the capacity to manufacture and sell non-infringing lovastatin in sufficient quantities from the time Apotex received its NOC on March 26, 1997 and at all times thereafter. Paragraph 19 of the Streamlining Agreement goes on to state that the agreement "does not affect or limit the Plaintiffs from arguing or leading evidence that uncertainty existed regarding the ability of the Defendants to meet the market demand for lovastatin with non-infringing lovastatin tablets formulated using lovastatin API made using the AFI-4 process at the AFI plant in Winnipeg" and that the Defendants abandoned any argument that they would have had other suppliers. However, in my view, these statements are relevant to the uncertainty of Apotex upon entering into a hypothetical negotiation for a reasonable royalty prior to March 26, 1997 and do not relate to Apotex's actual capacity once it obtained its NOC on that date.

[38] With respect to question 2, I agree that Apotex breached the undertaking in its initial Notice of Allegation under the *PM (NOC) Regulations*. Apotex gave an undertaking that it would not infringe the '380 Patent and, at the end of the day, approximately 60% of its sales of Apo-lovastatin during the life of the patent were infringing. I further agree with Merck that, in light of the breach of the undertaking, "grave consequences" may flow. This notion was discussed by the Federal Court of Appeal in *Hoffman-La Roche Ltd v Canada (Minister of National Health and Welfare)*, (1996), 70 CPR (3d) 206 at 213, 205 NR 331 (FCA) [*Hoffman-La Roche*] in which the Court stated:

> I have no doubt, nevertheless, that such an allegation is intended to be accurate. Once a second person's product reaches the market the first person is in a position to test the accuracy of the detailed

> statement; if it were shown to be inaccurate, the consequences for a second person could well be very grave indeed.

[39] The question, however, is whether this concept, which was clearly intended to apply in the setting of the *PM (NOC) Regulations*, should be transferred from that highly specialized legislative framework to the construction of a hypothetical "but for" world in the calculation of patent infringement damages. The facts of this case are unique, since an NOC was issued without an evaluation of the merits of an NOC proceeding. I think it dangerous and unhelpful to apply Apotex's undertaking across the two cases.

[40] The availability of the NIA defence at law is therefore the determinative question.

C. *General Principles of Damages*

[41] In *Jay-Lor International Inc v Penta Farm Systems Ltd*, 2007 FC 358 at para 123, 59 CPR (4th) 228 [*Jay-Lor*], I set out a series of principles which, in my view, applied where an assessment of damages under s. 55(1) of the *Patent Act* was to be made. I remain of the opinion that these principles are applicable to the determination of Merck's damages. The more significant of those guiding principles are as follows:

1. An award of damages seeks to compensate the plaintiff for any losses suffered by the plaintiff as a result of the infringement;

2. The profits made by the defendant are irrelevant;

3. Every sale of an infringing product is an illegal transaction for which the plaintiff is entitled to recover damages;

4. In assessing the award, the plaintiff is entitled to the profits on the sales it would have made but for the presence of the infringing product in the market;

5. For those sales made by the defendant that the plaintiff patentee would not have made or cannot persuade the Court it would have made but for the presence of the infringing product, the plaintiff is entitled to a reasonable royalty; and

6. The plaintiff bears the burden of proving: (a) the sales that it would have made but for the presence of the infringing product; and (b) what a reasonable royalty would be.

[42] Many facts of this case are either undisputed or have been addressed in the Streamlining Agreement. The parties agree that Apotex and Merck Canada were the only sources of lovastatin in Canada during the period in question (March 27, 1997 to January 31, 2001) and Merck Canada had the capacity to satisfy the lovastatin market. Thus, the infringing lovastatin tablets sold by Apotex in Canada, referred to as the Pre-Expiry Replacement Tablets, would have been sold by Merck Canada. Without Apotex's infringement through use of the AFI-1 process, Merck Canada would have made profits from the sale of such lovastatin tablets and Merck US would have made profits off lost sales of lovastatin API to Merck Canada.

[43] The evidence is clear that Merck does not, as a general practice, license the use of its inventions (2T122-123). Accordingly, both Merck Canada and Merck US would be entitled to their lost profits in respect of the Pre-Expiry Replacement Sales (see, for example, *Jay-Lor*, above at para 119).

[44] The parties agree on the general approach described above as it applies to the Pre-Expiry Replacement Tablets, but part company with respect to the relevance of Apotex's non-infringing AFI-4 process.

D. *Damages vs Accounting of Profits*

[45] Notwithstanding Apotex's efforts to argue the contrary, an award of damages differs fundamentally from an accounting of profits. Damages are a statutory right embedded in the *Patent Act*. A wronged patentee is entitled to damages as a matter of right.

[46] The key difference between the two remedies is the focus or starting point of the assessment. A claim for damages focuses on the plaintiff's loss. What loss did the plaintiff suffer from the unauthorized use of the invention by the defendant? On the other hand, an accounting of profits looks at the benefit or advantage that a defendant derived from the use of the invention. As described in the United States Supreme Court in *Mowry v Whitney*, 81 US 620 at 651, 20 L Ed 860 (1871), a case involving a claim for an accounting of profits for the infringement of patent for an improved method of manufacturing rail-car wheels:

> The question to be determined in this case, is what advantage did the defendant derive from using the complainant's invention over

> what he had in using other processes then open to the public and adequate to enable him to obtain an equally beneficial result. The fruits of that advantage are his profits.

[47] An accounting of profits is an equitable remedy only available upon election by a plaintiff and with the discretion of the Court. In *Laboratoires Servier v Apotex Inc*, 2008 FC 825 at paras 503-504, 67 CPR (4th) 241 [*Perindopril*], aff'd on other grounds 2009 FCA 222, 75 CPR (4th) 443, I described the difference as follows:

> While both damages and accounting of profits are intended to provide compensation to a wronged plaintiff, the fundamental principles underlying the two remedies and the practical considerations are substantially different.
>
> The object of an award of damages is to make good any loss suffered by the plaintiff as a result of the defendant's infringement of the patent. Quantification of the award is based on the losses suffered by the plaintiff; any gains realized by the defendant because of its wrongdoing are not relevant. On the other hand, an accounting of profits is based on the premise that the defendant, by reason of its wrongful conduct, has improperly received profits which belong to the plaintiff. The objective of the award is to restore those actual profits to their rightful owner, the plaintiff, thereby eliminating whatever unjust enrichment has been procured by the defendant. Calculation is based on the profits wrongfully gained by the defendant; any other losses suffered by the plaintiff are irrelevant.

[48] An accounting of profits originated in equity, although the *Patent Act* now refers to this remedy. As set out in s. 57(1)(b) of the *Patent Act*, a judge may, on application of the plaintiff, make an order "for and respecting inspection or account". The fact that the remedy is referred to in the *Patent Act* does not, as suggested by Apotex, change the remedy into a statutory remedy. It is an equitable remedy and remains so. On this basis, and as explained in further detail below, the extrapolation of principles governing accounting of profits to the statutory remedy of patent infringement damages is often inappropriate.

E. *Causation*

[49] In the context of an award of damages, a plaintiff may only be compensated for losses which, on a common sense view of causation, are caused by the infringement (see, for example, *Canson Enterprises Ltd v Boughton & Co*, [1991] 3 SCR 534 at 556, 85 DLR (4th) 129 (McLachlin J, as she then was, quoted with approval in *Monsanto/Schmeiser*, above at para 101)). The purpose of a compensatory remedy is to place a plaintiff in a position that he or she would have occupied but for the wrongful act. It would be inappropriate to award compensatory damages that place the plaintiff in a better position (*Athey v Leonati*, [1996] 3 SCR 458 at 472, 140 DLR (4th) 235 [*Athey*]).

[50] Merck submits that Merck Canada's lost profits were caused by Apotex's infringement of the '380 Patent. Stated differently, Merck asserts that but for the infringement by Apotex, it would have sold all of the Pre-Expiry Replacement Tablets and is entitled to lost profits in respect of each and every tablet.

[51] Apotex asks me to reject this conclusion on the basis of its non-infringing alternative, drawing analogies to jurisprudence in the matters of tort and breach of confidence. In spite of its infringement and in spite of Merck Canada's demonstrated lost profits, Apotex argues that Merck cannot prove that Merck Canada would have made those sales in the "but for" scenario because Apotex had available to it a different and non-infringing alternative. However, the legal principles highlighted by Apotex are irrelevant to the present circumstances.

[52] First, causation was considered in the *Liability Reasons*, where I found that Merck's lost sales were not recoverable where Apotex actually used the non-infringing AFI-4 process. Merck's losses during the 1996 to 2001 period exceed those claimed, since Merck Canada's lost sales during that period were due, in part, to the sales by Apotex of non-infringing Apo-lovastatin tablets; that is, Apo-lovastatin made by the AFI-4 process. Merck Canada does not claim that that it would have made those sales but for the infringement of Apotex. In other words, from a common sense view, these lost profits were not caused by Apotex's infringement and, therefore, cannot be recovered. The "causation" in issue is limited to the Pre-Expiry Replacement Sales.

[53] Second, principles of causation cannot support the relevance of a non-infringing alternative to an award of damages. The Supreme Court acknowledged in *Monsanto/Schmeiser*, above at para 101, that all non-punitive remedies are governed by a "common sense view of causation". However, in its discussion of accounting of profits, the Supreme Court considered the non-infringing alternative to be relevant to the quantification of the award only, after causation has already been proved. Apotex inaccurately conflates causation, which must be proven first, and the subsequent quantification of the remedy.

[54] Third, causation in the context of tort law is directed to the original position of the plaintiff and, therefore, tort law cannot provide support for Apotex's argument that its own (the Defendants') hypothetical actions are relevant. Tort law focuses on the existence of a relationship connecting the actions of the defendant to the harm the plaintiff suffered (*Clements v Clements*, 2012 SCC 32 at paras 6-10, 46, [2012] 2 SCR 181 [*Clements*]). As such, tort law will

not hold a defendant responsible for circumstances that change the plaintiff's original position in a manner that is completely unconnected to the defendant's conduct (*Athey*, above at 472-474; see also, *Clements*, above at para 40). The actions of Apotex, liable for infringement in this case, are not analogous to factors independent of the wrong that are inherent in Merck's initial position. Tort law is not concerned with whether the defendant could or would have acted differently in a "but for" world where no wrongful conduct occurred.

[55] Fourth, *Cadbury Schweppes Inc v FBI Foods Ltd*, [1999] 1 SCR 142, 167 DLR (4th) 577 [*Cadbury*], relied upon by Apotex, is a case concerning breach of confidence that is inapplicable to the present circumstances. Justice Binnie recognized that remedies for breach of confidence are *sui generis*, drawing on the flexibility of equitable principles as well as available remedies in many areas of law, including contract, tort, property and trust (*Cadbury*, above at paras 26-28). Further, Justice Binnie stated that it would be inappropriate to allow the plaintiff to receive patent remedies for breach of confidence, since the requirements for a patent may not be met, public disclosure does not occur and a trade secret can last far beyond the duration of a patent (*Cadbury*, above at paras 46-48). In particular, the confidential information, relating to juice formulation, was characterized as "nothing very special", involving no inventive step whatsoever (*Cadbury*, above at paras 48, 65). Therefore, the unique nature of remedies for breach of confidence, informed by equitable principles and the particular facts of the *Cadbury* case, preclude application of this case to statutory patent infringement damages.

[56] In sum, I reject Apotex's arguments regarding causation and conclude that Merck Canada's lost profits for the Pre-Expiry Replacement Sales were caused by Apotex's

infringement. Based on the record before me, Merck would have sold every one of the Pre-Expiry Replacement Sales if Apotex had not infringed the '380 Patent. I reach this conclusion based on a common sense view of causation, the current state of Canadian law and a rejection of Apotex's NIA defence.

F. *Canadian Law on the NIA Defence*

[57] Putting aside Apotex's arguments, for the moment, the current state of Canadian law is that the existence of a non-infringing alternative is not relevant to an assessment of damages. This tenet of Canadian law dates back to the House of Lords decision in *The United Horse Shoe and Nail Company, Limited v Stewart and Company* (1888), 5 RPC 260, 13 App Cas 401 (HL) [*United Horse Shoe*], which, in my view, remains good law in Canada. So, I begin with a review of the law of the United Kingdom, where the statutory provision for damages is similar to that of Canada.

[58] *United Horse Shoe* involved a claim for damages by United Horse Shoe and Nail Company, Limited (referred to as the Pursuers or the Appellants) for infringement by Stewart and Company (referred to as the Respondents or the Defenders) of a number of patents for improvements in the making of nails by the use of particular machinery. As set out by the Lord Chancellor, Lord Halsbury, in his judgment:

> The actual infringement complained of consists in the sale of cases of nails produced by patent machines, which are admitted to be infringements of the Pursuers' patents. Every nail thus produced was an infringement of the Pursuers' patents . . .
>
> (*United Horse Shoe*, above at 264.)

[59] The Defenders asserted that the Pursuers were entitled to nominal damages, because they might have produced the nails without infringing the Pursuers' patent rights.

[60] All three lords – The Lord Chancellor, Lord Watson and Lord Macnaghten – rejected this argument. Lord Halsbury described the situation in the following terms:

> I think it is nothing to the purpose to show, if it is shown, that the Defenders might have made nails equally good, and equally cheap, without infringing the Pursuers' patent at all. I will assume that to be proved, but if one assumes that the nails which were, in fact, made by the pirated machines injured the Pursuers' sales, what does it matter if it is ever so much established that the loss which the Pursuers have sustained by the unlawful act of the Defenders might also have been sustained by them under such circumstances as would give the Pursuers no right of action?
>
> Your Lordships had to deal with the facts as they exist, and those facts, as I say, are that the Defenders have in derogation of the Pursuers' rights sold cases of nails which they had no right to sell, and for which to the extent to which they have interfered with the sale of the Pursuers' patented nails, the Pursuers are entitled to damages.
>
> (*United Horse Shoe*, above at 264-265.) [Emphasis added].

[61] Lord Macnaghten summarized the issue as follows:

> It appears to be beside the mark to say that the Respondents might have arrived at the same result by lawful means, and that, without infringing the Appellants' rights, they might have produced a nail which would have proved an equally dangerous rival of the Globe nail. The sole question is, what was the loss sustained by the Appellants by reason of the unlawful sale of the Respondents' nails?
>
> (*United Horse Shoe*, above at 268.)

[62] It is interesting to observe that the Lords, in their judgments, very carefully questioned various factors which affected the Pursuers' lost profits. The amount recoverable against the

Defenders was limited to the "amount of damages as the Pursuers can establish to have been sustained by the infringement of the patent right" (*United Horse Shoe*, above at 264). For example, Lord Watson referred to the fact that "all legitimate competition to which [the Appellants] would have been exposed" [emphasis added] (*United Horse Shoe*, above at 267) must be taken into account. In addition, Lord Watson opined that the Appellants had failed to establish loss after the Respondents' illegal actions ceased (*United Horse Shoe*, above at 268).

[63] *United Horse Shoe* was not a one-off. In *Catnic Components Ltd v Hill & Smith Ltd*, [1983] FSR 512 (Pat Ct) [*Catnic*], Justice Falconer rejected the argument of the defendants that "[i]f the defendants had not made and sold infringing lintels they would have made and sold non-infringing lintels" (*Catnic*, above at 524). In holding that this argument was "not open to the defendants in law", Justice Falconer stated as follows (*Catnic*, above at 524-525):

> The *United Horse Shoe and Nail Company* case . . . is authority for the proposition that an infringer is barred from defeating a plaintiff patentee's claim for damages for loss of profits by saying: "Yes, I infringed but I could have taken this market from you by not infringing." Much of Mr. Gatwick's address on the "loss of profits" part of the claim was devoted to, and much of the defendants' evidence directed to, this argument, but as in my view the argument is wrong in law the evidence directed to it is irrelevant and I need not consider it further.
>
> [Emphasis added.]

[64] The same conclusion was reached by Justice Jacob (as he then was) in *Gerber Garment Technology Inc v Lectra Systems Ltd*, [1995] RPC 383 (Pat Ct) at 405-406 [*Gerber*], rev'd on other grounds [1997] RPC 443 (CA). At pages 394, 405-406, Justice Jacob explained the issue as follows:

> Sometimes defendants have sought to evade substantial liability by contending that they could have avoided infringement, for instance by using some other equally efficacious but non-infringing device. They suggest that they could have inflicted the same economic "injury" by lawful competition. The courts have consistently rejected this approach. The rejection follows from the compensation principle. One is concerned with compensation for what the defendant has done by acting "improperly".
>
> . . .
>
> Lectra [the defendant] also argued that they should be treated as if they had "acted properly, instead of acting improperly" . . .; that they should be treated as one who "properly" undertook to take and then took a licence. But it is well settled that one does not consider what the position would be if the defendant had achieved the same effect by an alternative, non-infringing means. That applies as mush to seeking a licence as to using an alternative, non-infringing device. "Acting properly" means no more than not having infringed; it does not mean adopting some alternative course inflicting the same economic "damage" but without infringement.
>
> [Emphasis added.]

[65] Similar remarks were made by Justice Kitchin in *Ultraframe (UK) Limited v Eurocell Building Plastics Ltd*, [2006] EWHC 1344 (Pat) at para 93 [*Ultraframe*]. As Lord Justice Jacob would no doubt say, further citations on this principle would be otiose (see *Gerber*, above at 394).

[66] The facts and arguments of all of these cases bear remarkable similarity to the case before me in this trial. Like the Respondents in *United Horse Shoe,* Apotex had the possibility of producing "an equally dangerous rival" – Apo-lovastatin – by "lawful means" – the AFI-4 process. Like the Respondents in that case, Apotex did not use the AFI-4 process but "pirated" Merck's property in the '380 Patent without consent or licence. Just like the defendants in *Catnic*, Apotex argues, "Yes, I infringed but I could have taken this market from you by not infringing".

[67] Apotex acknowledges the state of UK law on this question. However, Apotex submits that the law in the United Kingdom is evolving. In support of this proposition, Apotex refers to the decision of Lord Justice Aldous in *Coflexip SA v Stolt Offshore MS Limited*, [2003] EWCA Civ 296. This case involved a patent for a device for the laying of flexible pipe at sea. The issue before the Supreme Court of Judicature Court on Appeal (Civil Division), on appeal from Justice Jacob (as he then was), was a matter of the pleadings. In the course of argument, counsel for the defendants raised the question of the relevance of a non-infringing alternative and the approach to this question in the United States (citing *Panduit Corp v Stahlin Bros Fibre Works, Inc,* 575 F2d 1152 (6th Cir 1978) [*Panduit*], discussed below). Lord Justice Aldous opined, at paragraph 41, that:

> Despite the interesting submission on US law, it is not right at this stage of the enquiry to doubt the correctness of the United Kingdom cases. When the facts are found then perhaps guidance from [United States case law] could be of assistance.
>
> [Emphasis added.]

[68] Ultimately, the case never went to trial. I decline to accept one line from a pleadings motion decision and elevate it to a conclusion that UK law has changed or is about to change.

Moreover, this case was decided three years before *Ultraframe*, above, in which the Court unequivocally followed the *United Horse Shoe* line of cases.

[69] In sum, the law of the United Kingdom is clear and unequivocal; the non-infringing alternative defence is wrong at law.

[70] The reasoning of *United Horse Shoe* has been considered and followed in Canada in at least one decision of our court and referred to in another.

[71] The first of these cases is *Domco Industries v Armstrong Cork Canada Ltd* (1983), 76 CPR (2d) 70 at 74, [1983] FCJ No 1182 (FC, Preston Proth) [*Domco (FC Proth)*], rev'd on other grounds, (1986), 10 CPR (3d) 53 (FCTD, Collier J) [*Domco (FCTD)*]. The relevance of non-infringing alternatives was rejected by both Prothonotary Preston and Justice Collier. The defendants argued that damages should be reduced because, instead of infringing the plaintiff's patents, the defendants could have sold an existing non-infringing alternative, or could have developed a new non-infringing process, or could have avoided infringement altogether by obtaining a licence (*Domco (FC Proth)*, above at 73, 81-82). The Referee acknowledged these propositions but ultimately concluded that all such potential non-infringing alternatives were completely irrelevant:

> Armstrong infringed the patents and the argument <u>that they could have taken a licence or sold a non-patented product is irrelevant in the light of what actually happened</u>, and tends to obfuscate the main issue of the continued infringement by the defendant.
>
> (*Domco (FCTD)*, above at 91.) [Emphasis added.]

[72] The fact that the defendant already possessed and had marketed an existing non-infringing alternative (*Domco (FC Proth)*, above at 82) did not alter the Court's approach in rejecting the relevance of such alternatives.

[73] Although the issue of a non-infringing alternative was not raised in *Jay-Lor*, during a discussion of general principles, I cited, with approval, the conclusions stated in *Domco (FC Proth)* (*Jay-Lor*, above at para 115).

[74] Admittedly, the Canadian cases which refer to and apply *United Horse Shoe* may not constitute the highest authority. However, *Domco (FCTD)* has never been overturned. This may simply be a reflection that the law is so obvious and settled that there is nothing to be said. If this Canadian case law can be described as sparse, jurisprudence to support the position of Apotex is non-existent. There is not a single Canadian case that applies a non-infringing alternative defence to an award of damages.

[75] In sum, Canadian law reflects the jurisprudence of the United Kingdom and results in a rejection of the NIA defence. In other words, under current Canadian law of damages, the fact that Apotex had available to it (but did not use) a non-infringing alternative is irrelevant to a calculation of damages.

[76] I turn now to Apotex's submissions on how that law has changed (or, alternatively, should change).

G. *Evolution of the Law According to Apotex*

(1) *Monsanto/Schmeiser*

[77] Apotex argues that the case of *Monsanto/Schmeiser* effectively and completely changed the law of damages and provides authority for its position. I do not agree.

[78] In *Monsanto/Schmeiser*, the trial judge found that Mr. Schmeiser had infringed the patent in issue (use of Roundup Ready Canola) and awarded Monsanto an accounting of profits quantified at $19,832 (*Monsanto/Schmeiser*, above at para 98; *Monsanto Canada Inc v Schmeiser*, 2001 FCT 256 at paras 133-140, 12 CPR (4th) 204). This award was upheld on appeal (*Monsanto Canada Inc v Schmeiser*, 2002 FCA 309 at paras 72-74, 78-87, [2003] 2 FC 165. The Supreme Court overturned this aspect of the lower courts' decisions and awarded Monsanto nothing in respect of Mr. Schmeiser's lost profits (*Monsanto/Schmeiser*, above at paras 101-105).

[79] The decision of the majority of the Supreme Court differentiated a claim of damages from a claim for profits:

> The *Patent Act* permits two alternative types of remedy: damages and an accounting of profits. Damages represent the inventor's loss, which may include the patent holder's lost profits from sales or lost royalty payments. An accounting of profits, by contrast, is measured by the profits made by the infringer, rather than the amount lost by the inventor. Here, damages are not available, in view of Monsanto's election to seek an accounting of profits.
>
> (*Monsanto/Schmeiser*, above at para 100.)

[80] The Supreme Court's analysis of the issue of calculation of damages occupied a mere five paragraphs. Because of the importance that the Defendants place on this decision, I reproduce the entire discussion from the decision, at paragraphs 101 to 105:

> 101 It is settled law that the inventor is only entitled to that portion of the infringer's profit which is causally attributable to the invention: *Lubrizol Corp. v. Imperial Oil Ltd.*, [1997] 2 F.C. 3 (C.A.); *Celanese International Corp. v. BP Chemicals Ltd.*, [1999] R.P.C. 203 (Pat. Ct.), at para. 37. This is consistent with the general law on awarding non-punitive remedies: "[I]t is essential that the losses made good are only those which, on a common sense view of causation, were caused by the breach" (*Canson Enterprises Ltd. v. Boughton & Co.*, [1991] 3 S.C.R. 534, at p. 556, per McLachlin J. (as she then was), quoted with approval by Binnie J. for the Court in *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142, at para. 93).
>
> 102 The preferred means of calculating an accounting of profits is what has been termed the value-based or "differential profit" approach, where profits are allocated according to the value contributed to the defendant's wares by the patent: N. Siebrasse, "A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms" (2004), 20 C.I.P.R. 79. A comparison is to be made between the defendant's profit attributable to the invention and his profit had he used the best non-infringing option: *Collette v. Lasnier* (1886), 13 S.C.R. 563, at p. 576, also referred to with approval in *Colonial Fastener Co. v. Lightning Fastener Co.*, [1937] S.C.R. 36.
>
> 103 The difficulty with the trial judge's award is that it does not identify any causal connection between the profits the appellants were found to have earned through growing Roundup Ready Canola and the invention. On the facts found, the appellants made no profits as a result of the invention.
>
> 104 Their profits were precisely what they would have been had they planted and harvested ordinary canola. They sold the Roundup Ready Canola they grew in 1998 for feed, and thus obtained no premium for the fact that it was Roundup Ready Canola. Nor did they gain any agricultural advantage from the herbicide resistant nature of the canola, since no finding was made that they sprayed with Roundup herbicide to reduce weeds. The appellants' profits arose solely from qualities of their crop that cannot be attributed to the invention.

> 105 On this evidence, the appellants earned no profit from the invention and Monsanto is entitled to nothing on their claim of account.
>
> [Emphasis in original.]

[81] On the basis of this very brief analysis, Apotex argues that the law has been changed, not only with respect to the law of an accounting of profits but for a claim in damages as well, to permit the NIA defence.

[82] The Supreme Court made no comments whatsoever on whether the principles applicable to an accounting of profits could or should be applied to a claim of damages. Indeed, the decision very specifically begins with the statement that there are “two alternative types of remedies”.

[83] In its decision, the Supreme Court endorsed a two-step approach to the assessment of profits. The first step is one of causation: are the infringer’s profits “causally attributable to the invention”? On the facts in the case, the Supreme Court found that the plaintiff’s claim failed at the first step; that is, the trial judge failed to find that Mr. Schmeiser sprayed his crops with the infringing product. There was no Roundup Ready benchmark against which to apply the differential profits methodology. There was no causation.

[84] Once causation is established, the second task is the quantification of profits. The Court was of the view that the differential profits approach, as described in a journal article (Norman Siebrasse, "A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms" (2004), 20 CIPR 79 [Siebrasse 2004]) is the “preferred method” of calculating an accounting of profits. In addition, the Court appeared to accept that this method

was already part of Canadian law, citing *Collette v Lasnier* (1886), 13 SCR 563 at 576, [1886] SCJ No 50 [*Collette*] and *Colonial Fastener Co v Lightning Fastener Co* (1936), [1937] SCR 36, [1937] 1 DLR 21 [*Colonial Fastener*].

[85] *Collette* is a good example of how the differential profits approach has comprised part of Canadian law for over a century. *Collette* involved two patents for candle-making machines. Mr. Lasnier claimed that Mr. Collette had infringed the patent and asserted a claim for damages. This case does not assist the Defendants, for the simple reason that the case did not actually involve a claim for damages. It is obvious, from reading the judgment, that Mr. Lasnier was seeking a disgorgement of the profits made by Mr. Collette:

> [T]he respondent [Mr. Lasnier, the Plaintiff] alleges no actual loss, or that he suffered any damage, but simply alleges that the appellants [Mr. Collette], by using the respondent's patent or their fraudulent imitation of it, have realized a profit of $13,200 over and above the profits they would have or that might have been realized in making candles without resorting to this machine . . . Now, all the respondent claims, is the profits that the appellants made. . . .
>
> (*Collette*, above at 574.) [Emphasis added.]

[86] The Supreme Court's reference to *Collette* demonstrates that the Supreme Court was not changing existing law. Rather, the court was relying on existing jurisprudence.

[87] This view of the law of Canada is consistent with 1969 comments of Harold G. Fox (*The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: The Carswell Company Limited, 1969). At page 504, Mr. Fox described exactly what Apotex now argues is the "new" law of an accounting of profits:

> In arriving at the *quantum* of profits to be awarded regard must be had to the actual profit made by the defendant compared with the profit that would have been derived if he had used that which he would most probably have used had he not wrongfully taken the invention.

[88] Apotex also points to the decision of the Federal Court of Appeal in *Monsanto Canada Inc v Rivett*, 2010 FCA 207, [2012] 1 FCR 473 [*Monsanto/Rivett (FCA)*] as further support for the premise that the law has changed. In *Monsanto/Rivett (FCA)*, the Court of Appeal affirmed, for the most part, the decision of Justice Zinn in *Monsanto Canada Inc v Rivett*, 2009 FC 317, [2010] 2 FCR 93 [*Monsanto/Rivett (FC)*]. This case, which followed *Monsanto/Schmeiser*, involved infringing use of a Roundup Ready product (in this case, soybeans). In contrast to *Monsanto/Schmeiser*, Justice Zinn found that there was a causal connection between the profits made and the infringement (*Monsanto/Rivett (FC)*, above at paras 94-96). Only after finding causation did Justice Zinn direct his mind to the disgorgement of profits using a differential profits approach (*Monsanto/Rivett (FC)*, above at paras 97-102). Comparison of *Monsanto/Schmeiser* to *Monsanto/Rivett* clearly demonstrates that causation must be evaluated first. Only where causation is established does the court employ the differential profits approach, taking into account a non-infringing alternative. *Monsanto/Rivett* neither shows that the differential profits methodology is neither new law, nor stands for the general proposition that the differential profits approach is transferable to an award of damages.

[89] In sum, *Monsanto/Schmeiser* did not change the law. Instead, it merely affirmed an approach to the calculation of an infringer's profits that already existed in Canadian law.

[90] Even if I were to conclude that the Supreme Court has changed the law, it has done so only with respect to an accounting of profits and not for a claim in damages.

(2) Law of the United States on NIA Defence

[91] Apotex presented me with a comprehensive compilation of jurisprudence from the courts of the United States on the issue of the non-infringing alternative. In Apotex's submission, the law of the United States is crystal clear; the defence of a non-infringing alternative is available and, in fact, forms part of the threshold question of entitlement to lost profits. The point that Apotex appears to be making is that, given that the Supreme Court in *Monsanto/Schmeiser* has moved away from the law as stated in *United Horse Shoe*, the lacuna should now be filled by US law on this issue.

[92] I accept that an NIA defence exists in the United States. The availability of a non-infringing alternative is a threshold step in determining whether a plaintiff can claim lost profits or is limited to a reasonable royalty. In order to obtain a lost profits award in damages, a plaintiff bears the burden of demonstrating that there is no non-infringing alternative. This "rule" is set out in the case of *Panduit*, above at 1156, frequently cited in the United States jurisprudence for its general statement of the requirements for a patentee to obtain lost profits:

> To obtain as damages the profits on sales he would have made absent the infringement . . . a patent owner must prove: (1) demand

> for the patented product, (2) absence of acceptable non-infringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of profits he would have made.
>
> [Emphasis added.]

[93] The first and major flaw in Apotex's argument is that I do not accept that *Monsanto/Schmeiser* changed the law of damages. The case, as I read it, changed nothing – even with respect to the law applicable to an accounting of profits.

[94] The second problem with Apotex's argument is that the statutory provisions of the United States with respect to damages are very different from that of Canada and the United Kingdom.

[95] One major difference is that the relevant provision of the United States law, 35 USC §284, provides for up to triple damages, as follows:

> §284. Damages
>
> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.
>
> When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.
>
> The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.
>
> [Emphasis added.]

[96] Further, since 1946, the remedy of an accounting of the defendant's profits has been unavailable to American plaintiffs (Laura B Pincus, "The Computation of Damages in Patent Infringement Actions" (1991) 5 Harv JL & Tech 95 at 97 citing 35 USC §§ 67 and 70 (1946)). All matters relevant to remedying an act of infringement must be considered under the heading of "damages adequate to compensate for the infringement". While I would not wish to place too heavy a weight on the difference in the legislation, the point remains that law of the United States is different and has certainly evolved differently than that of the United Kingdom and, as a result, Canada.

[97] In brief, I accept that the law of damages in the United States requires that, prior to claiming an award of lost profits, a wronged patentee must demonstrate that there is no acceptable non-infringing substitute. If this case were before a court in the United States, Merck would be required to address whether the AFI-4 process is an "acceptable non-infringing substitute". However, as the law stands in Canada, Merck bears no such burden.

(3) The Professor Siebrasse Papers

[98] Apotex places great emphasis on two journal articles by Professor Norman Siebrasse: Sibrasse 2004, above and Norman V Siebrasse et al, "Damages Calculations in Intellectual Property Cases in Canada", (2008) 24 CIPR 153 [Siebrasse 2008].

[99] Professor Siebrasse's articles reflect a point of view that is different from the existing Canadian law of damages in patent infringement cases.

[100] As acknowledged by Professor Siebrasse, the primary focus of the 2004 article was the accounting of profits awarded for infringement of patents claiming “higher life forms” since, in his view, “the law relating to this remedy is unclear in Canada” (Siebrasse 2004, above at 80). This paper highlighted a differential profits approach to the accounting of profits to which the Supreme Court referred in *Monsanto/Schmeiser*. Although, in the course of his lengthy analysis, Professor Siebrasse expressed doubt about the applicability of *United Horse Shoe*, this criticism of *United Horse Shoe* was made in the context of an accounting of profits (see, for example, Siebrasse 2004, above at 94).

[101] Given that the platform of the Siebrasse 2004 paper was the decisions of the lower courts in *Monsanto/Schmeiser*, it is to be expected that, the parties referred to the paper in their arguments to the Supreme Court. The Supreme Court made one quick reference the Siebrasse 2004 paper in its discussion of remedy. The court agreed only with Professor Siebrasse’s use of the differential profit method of calculating lost profits. By no stretch, should this be elevated to an agreement by the Supreme Court with all of Professor Siebrasse’s arguments.

[102] It does not follow, from the acceptance of the value-based or "differential profit" approach, either that the Supreme Court would have adopted the reasoning set out in the entirety of the paper, or that every article written by this author possesses elevated importance. An academic’s opinions on the law or its interpretation may, in appropriate circumstances, assist a court. However, these opinions are not jurisprudential.

[103] In his 2008 paper, Professor Siebrasse commented extensively on the *Monsanto/Schmeiser* decision, turning his focus from an accounting of profits to damage awards (Siebrasse 2008, above). There is no mistaking his point of view that the existence of a non-infringing alternative should be a relevant factor in the analysis of an award of damages. At page 161, he states the following:

> . . . *United Horse-Shoe* may be inconsistent with modern Canadian cases and perhaps should not be followed in Canadian law today. The difficulty with the decision is that the defendant's non-infringing alternatives are clearly relevant in fact to what would most probably have happened but for the infringement. Ignoring this factor is inconsistent with the general principle that the plaintiff is to be put in the position it would have in fact been in but for the infringement, as best as this can be determined.
>
> [Emphasis added.]

[104] Professor Siebrasse appears to rely on *Monsanto/Schmeiser* as a basis upon which to conclude that *United Horse Shoe* is now in conflict with Canadian law of damages. As I have discussed above, I do not believe that this is a reasonable interpretation of the Supreme Court's findings in *Monsanto/Schmeiser* on the law of damages.

[105] Academic writing can be useful to a judge faced with a difficult and new issue, but it is not precedential. The opinion of a university professor – no matter how well-articulated – is merely an expression of a point of view that may be right or may be wrong. Even Professor Siebrasse does not conclude that the law of Canada now accepts the NIA defence; rather, he merely wishes that it would.

[106] It is also interesting to observe that Apotex was unable to point to any other academic who has expressed the same views as Professor Siebrasse or has endorsed Professor Siebrasse's opinion on the use of an NIA defence. In final oral argument, Merck's counsel referred to Professor Siebrasse as "the lone voice in the wilderness" (8T1099) supporting the adoption of the NIA defence.

(4) Section 8 Damages under the *PM (NOC) Regulations*

[107] Apotex refers to my decision in *Sanofi-Aventis Canada Inc v Teva Canada Ltd*, 2012 FC 552, 410 FTR 1 [*Teva Ramipril*] as support for its position on the availability of a NIA defence. *Teva Ramipril* involved the complex and uncharted waters of a claim for damages under s. 8 of the *PM (NOC) Regulations*. In constructing the "but for" world, I accepted the argument of the defendant (Sanofi) that, but for the infringement, it would have authorized a generic competitor to enter the ramipril market (*Teva Ramipril*, above at paras 172-208). As a result, Teva's damages were substantially reduced by this hypothetical competition. As summarized by Apotex in its final written argument in this case at page 13:

> Sanofi was found to have harmed Teva by excluding it from the ramipril market, but it argued successfully that, if it had not harmed Teva by commencing a prohibition proceeding, it could have caused some of the same harm lawfully by authorizing a generic competitor. This lawful "harm" substantially reduced Teva's damages.

[108] I do not accept this example of the calculation of damages under s. 8 of the *PM (NOC) Regulations* is applicable to a calculation of damages under s. 55 of the *Patent Act*.

[109] The components of the *PM (NOC) Regulations* operate in the context of a specialized and comprehensive scheme. As recognized by Apotex in its final written argument at page 40, "[f]rom virtually the moment the *PM (NOC) Regulations* were enacted, the Courts have recognized that the rights afforded to a patentee within those regulations … were distinct from the rights afforded to a patentee under the *Patent Act*". Moreover, as described by Justice Rothstein in *Apotex Inc v Canada (Minister of Health and Welfare)* (1993), 3 CPR (4th) 1 at para 28, 181 DLR (4th) 404 (FCA), the *PM (NOC) Regulations* are:

> . . . a comprehensive scheme provided in the Regulations which specifically addresses ineligible patents on the Register and the costs, loss and damage suffered by generic manufacturers arising from such ineligible patents being included on the Register.
>
> [Emphasis added.]

[110] It is important to understand and apply s. 8 within the entire scheme of the *PM (NOC) Regulations*. As has been written and commented on at length, the provisions of the *PM (NOC) Regulations* complement and counterbalance one another in the achievement of the overall equilibrium of the regulatory scheme envisioned by Parliament. In *Teva Ramipril*, above at paragraph 14, I described the consequences of the nature of the *PM (NOC) Regulations* as follows:

> The damages suffered by Teva are statutory in that they arise only because of the operation of s. 8 of the *PM (NOC) Regulations*. The liability of Sanofi, in this case, is better understood if s. 8 is examined in the context of the entire statutory scheme.

[111] The mere use of the word "damages", in s. 8 of the *PM (NOC) Regulations*, does not make an award of damages under s. 8 equivalent in all aspects to an award of damages under s. 55 of the *Patent Act*. The fact that, in *Teva Ramipril* (and in the companion case of *Apotex Inc*

v Sanofi-Aventis, 2012 FC 553, 410 FTR 78), I considered the hypothetical authorized generic to calculate the s. 8 damages award is of no great moment to the case now before me.

[112] As properly expressed by Merck in its final written argument at paragraph 151:

> The section 8 decisions that require a consideration of what if any third party competition the generic would have faced in the but for world, including authorized generics, are based on the correct interpretation of section 8 and its unique purpose. They are *not* support for a change in the longstanding and well-established law that precludes an infringer from arguing that in assessing the damages caused by the infringement, it could have harmed the patentee equally badly by not infringing.

H. *Policy Reasons Supporting the Rejection of the NIA Defence*

[113] There are also compelling policy reasons why Apotex's arguments in favour of the NIA defence should not be considered. The argument advanced in this case would result in an inadequate compensation for injured plaintiffs and the infringer escaping responsibility for its infringement. The submission of the Defendants is, quite simply, that "I would have harmed you just as much even if I had not infringed!"

[114] It is important to remember that a plaintiff, in claiming damages, is not permitted to claim any and all of its lost profits. A careful examination of those profits is required. Matters such as, for example, evolution of market share and production efficiencies, are obviously relevant to an assessment of lost profits. A valid defence of apportionment may be made. Legitimate competition, for example, by another generic or, as in this case, by the actual use of the AFI-4

process, is a relevant factor. In this case, I did not need to undertake this close examination since the Streamlining Agreement settled most of those matters.

[115] Moreover, if a defendant can show that a third party competitor would have been able to capture some of the sales, as was the case in *Jay-Lor*, the plaintiff will be entitled to a royalty only, and not to its lost profits. In this case, Merck Canada's claim to lost profits cannot and does not include any amount in respect of AFI-4 sales, lost export sales or post-expiry sales. However, it would be inappropriate to include in this list a fiction that the defendant could have used a non-infringing alternative (but did not) in a "but for" world in which infringement did not occur.

[116] Contrary to the submission of Apotex, it is not punitive to compensate Merck for lost profits where the Defendants could have (but did not) use the non-infringing alternative. This analysis simply recognizes that Merck, the party whose position is the focus of a compensatory award of damages, suffered losses as a direct result of the infringing acts. Apotex's unauthorized use of the AFI-1 process caused Merck Canada's loss of over $62 million in profits.

[117] Further, I have already taken the non-infringing alternative into account. In the liability phase of the trial, I concluded that some but not all of the Defendant's lovastatin was made with the infringing AFI-1 process; the balance of the lovastatin imported, manufactured and marketed by the Defendants was made with the non-infringing alternative process. Consequently, Merck lost many more sales than those caused by the infringement; Merck is not claiming – nor could it claim – lost profits in respect sales displaced by non-infringing Apo-lovastatin. The loss to Merck was clearly found to have been caused by and will be measured against the infringing

quantities only. In the words of Lord Watson, those sales comprised “legitimate competition” to which Merck was exposed (*United Horse Shoe*, above at 267).

[118] Merck’s claim of lost profits would also be reduced if a third party competitor would have entered the market prior to the expiry of the '380 Patent. In this case, the parties accepted that no other generic would have formed part of the market prior to expiry; therefore, there was no “legitimate competition”.

[119] In its final written argument at paragraphs 112-114, Merck expressed the following views:

> Where a patentee like Merck does not typically license its invention, a would-be infringer with a less efficient non-infringing alternative would simply proceed to infringe the patent with full knowledge that, at the end of the day, the infringer will only have to pay a reasonable royalty for its unauthorized use of the patent. Adopting such a rule amounts to a judicial sanction on infringers like Apotex taking for itself a compulsory license and is flatly inconsistent with Canada’s public reasons for repealing compulsory licensing, and inconsistent with Canada’s international obligations.
>
> Thus, if adopted, the NIA defence would render illusory the grant of the monopoly that this court has already found to be valid and infringed. Such an approach would be inconsistent with the intent of the *Patent Act*.
>
> Far from protecting valid and infringed patents, Apotex’s assertion, if accepted, would actually create an incentive to infringe. Apotex’s position in this litigation is that it should only have to pay (at most) the cost savings associated with using the infringing AFI-1 process. If this position is accepted, a competitor will always choose to infringe rather than use the more expensive and less efficient non-infringing alternative.
>
> [Footnotes omitted.]

[120] I could not agree more.

I. *Conclusion on NIA Defence*

[121] For these reasons, I reject Apotex's argument that the non-infringing alternative is a relevant factor or defence in the assessment of damages under s. 55 of the *Patent Act*. Briefly stated, Canadian law does not recognize the NIA defence and *Monsanto/Schmeiser* did not change that law. Merck Canada is entitled to an award of $62,925,126 as its lost profits with respect to the Pre-Expiry Replacement Tablets.

VIII. MACI Royalty

[122] Having concluded that Merck Canada is entitled to its lost profits in regard to the Pre-Expiry Replacement Sales, I turn to the question of the MACI Royalty in the assessment of lost profits.

[123] The term "profits" refers to the net proceeds to a party after all expenses incurred are deducted. The fixed and variable costs of production must be deducted from gross revenues.

[124] In calculating lost profits in the "but for" world, the Court must deduct expenses that have been saved because the infringement occurred, but should not deduct expenses that have been incurred or will be incurred in any event (see, for example, *Apex Construction v Ceco Developments Ltd*, 2008 ABCA 125 at paras 130-132, 88 Alta LR (4th) 26 [*Apex*]; *General Store*

Publishing House Inc v BD Waite Co, 1988 CarswellOnt 3131, [1988] OJ No 2050 (H Ct J) [*General Store*]).

[125] In this case, one expense upon which the parties disagree is a royalty payable to MACI pursuant to the terms of an agreement made as of January 1, 1985 between the predecessor in interest of Merck Canada and MACI (the MACI Royalty Agreement) (TX 64, Tab 1). Under the terms of the MACI Royalty Agreement, MACI granted a licence to Merck Canada with respect to a number of "Licensed Patents", "Licensed Know-How" and Licensed Trademarks" in return for a royalty payable on the "Net Receipts of Sales". Clause 5 of the MACI Royalty Agreement establishes the MACI Royalty. It is accepted by the parties that, under this agreement, Merck Canada is obligated to pay MACI an 8.5% royalty (the MACI Royalty) with respect to Net Receipts of Sales prior to the expiry of the '380 Patent.

[126] The issue has arisen as to whether Merck Canada's revenues in respect of the Pre-Expiry Replacement Tablets should reflect an expense for the MACI Royalty. The parties have agreed that the value of the MACI Royalty on the Pre-Expiry Replacement Tablets would have been $10,378,193 (Streamlining Agreement at para 8). Merck argues that the MACI Royalty should not be deducted, thereby increasing the award of lost profits on the Pre-Expiry Replacement Tablets by $10,378,193. Apotex submits that the MACI Royalty has been properly accounted for.

[127] In this case, Merck asserts that, because Merck Canada will be required to pay 8.5% of its damages award to MACI, the amount is not a proper expense deduction. Merck's two key arguments are:

1. The MACI Royalty Agreement is silent with respect to damages, but this ambiguity in the contract may be resolved by looking at the intentions and subsequent conduct of the parties. Merck's witnesses testified that they intend to pay the MACI Royalty on any damages received in this case. Merck also points to its conduct with respect to a settlement of a similar case involving the enalapril patent. In that case, the MACI Royalty was paid on the full amount of the settlement, thereby demonstrating the intention of the parties that the royalty in the present case would be payable in the event of legal damages.

2. The *surrogatum* principle, applied by courts in the tax context, teaches that lump sum damages take on the character of the interest settled. In this particular case, the damages are meant to replace Net Receipts of Sales. Since the damages award should be characterized as such, the MACI Royalty is payable based on the MACI Royalty Agreement.

[128] There are serious flaws in both of these arguments.

A. *The Terms of the MACI Royalty Agreement*

[129] Merck argues that the MACI Royalty is an expense that will be incurred pursuant to the MACI Royalty Agreement and, therefore, should not be deducted from Merck Canada's award of lost profits. I disagree.

[130] In my view, the MACI Royalty Agreement is clear and unambiguous, creating no obligation to pay upon receipt of lump sum damages. Since there is no obligation to pay any royalty on the an award of legal damages, the MACI Royalty is properly characterized as an expense that would have been incurred in the hypothetical scenario but saved because of the infringement. As such, it should be deducted in the calculation of Merck Canada's lost profits.

[131] The starting point for my analysis is the MACI Royalty Agreement. The agreement provides for a royalty based on "Net Receipts of Sales", defined as "gross receipt of sales of any Licensed Products manufactured, used or sold…" (TX 64, Tab 1 at 3, 8-11). But for Apotex's infringement, the MACI Royalty would have been paid under the terms of the MACI Royalty Agreement.

[132] I note that the MACI Royalty Agreement is governed by the laws of the state of New Jersey (TX 64, Tab 1 at 20). However, the parties both addressed the MACI Royalty Agreement in the context of Canadian law, and I will do the same in accordance with my analysis of in the liability phase of the trial (*Liability Reasons*, at para 47).

[133] In my view, the MACI Royalty Agreement explicitly provides for the circumstances under which a royalty is payable; and, those circumstances do not include a damages payment. There is no ambiguity in the MACI Royalty Agreement. An ambiguity only exists where a contractual provision or the words within it may be understood in multiple ways. An ambiguity is identified based on existing language in the contract, and parties should not be permitted to create ambiguities by adducing evidence (*General Motors of Canada Ltd, v Canada*, 2008 FCA 142 at paras 34-35, 292 DLR (4th) 331). Merck has not pointed to any words or phrases in the MACI Royalty Agreement that could sustain multiple interpretations.

[134] Merck's reliance on the silence of the contract with respect to lump sum damages is misplaced. Parties to a contract are assumed to intend the legal consequences of the words chosen (*Eli Lilly & Co v Novopharm Ltd*, [1998] 2 SCR 129 at para 57, 161 DLR (4th) 1 [*Eli Lilly*]). In the MACI Royalty Agreement, the parties specifically outlined that Merck Canada would pay the 8.5% royalty only on "Net Receipts of Sales". In addition, clause 12(e) provides that:

> This Agreement sets forth the entire agreement and understanding between the parties with respect to the license of Licensed Patents, Licensed Know-How and Licensed Trademarks.
>
> (TX 64, Tab 1 at 21-22.) [Emphasis added.]

[135] Moreover, patent infringement and subsequent damage awards are not unanticipated situations. If the parties – both of whom are sophisticated corporations – intended to provide for the circumstances of an award of legal damages in the MACI Royalty Agreement, they would have done so.

[136] Where an agreement is clear and unambiguous, there is no need to consider extrinsic evidence (*Eli Lilly*, above at para 55; *Liability Reasons*, above at para 47). Therefore, the court should not construe the agreement based on subsequent conduct relating to the enalapril lump sum payment and the testimony of Merck employees.

[137] Where expenses are saved, they should be deducted from a damage award. In this particular case, Merck Canada "saved" the expense of paying the MACI Royalty and has no legal obligation to pay MACI on any damages award based on the MACI Royalty Agreement. Therefore, this expense should be deducted (*Apex*, above at paras 130-132).

[138] *General Store*, raised by Merck, is distinguishable from this case. The *General Store* case dealt with a copyright royalty that the Ontario High Court of Justice declined to deduct from a payment of lump sum damages. Justice Potts stated that a third party "would be entitled to recover those royalty-costs from the plaintiff having regard to this judgment" (*General Store*, above at para 19). However, in *General Store*, there was an obligation to pay this royalty, even if this obligation is not specified in particular detail. This is confirmed in *Leslee Sports Importing (Brockville) Ltd v Reebok Canada Inc*, [1991] OJ No 1536 (Ct J (Gen Div)). In *Leslee Sports*, the court distinguished *General Store* since there was no "firm commitment" to incur the relevant expenses. Therefore, *General Store* is also inapplicable to the present case, since the contract at issue creates no obligation to pay the royalty on an award of damages.

B. *The Surrogatum Principle*

[139] By way of analogy, Merck asserts that I should apply a tax-related notion to characterize the MACI Royalty as an expense that should not be deducted. In my view, the *surrogatum* principle is not relevant to the present circumstances.

[140] Under tax law of Canada, the *surrogatum* principle treats a payment of damages, for tax purposes, in the same way as the interest that those damages replace (*Transocean Offshore Ltd v Canada*, 2005 FCA 104 at para 50, 332 NR 21; *Bourgault Industry v Canada*, 2006 TCC 449 at paras 33-34, 55 CPR (4th) 369 [*Bourgault*]). If I understand the principle correctly, the *surrogatum* principle dictates that, for tax purposes, MACI's income tax on its damages award would be assessed as though those amounts were the lost profits, or net receipts of sales, that the awarded is intended to replace.

[141] Although this principle may provide useful insight with respect to the tax treatment of patent infringement damages (*Bourgault*, above), neither party has cited any case law that applies this principle to trigger or create obligations where none otherwise exist. The *surrogatum* principle has been entirely restricted to cases in which a person's taxable income is at issue. The manner in which revenues are treated for tax purposes does not create an obligation to pay such revenues in the first place. Hence, this principle is unhelpful to Merck.

C. *Conclusion on MACI Royalty Issue*

[142] In sum, there is no obligation for Merck Canada to pay the MACI Royalty on any award of lost profits; in other words, the MACI Royalty is an expense saved. The MACI Royalty should be deducted from Merck Canada's award of pre-patent expiry lost profits.

IX. Calculation of a Reasonable Royalty on Blue Treasure Pre-Expiry Sales

[143] If I am wrong with respect to Apotex's NIA defence, a reasonable royalty should be fixed for all lost domestic sales where Apotex could have competed with Merck Canada without infringing the '380 Patent – the Pre-Expiry Replacement Tablets or Sales. In the scenario of a reasonable royalty, I would treat lost domestic sales as sales that Merck Canada cannot demonstrate that it would have made but for the infringement. Apotex submits that such a calculation should be carried out for Merck Canada's damages.

[144] It is important to recognize that Apotex does not argue that Merck US's damages should be included in the evaluation of a reasonable royalty. Rather, Apotex acknowledges that, if Merck US is to be awarded damages as the supplier of lovastatin API, "the parties have agreed on the quantum, which is CDN$51,965,921" (Apotex's Final Written Argument at 50-51). A more complete discussion of Merck US's damages and entitlement to such damages is contained in Section XII of these Reasons.

[145] The second exception to Apotex's calculation of a reasonable royalty applies to AFI Batch CR0157, a batch of lovastatin API made at the AFI Winnipeg facilities in November 1996 and shipped to Apotex Inc. for tableting and sales. Apotex submits that it is unnecessary to calculate a reasonable royalty for the period of Apotex's initial infringement with AFI Batch CR0157 because Apotex accepts that it could not have used its non-infringing AFI-4 process to make this batch. As there was no non-infringing alternative available, Merck Canada would have made all of the sales to replace batch CR0157 and is, thus, entitled to its lost profits. In Apotex's submission, that amount would be $521,641.

[146] According to Apotex, a reasonable royalty is payable to Merck Canada on account of the 294 batches of lovastatin produced by Blue Treasure after March 1998 and sold prior to expiry of the '380 Patent (BT Pre-Expiry Replacement Tablets or Sales). Post-expiry sales are considered in Section XI of these Reasons.

[147] Having determined that the NIA defence is not available to Apotex on the facts of this case, there is no need to reach an ultimate quantification of the reasonable royalty for the Pre-Expiry Replacement Tablets.

[148] Since it is not necessary for me to calculate a reasonable royalty, I have chosen not to do so, beyond the general findings below. In the event that the Court of Appeal determines that Merck is only entitled to a reasonable royalty on the Pre-Expiry Replacement Tablets and sends the matter back to me, I will retain my notes and could make the necessary final determination, in accordance with the findings below and any direction from the Court of Appeal.

A. *General Principles*

[149] For those sales made by an infringer that the patentee would not have made, a patentee is entitled to a reasonable royalty (*Colonial Fastener*, above at 45; *AlliedSignal Inc v Du Pont Canada Inc* (1998), 78 CPR (3d) 129 at 138, 142 FTR 241 (FCTD) [*AlliedSignal FCTD*]), aff'd (1999), 86 CPR (3d) 324, 235 NR 185 (FCA)). The award of a royalty, where a plaintiff cannot prove a lost sale, is recognition of the fact that every sale by an infringing party is an illegal transaction.

[150] In *AlliedSignal (FCTD)*, above at page 176, a reasonable royalty rate was described as:

> "that which the infringer would have had to pay if, instead of infringing the Patent, [the infringer] had come to be licensed under the Patent": *Unilever PLC v. Procter & Gamble*; *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd*. The test is what rate would result from negotiations between a willing licensor and a willing licensee.
>
> [Footnotes omitted.]

[151] The calculation of a hypothetical royalty is based on some established theories and constructs. As I stated in *Jay-Lor*, above at paragraph 126:

> This notion [of a hypothetical royalty] is premised on the assumption that someone who wishes to use patented technology would normally have sought permission and been willing to pay a royalty for its use. The patentee, if prepared to license its invention, would then negotiate the terms of the licence, including the amount of royalty, with the intended licensee. The construct is obviously artificial in the sense that the infringer, in this case, did not make the choice to seek permission from the patentee when it began to use the patented technology in its own device. Assumptions on how parties might have negotiated must be made. However, licensing is a very common practice in the intellectual property field and has developed into an area of academic study. It

> appears that the methodology is well established and somewhat consistent. Accordingly, evidence of how parties negotiate licence agreements and the theory applicable to the negotiations is available. In other words, from studying what is happening in the real world of licensing practices and applying generally-accepted methodology to the known facts in a specific case, we can form an opinion as to what would have happened in hypothetical negotiations between the parties in this case.

[152] Determination of a reasonable royalty is admittedly hypothetical. As described by Chief Judge Markey of the US Court of Appeals for the 6th Circuit in *Panduit*, above at page 1159:

> Determination of a "reasonable royalty" after infringement, like many devices in the law, rests on a legal fiction. Created in an effort to "compensate" when profits are not provable, the "reasonable royalty" device conjures a "willing" licensor and licensee, who like Ghosts of Christmas Past, are dimly seen as "negotiating" a "license". There is, of course, no actual willingness on either side, and no license to do anything . . .

[153] While the exercise may be a "legal fiction", it is not without precedent and a significant body of expertise has developed regarding how such a royalty could be calculated. Since such knowledge is outside the normal knowledge of a judge (at least, this judge), the assistance of expert opinions is essential. For one thing, the dispassionate perspective of a qualified expert avoids the hindsight and self-interest brought by the parties to the litigation. This lack of proper perspective was very apparent in the testimony of Dr. Sherman who brought nothing to the Court beyond his own after-the-fact view of how the hypothetical negotiations would have operated.

[154] In this case, I was presented with only one expert – Dr. Christine Meyer – who was qualified as an expert to opine on "economic issues related to the determination of a reasonable royalty as a result of a hypothetical royalty negotiation" (2T238-241).

[155] By way of general comment, I would remark that I found the methodology presented by Dr. Meyer to be reasonable. In particular, I would agree with Dr. Meyer's characterization of two conceptual elements of the reasonable royalty analysis: (a) a one-time negotiation on the eve of the first infringement; and (b) the use of a framework taking into account the hypothetical licensee's maximum willingness to pay (MWP) and hypothetical licensor's willingness to accept (MWA) methodology, as she describes it.

B. *One-time Negotiation on the Eve of First Infringement*

[156] The first of these general notions is that, in spite of the fact that Apotex's infringement occurred in two different ways and at two different times, a one-time negotiation in November 1996 covering all infringement is appropriate.

[157] Dr. Meyer described a hypothetical negotiation "designed to mimic real-world licensing negotiations" (Meyer Report, TX 182 at para 30). In her opinion, the date for such negotiation between the patentee and the infringer is a date just prior to the first act of infringement. The theory is that the infringer wishes to avoid all future acts of infringement by obtaining a licence for all such future acts of infringement. Dr. Meyer described how the one-time negotiation that would cover all future infringing use would have been "economically rational and efficient":

> Because this license would be assumed to cover all future use, there would be no need for any future licensing negotiations between the parties. Such an agreement would reduce the risk to either party of a change in future license terms, and, therefore, each party could make optimal business decisions based on this element

> of certainty. Furthermore, the parties would be able to avoid future transactions costs associated with renegotiating the license.
>
> (Meyer Report, TX 182 at para 40.)

[158] Although assertively cross-examined on this point, Dr. Meyer consistently held to her view that a one-time negotiation would have been rational and consistent with the theories of reasonable royalty negotiations (see, for example, 3T378-380).

[159] I see no principled reason to depart from Dr. Meyer's proposed one-time negotiation in this case. The fact that there were, as described by Apotex, two periods of infringement or that only 60% of the lovastatin was, in fact, infringing does not change the underlying premise of the hypothetical negotiations. That key premise is that, by entering into the licensing agreement, an infringer avoids all future acts of infringement, no matter how such infringement might occur or no matter how much infringement might take place. With a licence in hand, Apotex could have made every single batch of Apo-lovastatin API using the AFI-1 process. It was not faced with the uncertainty of whether Blue Treasure would or would not use the infringing AFI-1 or non-infringing AFI-4 process. Apotex could have mixed its non-infringing API with infringing API without a care. In my mind, there would have been economic efficiencies to be gained by a one-time licence.

[160] Apotex's argument is also inconsistent with the jurisprudence regarding the NIA defence. Apotex argues that the court should set the hypothetical negotiation based on the date AFI-4 process was known to be viable and approved. However, as the NIA defence is applied in the United States, it does not necessarily matter when the non-infringing alternative was developed

in the real world if it could have been developed earlier in the hypothetical world. For example, in *Grain Processing Corp v Am Maize-Prods Co*, 185 F 3d 1341 (Fed Cir 1999) [*Grain Processing*], Chief Justice Rader accepted a non-infringing alternative that was developed during the course of the litigation. The defendant in *Grain Processing* could have implemented the non-infringing process sooner but did not do so because it was more expensive and it thought that other, less expensive processes were non-infringing (*Grain Processing*, above at 1354). The clear parallels to the present case undermine Apotex's assertion that a later date of negotiation is required in this case.

[161] Moreover, Apotex's position that the two-phase infringement separated by an intervening period of non-infringement mandates a later date of negotiation is self-serving. Apotex knows now – although it did not know in November 1996 – that it would have the Health Canada "no objection" letter regarding its notifiable change to the AFI-4 process in February 1997. Thus, if the hypothetical negotiations were held on the eve of the second infringing period, risk connected to issues of regulatory approval of the AFI-4 process would be close to zero, thus decreasing any negotiated royalty. A party to the hypothetical negotiations should not be able to gain an advantage from structuring his infringement to benefit from after-the-fact knowledge of regulatory decisions.

[162] Apotex's position that each infringement is a separate tort is ultimately flawed. Taken to its illogical conclusion, one could ask: why not a separate negotiation for each of the 295 events of infringement? There is no principled reason to treat one of the acts of infringement any differently than another. The point of the hypothetical negotiation is to avoid <u>all</u> infringement,

however and whenever it occurs. It follows that I reject the separation of the infringement into two parts. For negotiating purposes, there is but one infringement.

C. *Framework for Hypothetical Negotiations*

[163] Dr. Meyer presented a model for the hypothetical negotiations to establish a reasonable royalty. Dr. Meyer's mandate was to "calculate Plaintiffs' reasonable royalty damages as a result of Defendants' infringement of [the '380 Patent]" (Meyer Report, TX 182 at para 5). In doing so, Dr. Meyer offered her view of the "Hypothetical Negotiation Framework", beginning at paragraph 30 of her report.

[164] The framework of the hypothetical negotiations proposed by Dr. Meyer differs from that used by the Courts in *Jay-Lor* and *AlliedSignal*, where a percentage of the defendant's anticipated profits formed the basis of the royalty. Dr. Meyer described and utilized a methodology which would result in a lump-sum, up-front licence payment rather than a percentage of the anticipated profits of the defendants. The parties to this case did not object to Dr. Meyer's overall approach of coming to a lump-sum payment; the dispute related to how the lump sum would be calculated.

[165] A critical determination in Dr. Meyer's model is the bargaining range. To establish the range, we need to set two end points.

[166] First, what would be the highest royalty that would leave the Defendants better off by taking a licence? This level is referred to as the maximum willingness to pay or "MWP". If a proposed royalty is lower than the MWP, Apotex would have the incentive to pay for a licence. However, it the proposed royalty is higher, Apotex would not have any motivation to negotiate further.

[167] The converse applies to Merck. What would be the lowest royalty that leaves the Plaintiffs better off by granting a licence? This level is referred to as the minimum willingness to accept or the "MWA". Merck would have no incentive to accept anything below its MWA.

[168] If Merck's MWA is lower than Apotex's MWP, the hypothetical negotiations will work in a manner consistent with real world negotiations. As stated by Dr. Meyer, "a royalty anywhere within the range would allow each party to expect to benefit from the license" (Meyer Report, TX 182 at para 113). Presumably, a willing patentee and a willing infringer with substantially equal bargaining power would agree to split the difference of the range to come up with a reasonable royalty. In Dr. Meyer's opinion:

> [I]t is economically reasonable to conclude that the parties would share equally in the gains from the license and that a reasonable royalty would fall at the mid-point of the bargaining range.

[169] By way of a simplistic example, let us assume that Merck's MWA is $1 million and Apotex's MWP is $1.2 million. In that case, a royalty of $1.1 million would be an economically rational outcome for both parties.

[170] In the context of Dr. Meyer's model, a problem arises when MWA is higher than the MWP and there is consequently no bargaining range within which the parties may negotiate. In the real world, no negotiated solution is available and no licence would be granted; the parties would simply walk away. However, in our hypothetical world, we must establish a royalty to remedy the infringement that occurred in the real world.

[171] In Dr. Meyer's opinion, the reasonable royalty flowing from the hypothetical negotiation where there is no bargaining range:

> . . . must compensate Plaintiffs for the infringement. Hence, the reasonable royalty must be at least equal to the cost to Plaintiffs of granting the license contemplated in the hypothetical negotiation.
>
> (Meyer Report, TX 182 at para 32.)

[172] In other words, the reasonable royalty is set at Merck's MWA. This amount will likely be higher than Apotex's anticipated profit. It will also be lower – in all likelihood – than Merck's lost profits. Nonetheless, in my view, an infringer's net profit margin does not constitute the ceiling at which a reasonable royalty is capped. Requiring a royalty equal to a plaintiff's MWA will be the only way of adequately compensating the patentee for the unauthorized use of its technology. That is not to say that a plaintiff's MWA should not be rigorously tested. However, if the factors and probabilities employed in that calculation are sound, the result will be a reasonable surrogate for establishing a floor royalty.

[173] Using another simple example, let us assume that Merck Canada's MWA is $2 million and Apotex's MWP is $1.2 million. Using the methodology as described by Dr. Meyer, the reasonable royalty would be set at $2 million.

[174] I am prepared to accept Dr. Meyer's "Merck gets it all" result if a bargaining range is unavailable. Apotex did not offer its own expert to present a contrasting methodology.

[175] With these two aspects of the hypothetical negotiations framed, the final calculation of Merck Canada's MWA and Apotex's MWP would require the Court to assess a number of factors, as set out in Dr. Meyer's report, and to assign probabilities to the factors. This would permit a determination of whether a bargaining range is available to the parties. I have not undertaken this exercise in my Reasons. However, if required to do so by the Court of Appeal, a final quantification could be made of a reasonable royalty on the basis of the record already before the Court in this case.

X. Export Sales

[176] In addition to domestic sales during the life of the '380 Patent and post-expiry infringing sales, Apotex also made some infringing export sales. Merck acknowledges that it would not have made these sales and claims a reasonable royalty in respect of the export sales. Apotex agrees.

[177] Pursuant to paragraph 4 of the Streamlining Agreement:

> The number and timing of export sales of infringing and non-infringing Apo-lovastatin tablets is accurately described in Schedules XVII(c) and XVII(d) of the Report of Howard Rosen dated January 25, 2013 …

Using these Schedules, the quantity of infringing export sales by Apotex is 21,495,322 tablets and 461.76 kg.

[178] Apotex argues that pre-expiry export sales should be separated from post-expiry export sales, since the royalty on post-expiry sales would be minimal (Apotex's Final Written Argument at 34-36; Final Oral Argument at 9T1383-1386). For reasons provided in more detail in Section XI, below, regarding domestic post-expiry sales, I do not accept this argument. In brief, Apotex would have known, entering the hypothetical royalty negotiation, that it would have infringing product upon patent expiry. Further, beyond vague assertions of Dr. Sherman that infringing product would be discarded and non-infringing product acquired on patent expiry (5T531-532, 550-551), there is no evidence upon which the court may quantify a royalty on this basis. Therefore, I will evaluate all of the export sales, pre and post-patent expiry, together as a whole.

[179] As endorsed by Dr. Meyer, this royalty should be calculated in reference to the total expected cost savings that would be achieved by Apotex if it entered into a licence with Merck. Merck submits that this is a situation where parties negotiating a hypothetical royalty would agree on a royalty that would fall in the mid-range of the difference between Apotex's costs to use the non-infringing AFI-1 process and their costs to use the non-infringing alternative (Meyer Report, TX 182 at para 113). The savings to Apotex attributable to the use of the infringing process would be [**Redacted**] per kilogram (Meyer Report, TX 182 at 49, Table 4). To obtain the royalty, the cost savings is multiplied by the total infringing export sales (461.76 kg) and then divided by 2. The result would be reasonable royalty amount of [**Redacted**].

[180] Apotex did not dispute this methodology. During his cross-examination, Dr. Sherman testified that he would have been willing to pay a royalty that split the difference on cost savings between the AFI-4 and AFI-1 processes (5T524-525). Although this approach is not applicable to infringing domestic sales, I accept it as a reasonable methodology for determining a reasonable royalty for those export sales which Merck would not have made.

[181] Accordingly, I conclude that Merck is entitled to an award of damages of [**Redacted**] as damages for the sale of infringing Apo-lovastatin tablets into the export market.

XI. Post-Expiry Sales

[182] There are two types of post-expiry sales for which Merck claims damages. As set out in the Introduction to these Reasons, Merck is claiming:

- A reasonable royalty in respect of infringing Apo-lovastatin tablets sold domestically after the '380 Patent expiry (the Post-Expiry Replacement Tablets); and

- Lost profits for MEVACOR tablets (and related lovastatin API) that would have been sold domestically to replace each and every Apo-lovastatin tablet sold after the '380 Patent expiry during the hypothetical ramp-up period (the Post-Expiry Ramp-up Tablets).

[183] There is nothing in the *Patent Act* that limits damages to those sustained during the life of the patent. Section 55(1) states that the infringer is liable "for all damages sustained by the patentee [or licensee] after the grant of the patent, by reason of the infringement". Merck is entitled to its damages for infringing sales even though those sales actually would take place during the post-expiry period.

[184] A separate analysis is required for each type of damages claimed by Merck.

A. *Reasonable Royalty for Post-Expiry Replacement Tablets*

[185] The first of Merck's claims for post-expiry lost profits consists of lovastatin tablets that were made by Apotex using infringing lovastatin but which tablets were sold domestically after the '380 Patent expired. Subject to their claim for lost profits for the Post-Expiry Ramp-up Tablets, Merck acknowledged in final argument, that Merck Canada would not have made the Post-Expiry Replacement Sales and that, therefore, a reasonable royalty would be the appropriate award. This section of the Reasons quantifies the reasonable royalty with respect to the Post-Expiry Replacement Tablets.

[186] These post-expiry tablets are referred to in paragraphs 13 and 14 of the Streamlining Agreement as the "Post-Expiry Replacement Tablets"; that is, those additional MEVACOR tablets that would have replaced "infringing Apo-lovastatin tablets sold domestically after patent expiry". These tablets and the API that was used for those tablets were manufactured before patent expiry and, thus, constituted infringement.

[187] Based on the Streamlining Agreement, determination of the number of Post-Expiry Replacement Tablets, by number of tablets and by quantity of API, is relatively straightforward. As set out in paragraph 3 of the Streamlining Agreement, the parties are agreed that:

> The number and timing of domestic sales of infringing and non-infringing Apo-lovastatin tablets is accurately described in Apotex Inc. Production No. 360 . . . and Schedules XVII(a) and XVII(b) of the Report of Howard Rosen dated January 25, 2013 . . .

[188] Thus, the calculation of the tablets sold and the amount of API involved is obtained by adding the relevant infringing sales numbers from Schedule XVII(a), entitled "Summary of Infringing Apo-Lovastatin – Domestic Sales":

Year	**Dosage/Tablets - Total**	**Kilograms –TOTAL**
2001 (Feb to Dec)	20,359,265	481.60
2002	4,469,500	99.27
2003	29,500	0.58
2004	(700)	(0.02)
Apotex Post-Expiry Infringing Sales	24,857,565	581.43

[189] The extent of Apotex's infringement post-expiry was 24,857,565 tablets or 581.43 kilograms of API. I note that Merck has used 581.42 kg, most likely as a result of differences in rounding; I will use the figures from Dr. Rosen's Schedule XVII (a). It is accepted by Apotex that Merck is entitled to a reasonable royalty in respect of every one the Apotex post-expiry infringing sales. The parties are, however, far apart on what the royalty should be.

[190] Merck asserts that, of the 581.43 kg of infringing product, 340.13 kg would be the subject of its claim to Post-Expiry Ramp-up Profits and they seek a reasonable royalty only for the

balance (241.30 kg). For the reasons discussed below, I have rejected Merck's claim to Post-Expiry Ramp-up Profits. Accordingly, Merck is entitled to a reasonable royalty on all of the 581.43 kg of infringing Apo-lovastatin sold post expiry.

[191] Merck submits that, for the royalty on the Post-Expiry Replacement Tablets, I should adopt the methodology endorsed by Dr. Meyer. In Dr. Meyer's opinion, this royalty should be calculated in reference to the total expected cost savings that would be achieved by Apotex if it entered into a licence with Merck. In Merck's view, this is a situation where parties negotiating a hypothetical royalty would agree on a royalty that would fall in the mid-range of the difference between Apotex's costs to use the non-infringing AFI-1 process and their costs to use the non-infringing alternative (Meyer Report, TX 182 at para 113). This cost savings would be [**Redacted**] per kilogram (Meyer Report, TX 182 at 49, Table 4). To obtain the royalty, the cost savings is multiplied by the total infringing quantity (581.43 kg) and then divided by 2. The result would be reasonable royalty amount of [**Redacted**].

[192] Apotex submits that the reasonable royalty for the Post-Expiry Replacement Tablets, taken together with post-expiry tablets sold for export, would be a *de minimis* payment of $338,892. This particular amount and its method of calculation were first referred to in Apotex's final written argument at page 35, although Dr. Sherman testified generally that Apotex routinely arranges to enter the market quickly upon patent expiry within a week or two weeks (5T537-538). The number proposed by Apotex is derived on the basis of 1% of Apotex's revenues from infringing post-expiry domestic and export sales ($33,889,170) as set out in the Streamlining Agreement. No rationale was provided to explain why 1% would be reasonable.

[193] For the most part, Apotex's arguments focus on the incentive and ability to switch immediately upon expiry to the AFI-1 process and to sell lovastatin using *Aspergillus terreus* shortly after January 31, 2001. While these arguments may go to the length of the post-expiry ramp-up period, they do not minimize the royalty payable with respect to the Post-Expiry Replacement Tablets. This is because the tablets in question were made with infringing product made before the '380 Patent expired. In the hypothetical negotiations described by Dr. Meyer, this would be known to Apotex going into such negotiations. In other words, Apotex would know that, at patent expiry, it was going to have 581.43 kg of infringing AFI-1 product on hand, either in API form or already made into tablets.

[194] In a footnote to their written argument (Apotex's Final Written Argument at 35-36, footnote 160), Apotex states that:

> In the event that this Court finds that Apotex does not have a non-infringing alternative available to it in the but for analysis, then Apotex could have simply discarded the infringing lovastatin API that it had, in fact, purchased pre-expiry and sold post-expiry and instead have repurchased lovastatin API post-expiry and sold that instead.

[195] Apotex's assertion that Apotex Inc. and AFI would simply have discarded the infringing lovastatin API and tablets may be speculative but is not completely illogical. If true, Apotex Inc. would throw away over 580 kilograms of perfectly fine lovastatin and tablets already produced with the infringing AFI-1 product and begin afresh after January 31, 2001 by making what would now be non-infringing AFI-1 product. The key question is whether that would make financial sense. It might.

[196] Apotex's per kilogram cost of producing non-infringing (AFI-4) lovastatin API and lovastatin tablets would have been [**Redacted**] (Streamlining Agreement at para 17(c)). As reflected in Dr. Meyer's Report (TX 182 at para 84) a reasonable estimate of the expected cost savings per kilogram from using API made with AFI-1 process would be approximately [**Redacted**] per kilogram. The difference of [**Redacted**] per kilogram – or [**Redacted**] for 581.43 kg - is an estimate of Apotex's costs to use the AFI-1 process. Accordingly, in this "throw-away" scenario, Apotex would be discarding [**Redacted**] worth of lovastatin API and tablets and would incur the same [**Redacted**] in costs to replace the discarded product after the '380 Patent expiry. The total cost to Apotex of proceeding in this manner would theoretically be less than half of the [**Redacted**] royalty based on Dr. Meyer's approach and sought by Merck. On the other hand, it is also well in excess of the *de minimis* payment of $338,892 offered by Apotex.

[197] Furthermore, whether Apotex would begin afresh after patent expiry depends on more than a simple arithmetic calculation. The complete response to the question would also require that Apotex take into account other direct and indirect considerations such as:

- What costs would be associated with destruction of 580 kg of API?

- How long would it take to produce a completely new batch of AFI-1 lovastatin with the first fermentation occurring after January 31, 2001 and to scale up thereafter to meet sales demands?

- What would be the cost of interrupting distribution of Apo-lovastatin to pharmacies and distributors during the very important post-expiry period when other generic suppliers would be fighting for market share?

[198] The fatal problem with Apotex's position on this royalty is that I have no evidence with respect to the full cost to Apotex of a notional destruction of the Post-Expiry Replacement Tablets. Moreover, I have no evidence that this is a course of action that Apotex (or anyone else for that matter) has ever undertaken. All the Court has before it are Dr. Sherman's unsubstantiated and self-serving assertions, expressed long after the fact, that infringing material would have been discarded (5T531-532, 550-551). Stated in terms used by Dr. Meyer, I have no way of knowing the "Defendants' maximum willingness to pay". In the absence of such evidence, I am prepared to accept that, for purposes of the hypothetical negotiations, the parties would agree on a royalty that would fall in the mid-range of the difference between Apotex's costs to use the non-infringing AFI-1 process and their costs to use the non-infringing alternative.

[199] In the circumstances, I accept the methodology proposed by Merck for calculating the reasonable royalty. Thus, based on the record before me, I conclude that Merck's damages in respect of the Post-Expiry Replacement Tablets should be [**Redacted**].

B. *Post-Expiry Ramp-Up Lost Profits*

[200] The second type of post-expiry damages that Merck claims to have suffered is with respect to lost profits on Post-Expiry Ramp-Up Tablets. In its submissions, Apotex referred to this part of Merck's claim as a claim to "springboard" damages. Whatever term is used, this aspect of Merck's claim is as I have described. I will refer to lost profits in respect of the Post-Expiry Ramp-up Tablets.

[201] I begin by describing my understanding of the source of Merck's claim.

[202] Once a generic drug company receives approval to market a drug, it may enter the market. In most cases, the approval would be issued immediately upon expiry of the listed patent. At that time, the patentee will begin to see the loss of sales to the generic entrant.

[203] However, the effects of generic entry are not instantaneous. Even with its Notice of Compliance (NOC) permitting the generic to commence sales, the new market entrant must negotiate agreements with pharmacies and distributors, acquire formulary listings and physically move product to drug stores, all of which takes some time. This period of time required for building a market to its ultimate level of sales or "steady state" is often referred to as the "ramp-up". Assuming that total sales of the product remain at the same total level after patent expiry and prior to the new entrants achieving their steady state, the patentee or original marketer will retain sales. The volume of sales retained will decline over the ramp-up period, as the generic market entrants capture more and more of the market.

[204] Because Apotex Inc. was already on the market, albeit with infringing product, it did not have a ramp-up period after the expiry of the '380 Patent and, from the other point of view, Merck did not experience a gradual erosion of its market. When the '380 Patent expired on January 31, 2001, Apotex was already selling Apo-lovastatin at its steady state; it did not need to ramp up from zero. Thus, Merck argues, had Apotex not infringed, Merck would have made additional MEVACOR sales. Merck claims lost profits of almost $28,000,000 in respect of those post-expiry sales that it says amounted to damage sustained by it, after the grant of the '380 Patent, by reason of Apotex's infringement.

[205] In my view, s. 55 of the *Patent Act* does not preclude Merck from claiming and recovering such damages. The problems with this particular claim for post-expiry lost profits have far more to do with the factual aspects than with legal entitlement. In this regard, the Defendants raise two possible barriers to the ramp-up portion of Merck's claim:

1. Merck should be precluded from this claim because it was a "surprise" to the Defendants; and

2. There is an inadequate evidentiary record to support the claim to lost profits in respect of the Post-Expiry Ramp-up Tablets.

(1) Lack of Notice

[206] Apotex first asserts that the claim to ramp-up lost profits should be refused due to a lack of notice that this would form part of the claimed damages. They submit that the first mention of the issue was made during Merck's opening argument. In their words:

> Prior to opening argument, Merck had never uttered an intention to seek springboard damages. To the contrary, Merck had repeatedly advised Apotex that its claims were limited such that springboard damages were not being pursued. As such, neither side delivered expert reports to address springboard damages.
>
> (Apotex's Final Written Argument at 58.)

[207] Merck, on the other hand, argues that Apotex was notified of its claim to ramp-up damages in a number of different ways, including through the service of the expert reports of Dr. Meyer and Mr. Hamilton (7T953-960).

[208] On balance, I prefer the submissions of Apotex.

[209] The court takes a dim view of a party who raises issues at the eleventh hour. As pointed out by Justice Létourneau in the decision of *Yacyshyn v R* (1999), 99 DTC 5133 (FCA), "the days of trial by ambush or surprise are fortunately gone . . .".

[210] Apotex relies on the case of *Bristol-Myers Squibb Co v Apotex Inc*, 2011 FCA 34, 91 CPR (4th) 307 [*Bristol-Myers Squibb*] in which the Court of Appeal refused to allow Apotex to amend its pleadings, very late in the course of the litigation and after the pre-trial conference, to include certain arguments of patent invalidity; namely, lack of sound prediction and inutility.

The Court of Appeal placed considerable weight on the findings of the Prothonotary and Federal Court judge that Apotex had adopted a strategy of "non-disclosure, non-clarification or inaction". I do not have such evidence before me. However, the fact that Apotex had not raised the issue at the pre-trial conference was "a matter quite central to this matter" (*Bristol-Myers Squibb*, above at para 36). Moreover, at paragraph 37, Justice Stratas identified an overarching principle which is applicable to the situation before me:

> Complex, high-stakes intellectual property proceedings are governed by procedural rules aimed at fairness, full and timely disclosure, and efficiency. Purposeful, strategic conduct involving non-disclosure, non-clarification or inaction . . . disrespects these rules and their aims.

[211] I agree with Merck that its general claim for "damages or an accounting of profits" set out in their amended pleadings could incorporate the claim for post-expiry ramp-up damages. However, this very general pleading is not the issue. The question is whether Apotex had adequate notice that Merck would pursue this particular claim for ramp-up damages.

[212] Apotex submits that the issue of ramp-up damages was not explicitly raised by Merck until its opening submissions. Having read the documents the parties put forward to support their respective positions, it appears that this is correct. Contrary to the assertions of Merck, the experts did not directly address this issue. Prior oblique references in expert reports did not bring the issue into play. Moreover, Merck representatives and counsel failed to clearly identify this $28 million question throughout discovery in spite of direct questions on the scope of their post-expiry claim.

[213] Merck points to Exhibit 17 of Dr. Meyer's Expert Report (TX 182) as proof that this issue was part of their case. The flaw in this submission is that Dr. Meyer was not retained to calculate damages; she was using calculations that had been provided to her by others to assess a reasonable royalty. Exhibit 17 does not constitute notice that this issue was in play.

[214] The issue is further complicated by the fact that all parties did understand that Merck was seeking damages, in the form of a royalty, for those tablets that were sold post-expiry but that were manufactured with infringing lovastatin. These are explicitly referred to in the Streamlining Agreement as the Post-Expiry Replacement Tablets (Streamlining Agreement at paras 13-16). The calculation of Merck's claim in respect of Post-Expiry Ramp-Up Tablets bears no relationship to the calculation of damages for the Post-Expiry Replacement Tablets. The Streamlining Agreement is completely silent with respect to the amount or the calculation of possible ramp-up damages.

[215] I am not certain why this issue was not fully and fairly put to Apotex earlier. It could have been oversight. It does not matter; the point is that Apotex did not have adequate notice of the issue and should not have to defend against it at this late date. As a result, I am prepared to disallow the claim for lost profits in respect of Post-Expiry Ramp-Up Tablets on that basis alone. However, even if Apotex was put on notice early enough, I have fundamental concerns with the evidence before me on this $28,000,000 issue.

(2) Inadequacy of the Evidence

[216] A second serious flaw in Merck's ramp-up claim is the lack of complete and reliable evidence on the quantum of any such damages. Referring to part of a chart included as Exhibit 17 in the Expert Report of Dr. Meyer (TX 182), Merck proposes that I use Apotex's 1997 ramp-up experience as a surrogate for the volume of lovastatin that Apotex would have sold in the hypothetical post-expiry ramp-up period. This forms the basis of relatively simple calculation that results in a claim for $27,790,400, without making the MACI Royalty deduction, and $26,817,736 with a MACI deduction.

[217] I observe that I had difficulty reaching the sums referred to by Merck. As shown in the chart attached (Appendix A), when I added the relevant numbers from Exhibit 17 of Dr. Meyer's Report, I obtained totals of $27,790,403 and $26,806,732 respectively. Nothing turns on these *de minimis* differences.

[218] As I am well aware, there are many complexities involved in determining damages for a hypothetical market scenario. In this case, the lost profits of Merck during the patent term are agreed (Streamlining Agreement) and are no longer in issue. However, with respect to the ramp-up damages, there are a number of considerations that, in my view, Merck has not adequately addressed.

[219] To establish a quantum for such lost profits, I must estimate the length of the ramp-up period and the rate of penetration by generic companies into that hypothetical market. The use of

Apotex's historical 1997 ramp-up experience may not be appropriate or take into account a number of factors:

- Apotex had approval for and marketed non-infringing Apo-lovastatin during the term of the '380 Patent. What impact would this have had on Apotex's ability to ramp up after patent expiry?

- What, if any, differences would there have been in times to obtain formulary listings in 2001, as opposed to 1997?

- What impact did the entry of other generics (specifically, in this case, Genpharm) have on the post-expiry ramp-up period?

[220] Merck submits that the opinion of Dr. Meyer supports its claim to damages in respect of Post-Expiry Ramp-Up Tablets. In paragraph 99 of her Expert Report (TX 182), Dr. Meyer describes how she approached her calculation. In Exhibit 17 of her report, Dr. Meyer tabulates the "Estimated Lost Profits from Apotex Sales of Lovastatin Tablets to Customers Located in Canada" for the period of the First Quarter (Q1) of 2001 to the Third Quarter (Q3) of 2012. As shown in her table, the alleged ramp-up period commenced on February 1, 2001 of 2001 Q1 and ended in 2003 Q4. For each quarter, Dr. Meyer carried out the following series of steps:

1. The calculation began with the Actual Total Generic API in kilograms sold by Apotex in the period (A).

2. From A, Dr. Meyer subtracted an amount referred to as the volume that would have been sold in the but-for world (B), had Apotex and other generics commenced marketing after the '380 Patent expired. During cross-examination, Dr. Meyer confirmed that she used IMS data for Apotex's ramp-up in 1997 and simply shifted that ramp-up to 2001 to estimate the ramp-up for the hypothetical generic market post-January 31, 2001 (3T391-392; TX 182, Exhibits 17, 12a and 12b). This volume was based on an assumption that the sales during the post-expiry ramp-up would have been the same as they were in the real world following Apotex's entry in 1997. The difference between A and B (C) represents the "Expected Lost API Volume".

3. Dr. Meyer multiplied C by the profit per kilogram (D or E depending on whether the MACI Royalty is included or not included), as agreed to by the parties in the Streamlining Agreement, to obtain the "Plaintiffs Lost Profits on Expected Lost Mevacor® Sales". Dr. Meyer calculated two final values: one including the MACI Royalty and (F) other excluding the MACI Royalty (G).

4. The total lost profits are obtained by summing the F or G-values for each of the 12 quarters.

The relevant portion of Dr. Meyer's Exhibit 17 is attached as Appendix A to these Reasons.

[221] There is absolutely nothing wrong with the arithmetic. The problem, however, is the underlying assumption with respect to calculation of B that one can apply the real world experience of Apotex's actual ramp-up in 1997 to the post-expiry period. Stated another way, are the volumes set out in column B reliable? In my view, they are not.

[222] It is important to remember that Dr. Meyer's mandate and qualification by the Court was to provide expert opinion evidence regarding the hypothetical royalty negotiations. To fulfill this role, she relied on a number of calculations and assumptions given to her by counsel or obtained from the Streamlining Agreement. The fact that Dr. Meyer applied those numbers to a particular model to determine post-expiry ramp-up damages does not necessarily mean that they reflect all the factors that must be taken into account.

[223] Dr. Meyer was qualified by this Court to provide expert opinion evidence on economic issues related to the determination of a reasonable royalty as a result of a hypothetical royalty negotiation (2T238-241). She has little experience in the pharmaceutical sector (2T305-306). She certainly cannot be presumed to know how provincial formularies or drug distribution would work. Quite simply, I cannot conclude that her assumptions about the ramp-up period and sales by generics during that time are reasonable. Since I question the reliability of the figures in column B in her calculations, I am not satisfied of the reliability of the total claimed post-expiry ramp-up lost profits.

[224] I wish to make it clear that I am not questioning Dr. Meyer's modelling of the hypothetical royalty negotiations. Dr. Meyer's expertise in that area was very helpful. Moreover,

it may be that the calculations in Exhibit 17 contribute to the overall determination of a reasonable royalty. That is a different question.

[225] Merck argues that Apotex could have produced responding expert opinion to Dr. Meyer's Exhibit 17. The problem is that the calculation of the post-expiry ramp-up lost profits was not something that Dr. Meyer presented as part of her expert opinion; it was an assumption that she made and then "plugged" into her model. Through cross-examination, Apotex successfully and properly challenged her assumptions, raising a number of inadequacies.

[226] One of the key omissions in Dr. Meyer's analysis of the hypothetical ramp-up is the failure to consider that Apotex was already in the market effective March 26, 1997, with an NOC for Apo-lovastatin made with the non-infringing AFI-4 process. Apotex already had formulary listings. Dr. Meyer's calculation assumes that Apotex would not have obtained formulary listings or an NOC. The hypothetical world may ignore the existence of infringing sales but it cannot ignore non-infringing sales. Apotex made substantial non-infringing sales prior to the patent expiry. This – at least theoretically – would permit Apotex to shorten any ramp-up period after expiry. Apotex would already have had distribution networks in place.

(3) Conclusion on Post-Expiry Ramp-Up Lost Profits

[227] In sum on this issue, I am not prepared to include, as part of Merck's overall damages award, any part of the claim of lost profits for Post-Expiry Ramp-Up Tablets for the reason that either:

1. Merck is precluded from bring this claim at this late stage of the proceedings; or

2. Merck has not met its burden to demonstrate, on a balance of probabilities, that it suffered almost $28,000,000 in lost profits in respect of the Post-Expiry Ramp-Up Tablets.

XII. Lost Profits of Merck US

[228] Merck US claims an amount of $51,965,921 in damages for the breach of the '380 Patent. The injury to Merck US arises, in Merck's submission, because of the supply chain that requires Merck Canada to purchase its lovastatin API from Merck US.

[229] From the uncontradicted testimony of the Merck witnesses, Mr. Duguid and Mr. O'Sullivan, we know that, but for the infringement, Merck Canada would have, at least for the most part, purchased its API from Merck US, and Merck Canada would have purchased the API at [**Redacted**] per kilogram (Testimony of Mr. Duguid, 2T130-131; Testimony of Mr. O'Sullivan, 2T215-216, 219-220).

[230] The parties, as reflected in the Streamlining Agreement, have agreed that, subject to resolution of the two remaining issues described below, the pre-expiry profits that Merck US would have earned if it had supplied lovastatin API required by Merck Canada to replace each and every infringing tablet sold domestically prior to January 31, 2001 would have been $51,965,921 (Streamlining Agreement at para 7).

[231] The parties have also agreed that Merck US had the capacity to manufacture and sell lovastatin API in sufficient quantities to satisfy all of Merck Canada's demand (Streamlining Agreement at para 20).

[232] Apotex raises two issues that could potentially limit the claim for damages by Merck US:

1. Should Merck US be limited to nominal damages only because of the exclusive licence given to MACI?

2. Should Merck's claim be reduced to reflect that a third party – Quimica – would have made 3.6% of the sales of API to Merck Canada, thereby reducing the damages of Merck US?

A. *Merck US Assignment to MACI*

[233] Under s. 55 of the *Patent Act*, "[a] person who infringes a patent is liable to the patentee . . . for all damage sustained by the patentee. . . by reason of the infringement".

[234] Merck US is the named patentee in the '380 Patent. No matter how many licences or other patent rights it grants to others, it remains the patentee. The term "patentee" is defined in s. 2 of the *Patent Act* to mean "the person for the time being entitled to the benefit of a patent".

[235] The issue of Merck US's entitlement to damages arises because of a chain of inter-corporate agreements. The '380 Patent was granted to Merck US. Effective as of January 1, 1992, Merck US entered into an agreement (the MACI Licence Agreement, TX 64) with Merck and Company, Incorporated (MACI) pursuant to which Merck & Co., as Licensor, granted to MACI, as Licensee:

> a permanent and exclusive royalty-free license for the Intellectual Property which Licensor owns or hereinafter acquires, but for any outstanding licenses for the Intellectual Property which already granted pursuant to the License Agreement, dated January 1, 1985, and amendments thereto between Merck & Co., Inc. and Merck Frosst Canada Inc.

[236] It is uncontested that the '380 Patent was included in the Intellectual Property covered by the MACI Licence Agreement.

[237] In the liability phase of this action, Apotex argued that Merck US (referred to as Merck & Co. in the *Liability Reasons*) did not have standing to bring this action. I rejected that argument. The following portions of the *Liability Reasons* reflect my reasons for doing so.

> **44** . . . Apotex submits that Merck & Co. has no standing to bring this action, having assigned all of its interest in the '380 Patent to MACI pursuant to the MACI Agreement. Apotex asserts that, as of November 1992, MACI had the "full and unrestricted benefit of the '380 Patent". Merck & Co. lost all benefit of the patent and, as a result, the right to damages under s. 55 (1) of the *Patent Act*. Apotex argues that, although the agreement is entitled "License Agreement", a review of the words of the agreement demonstrates that the intent of the parties to the MACI Agreement was to convey the entire right, title and interest in the '380 Patent to MACI.
>
> . . .
>
> **47** Rather, I would look at this issue in the context of the Canadian law of contracts. As I understand the state of the Canadian law of contracts, the express language of the parties to a contract is the core of their contractual obligations. Where the words of a contract are clear and unambiguous, a court need not look beyond those clear words to determine its intent and effect.
>
> **48** Apotex was unable to point me to a single Canadian case that supports its position. Nevertheless, I would agree that the title of the License Agreement would not be determinative if there is clear and persuasive evidence that Merck & Co. intended to convey all of its rights in the '380 Patent to MACI, retaining nothing to itself. Whether this is so or not will depend on an examination of the words of the MACI Agreement and the facts and circumstances surrounding the MACI Agreement.
>
> **49** In this case, the express language of clause 2 of the MACI Agreement uses the word "license". On its face, the MACI Agreement only grants a "license". The Supreme Court of Canada in *Domco Industries Ltd., v. Armstrong Cork Canada Ltd.*, [1982] 1 S.C.R. 907 at p.912, 66 C.P.R. (2d) 46, adopted the comments of Fry L.J. at p. 470, in *Heap v. Hartley* (1889), 42 Ch. D. 461:
>
> > An exclusive license is only a license in one sense; that is to say, the true nature of an exclusive license is this. It is leave to do a thing, and a contract not to

> give leave to anybody else to do the same thing. But it confers like any other license, no interest or property in the thing. [Emphasis added.]
>
> **50** I also note the language of certain clauses in the MACI Agreement that refer to rights retained by Merck & Co. For example, clause 3 provides the Licensor with the rights to inspect the Licensee's facilities. Under clause 5.2, the Licensee is to supply the Licensor with a detailed description of any disclosure of "licensed know-how" to any governmental authority. In my view, retention of rights such as these is inconsistent with an intention to transfer all rights under the patent.
>
> . . .
>
> **54** In my view, the words of the MACI Agreement establish the creation of a licence and not a conveyance of all rights in the '380 Patent. The use of the word "remaining" in the recital does not "triumph over" the words of the agreement. This is sufficient to defeat the argument of Apotex.
>
> **55** However, even if I accept that there may be ambiguity in the MACI Agreement, I am satisfied that the parties to the MACI Agreement did not intend to convey the entire right, title and interest in the '380 Patent. One indication of the intent of the parties to an agreement is the behaviour of the parties. If the MACI Agreement is not clear on its face, it is of assistance to examine the behaviour of the parties after the execution of the agreement. Was the behaviour of Merck & Co., from November 1992, consistent with a company who had given up its entire right, title, estate and interest in the '380 Patent? Clearly, the answer is "no". If there had been such intent, why would Merck & Co. commence and pursue this litigation for 13 years in its own name? Further, why would Merck & Co. remain as the named patentee on the '380 Patent?
>
> **56** I am satisfied that the MACI Agreement did not operate as a conveyance of the entire right, title and interest of Merck & Co. to MACI. Merck & Co. has standing to bring this action.

[238] Apotex accepts this Court’s finding that Merck US has standing to bring this action but submits that the *Liability Reasons* did not address the question of whether Apotex’s infringement caused compensable harm to Merck US. In Apotex’s view, any such compensable harm can only

arise from rights that Merck US did not assign to MACI under the terms of the MACI Licence Agreement. Apotex argues that the effect of the MACI Licence Agreement was to confer the right to recover damages to MACI. I do not agree.

[239] I begin with a very important right held by a patentee. As described by Justice Wood of the British Columbia Court of Appeal in *Forget v Specialty Tools of Canada Inc* (1995), 62 CPR (3d) 537 at para 16, [1996] 1 WWR 12 (BCCA), "the effect of a patent is to exclude others from the exploitation of an invention, rather than to confer rights with respect to that invention on the patent holder(s)". With this fundamental patent right comes the right of the patentee to claim any damages that it sustained by reason of the infringement.

[240] Moreover, this right is not necessarily affected by a licence. In *Armstrong Cork Canada v Domco Industries Ltd*, [1982] 1 SCR 907 at 916, 136 DLR (3d) 595 [*Armstrong*], the Supreme Court stated as follows:

> It seems to me to be made manifest by the legislation that what the patentee is entitled to and what the persons claiming under him are entitled to are basically the same, namely, "all damages sustained" by them respectively by reason of the infringement. <u>It would, of course, be inconceivable that the patentee with a valid patent would not be entitled, from the person who infringes, to damages in compensation for his loss by reason of the infringement</u>… all person claiming under the patentee, who would include non-exclusive licencees, now have the same basic right, as has the patentee, namely, to recover from the person who infringes, damages in compensation for their losses by reason of the infringement.
>
> [Emphasis added.]

[241] What then is the position of the licensee? I agree with Merck that an exclusive licence grants the licensee leave to use the patent, coupled with a contract not to permit anyone else to do the same thing. It is well-established in the jurisprudence that an exclusive licence does not confer any interest or property in the patent (*Electric Chain Co of Canada Ltd v Art Metal Works Inc*, [1933] SCR 581 at 587, [1933] 4 DLR 240; *Armstrong*, above at 912-913; *Liability Reasons*, above at para 49). Under s. 55 of the *Patent Act*, as a person claiming under the patentee, the licensee is given the right to sue an infringing person for its damages. However, as set out in *Armstrong*, this does not mean that the patentee who has granted a licence is precluded from claiming its own damages, if sustained as a consequence of the infringement.

[242] In short, an exclusive licence establishes a contractual relationship between the licensor and the licensee, which relationship must be interpreted in accordance with the terms of the agreement. The agreement should not be interpreted to give away more than was agreed by the parties. With respect to the MACI Licence Agreement, did Merck US give away its right to exclude others from the exploitation of the '380 Patent? I do not believe that it did.

[243] Apotex refers to paragraph 50 of the *Liability Reasons*, where I set out two examples of retained rights: the right to inspect the licensee's facilities; and the right to a detailed disclosure of licensed "know-how" to any government authority. In Apotex's submission, my determination that Merck US had standing was made "on the basis of these retained residual rights". This is not a correct or reasonable interpretation of my decision. As noted, these two rights were set out as examples only.

[244] In my view, the MACI Licence Agreement is clear on its face that not all rights were conveyed to MACI. In this case, I agree with Merck that, under the MACI Licence Agreement, “MACI acquired nothing but leave to use the invention and a promise from Merck not to license anyone else” (Merck’s Final Written Argument at para 40). In particular, the agreement cannot be read to exclude Merck US from claiming damages that have arisen by reason of an infringement of the '380 Patent. Furthermore, it is important that Merck US remains the patentee; it could have assigned its title in the '380 Patent and obviously meant to retain certain rights when it decided not do so.

[245] If there is any lack of clarity in the MACI Licence Agreement as to the question, the conduct of the parties to the agreement may be considered (see *Liability Reasons*, above at para 55). The reality is that Merck US behaved throughout as though it retained the right to manufacture lovastatin API, a right which it would not have had if it had conveyed all of its rights in the '380 Patent to MACI. Further, it would be totally inconsistent with the retention of the right to bring a patent infringement action for Merck US to give away, without any further consideration, the accompanying right to claim damages for such an infringement. The behaviour of Merck US in pursuing this lawsuit for 16 years certainly presents strong evidence that the parties to the MACI Licence Agreement believed that the right to standing in this action, together with the right to damages, remained with Merck US.

[246] In closing on this issue, not only does Merck have standing to bring this action (as I found in the *Liability Reasons*), it has the right to claim its damages sustained by reason of the infringement.

B. *Quimica*

[247] In addition to the entitlement of Merck US to anything more than nominal damages, the parties disagree on the role of Quimica. In the real world, Quimica, an affiliate of Merck US and Merck Canada, supplied a small amount of API to Merck Canada. In the "but for" world, how much, if any, API would have been supplied to Merck Canada by Quimica?

[248] Merck's position is, but for the infringement, Merck US would have supplied all of the lovastatin API. According to Merck, there is no history of regular supply from Quimica, and such instances are an aberration, which should not be reflected in the damages award.

[249] Apotex asserts that invoices produced by Merck (TX 178, Brief of Lovastatin Purchases by Merck Canada) demonstrate that, out of a total of 7,809 kg of lovastatin API purchased by Merck Canada during the period of 1996 to 2001, 277.66 kg of API actually were supplied by Quimica. In other words, Merck Canada bought 3.6% of its lovastatin API from Quimica – and not from Merck US. Apotex submits that the actual purchasing pattern of Merck Canada is the best proxy for what would happen in the hypothetical world. In their view, this justifies the reduction in the lost profits claimed by Merck US of $1,870,773. I agree with Apotex that the real world experience of Merck is a fair proxy for the "but for" world. I disagree, however, that a reduction of 3.6% is warranted.

[250] The testimony of both Mr. Kirk Duguid and Mr. Barry O'Sullivan was that there was a policy in place that required Merck Canada to purchase its API from Merck US (Testimony of

Mr. Duguid, 2T130-131; Testimony of Mr. O'Sullivan, 2T215-216, 219-220). Unfortunately, that "policy" is not supported by any document. While I accept the testimony of the usual policy, absent more supporting documentation, I cannot rule out that, from time to time, lovastatin API could and would be provided by other suppliers.

[251] Based on my review of the invoices, coupled with the testimony of the Merck witnesses, it appears that the normal supply chain would result in almost all API being supplied by Merck US. However, for whatever reason, some lovastatin API was supplied by Quimica between 1996 and 2001. I accept the testimony of the Merck witnesses that some of the Quimica API that was supplied to Merck Canada was destroyed or returned (Testimony of Mr. Duguid, 2T125-129). In the end result, Quimica supplied 1.3% of the lovastatin API that was ultimately used in production. I am persuaded that the real world experience – at least with respect to the API that was actually used in production – is a reasonable proxy for the "but for" world. In the absence of documents that would lead me to conclude otherwise, I believe that it is more likely than not that, in the "but for" world, Quimica would supply some API, even though the usual supply chain would result in purchases from Merck US. Based on the actual experience of Merck, I conclude that it is reasonable that 1.3% of lovastatin API would have been supplied by Quimica and 98.7% by Merck US.

C. *Conclusion on the Lost Profits of Merck US*

[252] As a result of these findings, I am satisfied that Merck US is entitled to its lost profits based on its sale of API to Merck Canada. However, in recognition that the real world is a

reasonable proxy for the hypothetical world, the lost profits incurred by Merck US should be reduced by 1.3% – $675,557 – to $51,290,364.

XIII. Pre-Judgment Interest

[253] As stated in the Liability Reasons, I have already concluded that Merck is entitled to pre-judgment interest on its award of damages (*Liability Reasons*, above at para 640). The parties disagree on the rate of interest for that calculation.

[254] The first question is to determine where the infringement occurred. In this case, infringing product was either manufactured in Manitoba or imported by AFI into Manitoba, and was then shipped to Apotex Inc. in Ontario for tableting and sale throughout Canada. Since the parties agree that infringement occurred in more than one province, s. 36(2) of the *Federal Courts Act*, RSC 1985, c F-7 [*Federal Courts Act*] is applicable and provides that the award of interest be "at any rate that the Federal Court of Appeal or the Federal Court considers reasonable in the circumstances". Further discretion, as to the appropriate rate, is found in s. 36(5) which provides that:

36. (5) The Federal Court of Appeal or the Federal Court may, if it considers it just to do so, having regard to changes in market interest rates, the conduct of the proceedings or any other relevant consideration, disallow interest or allow interest for a period other than that provided for in subsection (2) in respect of the whole or any part of the	36. (5) La Cour d'appel fédérale ou la Cour fédérale, selon le cas, peut, si elle l'estime juste compte tenu de la fluctuation des taux d'intérêt commerciaux, du déroulement des procédures et de tout autre motif valable, refuser l'intérêt ou l'accorder pour une période autre que celle prévue à l'égard du montant total ou partiel sur lequel l'intérêt est

amount on which interest is payable under this section.	calculé en vertu du présent article.

[255] Pursuant to s. 36(4) of the *Federal Courts Act*, interest shall not be awarded "on interest accruing under this section". Stated differently, interest is not to be compounded.

[256] Apotex submits that pre-judgment interest ought to be calculated using a floating annual average rate commencing at the first quarter of 1997 at which the Bank of Canada made short-term advances (1997 Bank Rate). Apotex states that this rate is approximately 3.3%.

[257] Merck, on the other hand, proposes that I award pre-judgment interest at a rate equal to one of:

a) Merck's long-term borrowing rate during the period, resulting in an interest award of about 6%;

b) Merck's WACC, for an interest rate of 11%; or

c) Apotex's borrowing rate of about [**Redacted**].

[258] The Federal Court has awarded pre-judgment interest at the Bank Rate (uncompounded) in a number of recent cases (including, for example, *Janssen-Ortho Inc v Novopharm Ltd*, 2006 FC 1234 at para 135, 57 CPR (4th) 6; *Perindopril*, above at para 513). Of particular relevance, in *Merck & Co v Apotex Inc*, 2006 FC 524 at para 240, 53 CPR (4th) 1 [*Lisinopril FC*], a case

involving both infringement in a very similar period and the same parties, Justice Hughes concluded that pre-judgment interest at the Bank Rate was appropriate. On appeal, Merck sought an interest rate of the annual bank rate plus 1.5% or, at a fixed rate of 5.75%, “to reflect modern commercial reality” (*Merck & Co v Apotex Inc*, 2006 FCA 323 at paras 137-145, [2007] 3 FCR 588 [*Lisinopril FCA*]). The Court of Appeal upheld Justice Hughes’s award of pre-judgment interest at the Bank Rate.

[259] Merck, in this trial, developed a more robust evidentiary record and argument for seeking a higher interest rate than in *Lisinopril FCA*.

[260] The fact that the Court has discretion in setting the rate of pre-judgment interest means that I must carefully consider the submissions for a rate that differs from the 1997 Bank Rate. I am also cognizant of the guidance of the Federal Court of Appeal in *Apotex Inc v Wellcome Foundation Ltd* (2000), [2001] 1 FC 495 at paras 122-123, 10 CPR (4th) 65 (CA) [*Apotex v Wellcome*], where the Court of Appeal referred to the purpose of pre- and post-judgment interest in the following terms:

> . . . prejudgment and postjudgment interest serve a two-fold purpose: it compensates the plaintiff for the cost of the money claimed; and, it "deprives the wrongdoer of a windfall benefit he would otherwise receive." Or, as Finlayson J.A. observed in *Irvington Holdings Ltd. v. Black et al. and two others* "[i]nterest is the cost of money to the borrower just as it is the return to the lender or investor."
>
> . . . I would adopt the longstanding principle in the Anglo-Canadian jurisprudence that interest should be used neither as penalty nor reward, but should stand as part of an award to make the aggrieved party whole. In that, I endorse Denning M.R.'s statement in *Panchaud Freres S.A. v. R. Pagnan and Fratelli* that the exercise of discretion in awarding interest "must be related to

> the task of putting the plaintiff in the same position, so far as money is concerned, as he would have been if he had not suffered the loss."
>
> [Citations omitted.]

[261] Apotex has deprived Merck of the use of a substantial amount of money due to its infringement of the '380 Patent. The various scenarios and evidence with respect to those scenarios presented by Merck amply demonstrate that, in this case, the 1997 Bank Rate would not reflect “commercial reality” for either Merck or Apotex.

[262] I reject the WACC as a standard by which to set a rate of interest. As described by Mr. Promo, the WACC is an internally generated rate used to evaluate the feasibility of investments (3T444-451). Merck’s WACC ranged between 10% and 13% for the relevant period (3T445). In my view, the rate at which a very large and wealthy corporate entity would choose to screen investments has little relevance to the assessment of a rate of pre-judgment interest.

[263] Far more relevant is Merck’s cost of borrowing during the relevant period. In both *Hertzog v Highwire Information Inc*, [1997] FCJ No 968 at paras 27-30 (FC, Proth Hargrave) and *Universal Sales, Ltd v Edinburgh Assurance Co*, 2012 FC 1192 at paras 12-17, 23, 2012 FCJ No 1292, pre- and post-judgment interest was awarded with reference to the plaintiffs’ borrowing rate.

[264] In this case, Mr. Promo testified as to two long-term debentures issued by Merck in 1998. These instruments bore fixed interest rates of 6.4% and 5.95% (3T454-457; see also, TX 187,

Debentures). Merck acknowledges that its short-term borrowing rate was below prime and, thus, below the rates of the debentures.

[265] Merck lost the use of a significant amount of money and must receive pre-judgment interest to be made whole. Apotex opposes any award in excess of the Bank Rate. The primary justification for Apotex's argument is that "Merck had enough money to fund its ongoing operations out of its own capital at all times" (9T1478). This may be true but misses the point that Merck did indeed enter into debt arrangements during the relevant period.

[266] Apotex also argues that I should follow my fellow judges in awarding the Bank Rate. However, in those cases, I cannot be certain of what evidence, if any, of long-term debt rates was advanced. Before me, I have such evidence.

[267] Merck also proposes, as an option, that I use Apotex's rate of borrowing. As reflected in the Plaintiffs' read-ins (TX 197, Tab 4) this would result in a rate of about [**Redacted**]. Merck's rationale is as follows:

> Apotex has in effect taken a forced loan from Merck for 16 years. The Court knows with certainty what Apotex was required to pay voluntary lenders to obtain loans. Apotex should not get a more favourable interest rate by taking a loan without consent or collateral than it would have had to pay its own bankers.
>
> (Merck's Final Written Argument at para 65.)

[268] Awarding interest at this rate would certainly achieve the objective referred to by the Court of Appeal in *Apotex v Wellcome*, above at paragraph 122, of depriving "the wrongdoer of a

windfall benefit he would otherwise receive". As such, this rate is a relevant factor to consider and suggests that a rate of [**Redacted**] would not be inappropriate.

[269] One factor identified in s. 36(5) is the "conduct of the parties". In this case, the litigation has dragged on for almost 16 years. As to the conduct of the action, I am unable to place blame on either the Plaintiffs or the Defendants. However, it ought not to be ignored that Merck's action became necessary by its failure to pursue its NOC claim within the 30-month period provided for in the *PM (NOC) Regulations*, as they were in the mid-1990s. Consideration of Merck's actions would tend to reduce the rate of pre-judgment interest.

[270] Overall, exercising my discretion after considering all of the relevant factors, I conclude that the pre-judgment interest rate should be set at a rate equal to the 1997 Bank Rate plus 1%, not compounded.

XIV. Post-Judgment Interest

[271] As submitted by Apotex, post-judgment interest should be calculated at the rate of 5%, not compounded, as established by s. 4 of the *Interest Act*, RSC 1985, c I-15.

XV. Costs

[272] As a general rule, costs are to be awarded to the successful party; in this case, that is Merck. Merck was awarded its costs in the liability phase of this trial and is entitled to its costs in

this damages phase. During final argument, parties made submissions on the principles to be applied to the assessment of costs for this phase of the trial. The parties propose different approaches on a number of the key areas. Directing my mind to the submission of the parties and the factors set out in Rule 400(3) of the *Federal Courts Rules*, SOR/98-106 [*Federal Courts Rules*], I propose to exercise my discretion in the following manner.

A. *Scale*

[273] Merck submits that the costs be assessed at the upper end of Column IV of Tariff B for the period preceding the execution of the Streamlining Agreement and mid-Column III thereafter. Apotex submits that all costs – before and during trial – be assessed at the upper end of Column IV. I will accept Merck's proposal.

[274] These scales will establish, for the most part, the rules to be applied to the assessment of counsel fees and disbursements. The exceptions are described below.

B. *Split or Differentiated Costs Awards*

[275] Apotex describes the damages phase of this trial as consisting of two parts – the availability of a non-infringing alternative and the computation of damages, whether by lost profits or reasonable royalty (depending on the success of Apotex on its NIA defence). Apotex urges me to recognize this differentiation through a split costs award or reduction in costs otherwise payable to Merck.

[276] In concept, I agree with Apotex that there may be circumstances where a fair and reasonable costs award reflects different success on key issues. I would even go so far as to say that, had Apotex succeeded in its NIA defence in this case, I would have likely found that the costs to Merck should be reduced. This would have reflected the importance of this issue and the time taken up with this question at trial. However, I have rejected Apotex's NIA defence. Accordingly, Merck is the successful party and is entitled to its costs with respect to all of the issues at trial.

[277] Although Merck did not succeed with respect to two issues (the Post-Expiry Ramp-Up and MACI Royalty), these issues are not of sufficient importance to the overall judgment that a reduction in costs is warranted.

C. *Counsel*

[278] Merck proposes that the costs award should include a direction for one senior and one junior counsel at discoveries and two senior and two junior counsel at trial. Apotex submits that the costs award should allow for one senior and one junior counsel, if present, at examinations for discovery and one senior and two junior counsel at trial.

[279] The trial itself was comparatively short. Nevertheless, the issues developed quickly and were complex and varied, as evidenced by three days of final argument, warranting an increase in costs to reflect the need for more than one lawyer at the trial. However, contrary to the request of Merck, I believe that an award for two senior and two junior counsel is excessive.

[280] Accordingly, I will accept Apotex's submission on this point; costs for one senior and two junior counsel at trial will be permitted. The request for one senior and one junior counsel, if present, at examinations for discovery is reasonable and will be allowed.

D. *Experts*

[281] The most common approach for the costs of experts is that a party is only entitled to recover costs for experts who actually appeared at trial. In this case, that approach would permit Merck to recover only those costs associated with Dr. Meyer. There is, however, no rule or jurisprudence precluding recovery of the costs of experts who do not testify (see, for example, *Merck & Co v Apotex Inc*, 2002 FCT 842 at para 40, [2002] FCJ No. 1116 (Assessment Officer, Stinson), aff'd 2002 FCT 1037, 22 CPR (4th) 377). Each case must be examined on its facts. In this case, many experts were retained and delivered reports, although they did not testify.

[282] Merck refers to the role of the Streamlining Agreement in obviating the need for many of the experts. Merck described the work of those experts as follows:

> In the present case, many of the experts retained did not need to be called because the issues their reports addressed were settled by the Streamlining Agreement. As such, their reports were clearly relevant to the issues – it is precisely *because* these experts' reports were relevant that the experts did not testify. The Streamlining Agreement was arrived at only after the parties had exchanged expert reports and replies; it incorporates, explicitly or implicitly, the opinions of the parties' numerous experts relating to issues of capacity, market size, production expenses and revenues, the number and timing of sales, and mitigation.
>
> (Merck's Final Written Argument at para 230.)

For this reason, Merck requests that I allow costs for all of its experts.

[283] The first problem with Merck's argument is that it ignores the role that experts play at the trial. Expert witnesses provide the court with the benefit of their specialized knowledge and expertise, so that the trier of fact may evaluate evidence and arguments of a particularly technical nature. Without hearing their evidence and reading their reports, I cannot conclude that the non-appearing experts assisted the Court in any way. They certainly did not assist the Court in understanding the subject matter of their reports; I never considered the opinions of those reports. The fact that the experts may have helped the parties resolve some major issues does not mean that they fulfilled the role expected of experts.

[284] The other difficulty I have with awarding costs to one side over the other is that I am unable to evaluate what role those experts had in the development of the Streamlining Agreement.

[285] Accordingly, I conclude that recovery of fees in respect of experts should be limited to reasonable fees for Dr. Meyer, including the preparation of her report and work done by Dr. Meyer to assist counsel.

E. *Conclusion on Costs*

[286] As part of my Judgment, I will direct that costs be assessed by an Assessment Officer, under Rule 405 of the *Federal Courts Rules*, in accordance with the foregoing conclusions.

XVI. Overall Conclusions

[287] In summary and for the foregoing reasons, I conclude that Merck is entitled to an award of $119,054,327 in damages (the Damages Award), made up of the following amounts:

- $62,925,126 as lost profits of Merck Canada, in respect of Pre-Expiry Replacement Sales;

- $51,290,364 as lost profits of Merck US, in respect of Pre-Expiry Replacement Sales;

- [**Redacted**], based on a reasonable royalty calculation, for post-expiry infringing domestic sales; and

- [**Redacted**], based on a reasonable royalty calculation, for infringing export sales.

[288] In addition, Merck is entitled to pre-judgment interest on the Damages Award at a rate of the 1997 Bank Rate plus 1% (Reasons, Section XIII) and post-judgment interest at a rate of 5% (Reasons, Section XIV).

[289] The calculation of these amounts reflects, for the most part, those facts and figures set out in the Streamlining Agreement. Further, with reference back to the Issues before me as set out in Section V of these reasons, I make the following conclusions and findings:

1. In calculating Merck Canada's damages, the availability of a non-infringing alternative is not relevant (Section VII);

2. If I am wrong in the relevance of the NIA defence, I conclude that a reasonable royalty would be payable for the Pre-Expiry Replacement Sales, with such royalty being calculated on a one-time basis on the eve of the first infringement and in accordance with the framework described by Dr. Meyer (Section IX);

3. Merck is not entitled to lost profits for the Post-Expiry Ramp-Up Sales (Section XI.B);

4. Merck Canada's lost profits should be reduced by the amount of the MACI Royalty to reflect that royalty as an expense saved (Section VIII);

5. In a calculation of Merck US's lost profits, Merck is entitled to its lost profits in respect of the sale of lovastatin API to Merck Canada, taking into account a 1.3% deduction for sales that would have likely been made by Quimica (Section XII);

6. The reasonable royalty with respect to post-expiry (excluding the Post-Expiry Ramp-Up Sales) and export infringing sales should be established at an amount that would fall in the mid-range of the difference between Apotex's costs to use the infringing AFI-1 process and their costs to use the non-infringing alternative Section XI.A).

7. Merck is entitled to its costs of this phase of the action assessed in accordance with the findings and directions set out herein (Section XV).

POSTSCRIPT

[1] The Confidential Reasons for Judgment and Confidential Judgment were released to the parties on July 5, 2013. Upon release of the Confidential Reasons and the Confidential Judgment, the parties were requested to advise the Court of portions of the Reasons and Judgment that they wished redacted for the Public Reasons and Public Judgment. This version of the reasons contains redactions of small portions of the Confidential Reasons for Judgment. Each of Merck and Apotex were very reasonable in their requests and I have accepted that all of the suggested redactions will be incorporated into the Public Reasons and Public Judgment. In each case, I am satisfied that the risks to a party of the release of the sensitive commercial information

outweigh any public interest in having access to that information. Moreover, even with the redactions, I believe that a reader is able to understand the nature of the evidence and the reasoning applied to reach the relevant findings. Parallel redactions have also been made to paragraphs 1(c) and 1(d) of the Confidential Judgment.

"Judith A. Snider"
Judge

Ottawa, Ontario
Public Reasons for Judgment - July 16, 2013
Confidential Reasons for Judgment - July 5, 2013

Appendix A-Estimated Lost Profits from Post-Expiry Ramp-Up Tablets

(Adapted from Exhibit 17, Dr. Meyer's Report (TX 182))

	Actual Total Generic API Volume			**Plaintiffs Lost Profit on Expected Lost Mevacor® Sales**	
	Actual (A)	But for (Kg) (B)	Expected Lost API Volume (A) – (B) = (C)	Including MACI Royalty (C) x (D) = (F)	Not Including MACI Royalty (C) x (E) = (G)
2001 Q1	79.56	22.10	57.47	4,695,134	4,528,945
2001 Q2	163.43	53.55	109.88	8,977,716	8,659,940
2001 Q3	136.15	94.32	41.83	3,417,515	3,296,548
2001 Q4	174.71	138.93	35.77	2,922,918	2,819,458
2002 Q1	123.59	108.36	15.23	1,244,458	1,200,409
2002 Q2	111.90	100.19	11.71	957,113	923,235
2002 Q3	180.30	160.44	19.86	1,622,905	1,565,461
2002 Q4	135.27	124.83	10.44	853,198	822,999
2003 Q1	116.04	110.30	5.74	468,628	452,040
2003 Q2	133.05	122.33	10.72	875,807	844,807
2003 Q3	126.52	115.91	10.62	867,464	836,759
2003 Q4	112.97	102.11	10.86	887,547	856,131
			TOTAL RAMP UP DAMAGES:	$27,790,403	$26,806,732

Note: For all quarters, as per the Streamlining Agreement, the Plaintiffs' Profit per kilogram of Mevacor is: $81,704 when the MACI royalty is included (D); and $78,812 when the MACI royalty is <u>not</u> included (E).

FEDERAL COURT
SOLICITORS OF RECORD

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DATED:	JULY 16, 2013

APPEARANCES:

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Mr. John A. Myers, Mr. Patrick Riley	FOR THE DEFENDANT APOTEX FERMENTATION INC.

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