Federal Court of Appeal  Cour d'appel fédérale

Date: 20181123

Docket: A-64-15

Citation: 2018 FCA 217

CORAM: **GAUTHIER J.A.**
GLEASON J.A.
LASKIN J.A.

BETWEEN:

APOTEX INC.

Appellant

and

ELI LILLY AND COMPANY AND ELI LILLY CANADA INC.

Respondents

Heard at Toronto, Ontario, on September 17-18, 2018.

Judgment delivered at Ottawa, Ontario, on November 23, 2018.

REASONS FOR JUDGMENT BY: GAUTHIER J.A.

CONCURRED IN BY: GLEASON J.A.
LASKIN J.A.

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REASONS FOR JUDGMENT

GAUTHIER J.A.

I. INTRODUCTION

[1] This is the latest in a long saga of proceedings opposing generic drug producer Apotex Inc. and global pharmaceutical giant Eli Lilly and Company and its Canadian subsidiary, Eli Lilly Canada Inc. [together, Lilly]. Here, Apotex appeals the judgment of Zinn J. of the Federal

Court (2014 FC 1254) [Damages Decision]. In that decision, the Federal Court was tasked with assessing the damages suffered by Lilly as a result of the infringement of eight Canadian patents for the processes relating to the making of a key intermediate compound (referred to as "7-ACCA") required to make cefaclor, a cephalosporin antibiotic used to treat certain bacterial infections.

[2] Liability for the infringement was attributed to Apotex in 2009 following a trial spanning 67 days between April and December 2008 (2009 FC 991) [Liability Decision]. The Federal Court found that the patents at issue were valid and that they had been infringed by Apotex as a result of its importation and use of cefaclor produced by South Korean drug maker Kyong Bo Chemical Ltd. [Kyong Bo] and Lupin Laboratories Ltd. of India [Lupin] before June 1998. That decision was later confirmed by this Court in 2010 (2010 FCA 240), and leave to appeal to the Supreme Court of Canada was refused in May 2011.

[3] In the decision under appeal before us, the Federal Court ordered Apotex to pay Lilly $31,234,000.00 in damages pursuant to subsection 55(1) of the *Patent Act*, R.S.C. 1985, c. P-4 [Patent Act]. Lilly was also awarded $75,040,649.00 in prejudgment interest as damages for the time value of the money lost in the 17 years before the reference trial on damages took place, bringing the total award to $106,274,649.00.

[4] Though the parties raised many issues given the amounts involved, I do not agree with Apotex that new questions of law requiring the consideration of new policy concerns are at play.

The facts of this case are so unusual that it would be unwise to use them as a backdrop for stating general principles of law. As the adage goes, “hard facts” often make “bad law”.

[5] I realize that much time has been spent and resources deployed, including those of the judiciary, in these proceedings. Still, for the reasons that follow, I propose that the appeal be allowed, but solely on the question of interest granted as damages.

II. OVERVIEW AND BACKGROUND FACTS

A. *General facts*

[6] Four of the cefaclor process patents at issue during the liability phase of the proceedings were filed in 1979. They were subsequently issued to Lilly between October 1982 and July 1983. The first patent issued expired in October 1999, and the last in July 2000. The other four relevant patents were issued to Shionogi & Co. Ltd. [Shionogi], a Japanese pharmaceutical company, between February 1981 and April 1983. The first of these expired in February 1998, while the last expired in April 2000. Lilly became the owner of the Shionogi patents by way of assignment in 1995 (see Liability Decision at paras. 3-4).

[7] Litigation between Apotex and Lilly over the process patents began in 1993, when Apotex filed a Notice of Compliance [NOC] submission for its own generic version of cefaclor (known as “Apo-Cefaclor”) with Health Canada. Lilly subsequently commenced an application under the then recently enacted *Patented Medicines (Notice of Compliance) Regulations*,

SOR/93-133 [PMNOC Regulations], seeking an order prohibiting Apotex from selling its cefaclor product in Canada.

[8] In a decision dated September 12, 1995, Simpson J. dismissed Lilly's application (see *Eli Lilly and Co. v. Apotex Inc.* (1995), 101 F.T.R. 33 (T.D.)). She held that the claims in the eight patents at issue did not relate to substances that were medicines in themselves as per the criteria set out in section 2 of the PMNOC Regulations at that time. It is in that context that Simpson J. made the following statement:

> **9** The uncontradicted expert evidence before me discloses that there is no commercially viable means of producing Cefaclor without using at least two of the Intermediates. Canadian Patents 1,097,611 and 1,146,536 contain the claims for those crucial intermediates. Apotex has not suggested that it has developed a non-infringing process. It is, therefore, reasonable to infer that Apotex plans to infringe the Patents by copying Lilly's production methodology if it is not prohibited from manufacturing the Intermediates by a prohibition order made in this application. In that event, it will be open to Lilly to seek remedies for infringement at common law.
>
> [Emphasis added.]

[9] The decision was later confirmed on appeal: *Eli Lilly and Co. v. Apotex Inc*. (1996), 199 N.R. 4 (F.C.A.), leave to appeal to S.C.C. refused, 25477 (January 30, 1997).

[10] In light of the above, it was expected that Apotex would obtain an NOC with respect to cefaclor. As he indicated in an affidavit dated November 13, 2003, counsel for Apotex, Mr. Harry B. Radomski, advised Apotex in late 1996 to prepare to face an infringement action brought by Lilly should it enter the market with its generic version of cefaclor (Exhibit TX-641 at para. 4, Appeal Book, vol. 58, tab 256 at pp. 17191-204).

[11] On January 17, 1997, Apotex obtained its NOC for capsules of cefaclor, and another NOC was issued for the sale of cefaclor in oral suspension form on March 6, 1998. Promptly after obtaining the first NOC, Apotex began selling its various capsules of cefaclor on the Canadian market. As predicted, Lilly commenced an infringement action. Its first action was launched on January 23, 1997, but was subsequently discontinued. The action that eventually led to the liability trial in 2008 was commenced on June 18, 1997. That action specifically referred to the "Kyong Bo process" – the process used by the manufacturer Kyong Bo for the production of Apotex's generic cefaclor. This was the only process Lilly knew Apotex was using at the time. However, Apotex had in fact two suppliers of cefaclor: Kyong Bo and Lupin.

[12] Apotex received its first commercial batch of cefaclor from Kyong Bo on November 25, 1996, ordered its last batch on June 16, 1997, and received this last batch on September 9, 1997. This portion of the total cefaclor received by Apotex is referred to as "Kyong Bo cefaclor".

[13] Apotex received its first commercial batch of cefaclor produced by Lupin on May 23, 1997, ordered its last batch on April 3, 1997, and received this last batch on November 20, 1997. This portion is referred to as "Lupin 1 cefaclor".

[14] Both the Kyong Bo (Shionogi patents) and Lupin 1 (Lilly patents) portions of cefaclor were found to be infringing by the Federal Court in 2009 following the liability trial.

[15] In addition to the 9,126 kg of Kyong Bo and Lupin 1 cefaclor referred to above, Apotex imported a third portion. On March 13, 1998, Apotex entered into a contract with Lupin for the

supply of an additional 7,500 kg of cefaclor [1998 Agreement]. Notably, the 1998 Agreement involved cefaclor made by a new process (referred to as Process "E" in the Liability Decision). This process was developed after exchanges with Apotex (particularly its in-house counsel, Ms. Brigitte Fouillade) in order to design around the processes patented by Lilly and Shionogi. As a result, Lupin undertook to "use only the teachings" of the purportedly expired patents detailed in Appendix A of the 1998 Agreement when producing these 7,500 kg of cefaclor (Exhibit TX-1656, Appeal Book, vol. 57, tab 246 at pp. 15290-91; Liability Decision at para. 788). The process detailed in Appendix A (hereinafter the "Lupin 2 process") was to be kept confidential, and was intended solely for the purposes of production for Apotex. This third portion is referred to as "Lupin 2 cefaclor".

[16] Apotex imported its first batch of Lupin 2 cefaclor in June 1998, and received all 7,500 kg by October 22, 1998.

[17] The Federal Court held that Lilly had not established infringement of the Lilly and Shionogi patents in regard to the Lupin 2 process (see Liability Decision at paras. 228-29). In that sense – and only for the purposes of the proceedings before the Court in 2008 –, the Lupin 2 process was described as a legal process in the reasons dealing with Apotex's counterclaim, which the Federal Court also dealt with in 2008. As will be discussed, it now appears that one of the patents listed in the 1998 Agreement, Canadian patent 1,218,646 [646 Patent] relating to Step VI of the Lupin 2 process, did not expire until 2004 (see Exhibit RX-207, Appeal Book, vol. 53, tab 220 at p. 15292).

[18] I also note that the initial NOC that Apotex received on January 17, 1997, was based on submissions which described Kyong Bo as its supplier and provided some detail regarding the Kyong Bo process. When Apotex decided to buy Lupin 1 cefaclor as well, it notified Health Canada through a Notifiable Change filed in April 1997 that it wanted to add Lupin as a supplier (Facts Agreed to by the Parties at p. 10, Appeal Book, vol. 2, tab I at p. 557). Health Canada requested details regarding the Lupin 1 process, which were duly provided. On June 25, 1997, Health Canada confirmed that it had no objection to the change (see Liability Decision at para. 227; see also Parra Direct Examination, Lilly's Day Book for Re-Hearing, vol. 1, tab 30, Appeal Book, vol. 76, tab 378 at pp. 22586-87). However, Apotex did not update its file with Health Canada after the Lupin 2 process was developed for use pursuant to the 1998 Agreement. Although Lilly argued emphatically that this omission was relevant to the issues to be determined at both the liability and reference stages, I do not intend to discuss the matter further; indeed, it was held to be irrelevant in the Liability Decision at paragraph 74. Considering my other conclusions, I find it unnecessary to address it in this appeal.

B. *Liability Decision (2009 FC 991)*

[19] Having found Kyong Bo and Lupin 1 cefaclor to be infringing, the Federal Court granted Lilly the right to elect either an accounting of Apotex's profits as a remedy, or an award of all damages sustained by reason of sales lost as a result of the infringement by Apotex of the eight Lilly and Shionogi patents (Liability Decision at p. 324). As per the bifurcation order dated November 29, 1999, such damages would be assessed by reference (i.e. after a separate trial).

[20] The Federal Court also awarded Lilly "pre-judgment interest on the award of damages (if elected), not compounded, at a rate to be calculated separately for each year since infringing activity began at the average annual bank rate established by the Bank of Canada" (Liability Decision at p. 325, para. 4; see also para. 674). Notably, under paragraph 36(4)*(f)* of the *Federal Courts Act*, R.S.C. 1985, c. F-7 [FC Act], this award would only apply if no interest was awarded by the reference judge as part of the damages (see para. 27 below).

C. *Damages Decision (2014 FC 1254)*

[21] The Damages Decision under appeal was issued on December 23, 2014, following an 18-day trial during the months of September and October 2014. What follows is meant to be a brief overview of the Federal Court's findings. They will be developed in greater detail in the analysis.

[22] First, a word on the form and length of the Federal Court's reasons, which span 48 pages. It appears that the structure of the Damages Decision follows that of the main issues as put forth by the parties before the Federal Court at trial. Considering the voluminous amount of evidence in the record, as well as the fact that the parties fought vigorously on almost every relevant factual issue, the reasons are comparatively brief. To my mind, the Damages Decision was drafted with only the parties as the intended audience, as it contains little reference to the many controversies regarding the evidence as a whole. Indeed, the reasons assume that the reader is particularly familiar with the evidentiary record.

[23] Second, the substance. Since Lilly elected an award of damages under subsection 55(1) of the Patent Act rather than an accounting of profits, the Federal Court applied the framework

established by the Supreme Court in *Clements v. Clements*, 2012 SCC 32 [*Clements*], given that patent infringement is a statutory tort. The guiding question was thus: "But for the infringing product being on the market, what would the patentee's position have been?" (Damages Decision at para. 20). The Federal Court noted that, in this "but-for" world, Lilly had the burden of proving the causal connection between its lost sales and infringing ones made by Apotex. Lilly also had to prove on the balance of probabilities that, *but for* the sales of the infringing product, it would have made additional sales. Finally, it had to prove the volume of those additional sales and the profit that it would have realized on them (Damages Decision at para. 33).

[24] However, using the authorities available to it at the time, the Federal Court concluded that the defence of a "non-infringing alternative" (or NIA) raised by Apotex was not available to an infringer in Canada (Damages Decision at para. 57).

[25] Still, given the framework adopted, the Federal Court had to determine when Apotex would have entered the market in the "but-for" world. It found that Apotex would not have been in the cefaclor market prior to April 19, 2000, when the last of the Shionogi patents expired. In other words, the Federal Court found that it is only from that date forward that Apotex would have entered the market with non-infringing cefaclor (see Damages Decision at paras. 62-63, 70-71; see also paras. 27-35 for discussion on causation). In doing so, it accepted Lilly's position that there was a fundamental difference between the actions one takes to enter the market and those taken to remain in it. Apotex did not persuade the Federal Court that in the "but-for" world it would have had sufficient incentive to enter the market as opposed to remaining in it, as it in fact did when it ordered the Lupin 2 cefaclor (Damages Decision at para. 68).

[26] Next, the Federal Court awarded Lilly a royalty of $1,500.00 per kg for each sale made by Apotex in breach of the patents that Lilly could not have made (Damages Decision at paras. 101-03). The Federal Court thereby rejected Apotex's expert evidence which was based on the assumption that an NIA could have been available to Apotex at the relevant time – that is, when initial infringement occurred. It is in that context that the Federal Court ruled that such a premise was not supported by the evidence; in other words, Lupin 2 cefaclor could not have been available to Apotex. This had not been proven as a fact (Damages Decision at para. 100).

[27] Finally, in regard to prejudgment interest, the Federal Court held that Lilly was not required to prove exactly what use it would have made of the profit it lost as a result of Apotex's actions. The Federal Court also concluded that, "in today's world", there is a presumption that a plaintiff such as Lilly would have generated compound interest on the funds owed to it, and that Apotex also did so in the period during which it withheld the funds (Damages Decision at para. 118). The Federal Court found that Lilly would have invested in its business, and it was awarded prejudgment interest compounded annually at Lilly Canada's historical average annual profit margin on sales for the years 1997 through 2012 (Damages Decision at paras. 122, 125; Expert Report of Stephen Foerster, Exhibit RX-115, Appeal Book, vol. 34, tab 26 at p. 9862).

III. ISSUES

[28] The standards of review applicable to the issues raised in this appeal are as described by the Supreme Court in *Housen v. Nikolaisen*, 2002 SCC 33. The standard of review to be applied to questions of law is correctness, while findings of fact and inferences of fact are to be reviewed on the basis of palpable and overriding error. Findings of mixed fact and law are to be reviewed

on the same deferential standard unless an extricable legal error can be demonstrated, in which event the correctness standard applies.

[29] As such, I will frame the issues in the analysis as follows:

1) Did the Federal Court err in finding that no NIA defence was available to Apotex?

2) Did the Federal Court err in finding that Apotex would not have entered the market until April 2000 in the "but-for" world (causation)?

3) Did the Federal Court err in determining the reasonable royalty rate?

4) Did the Federal Court err when it held that Lilly was entitled to interest as damages?

IV. ANALYSIS

A. *Preliminary Comments*

[30] Before tackling the analysis, it is opportune to lay some groundwork. Two issues need to be addressed from the get-go: 1) the importance of Lupin 2 cefaclor for the majority of the issues to be addressed; and 2) the relevance of certain additional facts relating to the actual world and evidence before the Federal Court.

(1) The relevance of Lupin 2 cefaclor

[31] Except for the last issue, all the questions before us to some extent involve evaluating the availability of Lupin 2 cefaclor. It is thus useful to recall the role the notion of an NIA plays in the various hypothetical scenarios that the Federal Court, as trier of fact, had to construct in order to assess damages.

[32] First, as noted by the Federal Court, Lilly had to prove that its damages were caused by the wrongful conduct, i.e. the infringement of the patents at issue (subsection 55(2) of the Patent Act). Using the principles it properly referred to, the Federal Court had to construct a fictional, hypothetical situation on the basis of all the evidence before it. The fiction in question concerned the landscape of the cefaclor market in Canada – and Lilly's position within it – had Apotex not infringed the patents. This exercise was necessary for assessing what sales Lilly effectively lost because of Apotex's wrongful conduct. As noted above, this is sometimes referred to as the "but-for" world (causation).

[33] The parties agreed that, in respect of cefaclor sold by Apotex that Lilly would not have sold in the "but-for" world (such as product exported by Apotex), the damages would be limited to a royalty at a rate to be determined by the Court.

[34] Regarding the sales actually lost in the "but-for" world, replicating a fictionalized version of the Canadian cefaclor market, the experts agreed on many of its components relevant to the calculation of the damages according to various scenarios. Many of the differences were identified and dealt with by the Federal Court. These are not at issue. Still, there remained three main issues for the Federal Court to determine. The first and second concerned whether Lilly would have had exclusivity in this market, and if so, until when. The third related to the actual size of the market, notably in regard to the level of demand for the product.

[35] Lilly asserted that it would indeed have had exclusivity until all its patents expired. It argued that, but for the use of infringing material and subsequent initiation of its legal

proceedings, Apotex (or any other generic drug manufacturer) would not have entered the market before the expiry of all the patents at issue. Particularly, Apotex would not have sold the Lupin 2 cefaclor at all because it was not commercially viable to do so. Later on, Lilly admitted that once the last Shionogi patent expired in April 2000, the Shionogi process would have provided an NIA to make cefaclor. This NIA would have been available to Apotex and any other generic drug manufacturer as of April 19, 2000. It is in that context that the Federal Court had to also determine when Apotex would have been in a position to actually sell its products in the various provinces (the formulary issue will not require any comment to determine this appeal).

[36] Apotex strenuously contested the position of Dr. Iain Cockburn, Lilly's expert, to the effect that, in the particular circumstances of this case, it was unlikely that Apotex would have entered the cefaclor market with Lupin 2, given the nature of the product, including its economics. In Dr. Cockburn's view (also in that of Mr. Raymond Sims, another expert for Lilly), Lupin 2 cefaclor was not a viable option in an economic sense. To explain why Apotex nevertheless ordered such a commercially non-viable product in the actual world, Dr. Cockburn explained what, in his view, was an important distinction between entering this market and remaining in it (see Exhibit RX-88, Appeal Book, vol. 28, tab 93 at pp. 8380-84; Cockburn Direct Examination at pp. 70, 93, 97, 102, Lilly's Day-Book for Re-Hearing, vol. 1, tabs 20-22, 36, Appeal Book, vol. 54, tab 228 at pp. 15553, 15547, 15554-55; Sims Cross-Examination at pp. 78-79, Lilly Day-Book for Re-Hearing, vol. 1, tab 38, Appeal Bool, vol. 54, tab 234 at p. 15957).

[37] The availability of an NIA was also important to Apotex in relying on additional and different hypotheses in the "but-for" world. In doing so, Apotex advanced a positive defence: Apotex sought to establish that it could have entered the market with Lupin 2 cefaclor well before it actually did sell such product in 1999; it could thus have captured the sales that Lilly would have lost before Apotex's actual use of Lupin 2 cefaclor began. While this defence would not absolve Apotex of liability for the infringement that actually took place, it would reduce the quantum of damages to a reasonable royalty for the period at issue.

[38] Apotex suggested various dates at which such an NIA could and would have been available. However, I will only discuss the dates argued before us: October 1997 and July 1998. These are described in Apotex's relevant outline, which was filed at the beginning of the appeal hearing (Apotex's Outline of Argument – Part III at p. 4). I understand that this outline reflects Apotex's final position on this question.

[39] Finally, with respect to royalties, the Federal Court had to contemplate a hypothetical negotiation between the parties which would have taken place at the beginning of the infringing period. Here again, the Federal Court had to consider whether or not an NIA would have been available at the relevant time, since this would have an impact on the rate of royalty.

[40] Otherwise, the Federal Court did not find it necessary to expressly deal with some of the issues raised by the parties, such as whether a true NIA (i.e. an economically viable alternative or one that did not infringe patents other than those at issue in the Liability Decision) would have been available. Considering its finding that Apotex would not have used Lupin 2 cefaclor prior to

April 2000, and that it was not established on the evidence that Lupin 2 cefaclor could have been available as of January 1997, one can understand how it was not readily apparent to the Federal Court to rule on the matter of the true NIA.

[41] While it would certainly have made our task easier had the Federal Court done so, at any rate, considering the parties' litigious behaviour, an appeal would have been unavoidable.

[42] The fact remains for this Court that many findings of fact and mixed fact and law relating to various hypothetical scenarios were effectively made by the Federal Court in this case, and we are in large part bound by them on appeal. And indeed, these findings address important issues that are relevant to the first question before us, especially as it is now well established in our Court's jurisprudence that an NIA defence can be raised by an infringer, provided that the infringer establishes that a true NIA could and would have been available to it (*Apotex Inc. v. Merck & Co., Inc.*, 2015 FCA 171 [*Lovastatin*]; see also *Pfizer Canada Inc. v. Teva Canada Limited*, 2016 FCA 161; *Apotex Inc. v. ADIR*, 2017 FCA 23; *AFD Petroleum Ltd. v. Frac Shack Inc.*, 2018 FCA 140).

[43] In other words, even though Apotex asks this Court to make the necessary inferences of fact to determine that an NIA could and would have been available to it as of October 1997, or at least by July 1998, we can only consider doing so if it also successfully establishes that the Federal Court's relevant findings of fact or mixed fact and law are tainted by a palpable and overriding error.

(2) Additional background relating to the actual world

[44] As mentioned, the reasons for the Damages Decision before us are not very detailed, and, in order to better understand them in the context of the arguments and evidence, it is important to summarize pertinent previously established or undisputed facts relating to the actual world, in addition to those listed at paragraphs 6-18 above. I thus take note of the following:

a) It is not disputed that, at all relevant times, there was no publicly known and viable alternative process to make 7-ACCA, the key intermediate compound necessary for producing cefaclor, other than the ones disclosed in the Lilly and Shionogi patents (see Liability Decision at paras. 709, 798; Liability Trial Transcript, vol. 39 at pp. 75-76, Appeal Book, vol. 80, tab 398 at p. 24227);

b) At the time that Apotex sought a compulsory licence for the patents covering cefaclor itself (1986-1988), Lilly filed an objection stating that, in order to make cefaclor, Apotex would also need a licence to make 7-ACCA. Apotex refused to seek that licence at that time – more than ten years before its entry in the market (Liability Decision at paras. 773-75);

c) In its Notice of Allegation pursuant to section 5 of the PMNOC Regulations served on Lilly on May 6, 1993, Apotex addressed all the patents listed in the form IV that was filed with Health Canada for cefaclor (this included the Lilly and the Shionogi Patents) (Liability Decision at para. 776). After the filing of Lilly's NOC application, Apotex knew that Lilly had presented expert evidence as to the importance or relevance of these patents before the Federal Court. Indeed, Simpson J.'s decision expressly references that fact (see paragraph 8 above);

d) Apotex presented expert evidence to the effect that there were no publicly known and commercially viable processes to make cefaclor other than the Lilly and Shionogi patents in the context of its own counterclaim before the Federal Court in 2008. This opinion was based on research first conducted on behalf of Apotex by Dr. Robert McClelland in 1997 or 1999 (probably 1997, considering the evidence he gave during direct examination: see Appeal Book, vol. 80, tab 401 at p. 24478, particularly the reference to the Shionogi process (Kyong-Bo cefaclor)) and again in 2003 (Liability Decision at paras. 709-10). Dr. McClelland acknowledged that anyone undertaking such research in 1985 would have come to the same conclusion;

e) Unbeknownst to the parties, Lupin had tried to design around the Lilly patents at some time in 1995, but discontinued its efforts, having concluded that the two avenues it tried would not be practically viable because of their inefficiencies and the resulting costs (see Exhibit Satpute-2, Appeal Book, vol. 69, tab 338 at pp. 20930-31);

f) In 1996, Apotex was advised by its own counsel that it would be sued for infringement if it entered the market with a cefaclor product (see para. 10 above);

g) Except for one letter in December 1996 addressed to Kyong Bo, which only dealt with the Lilly patents, Apotex did not inquire about the legality of the processes used by its suppliers before ordering and/or using the Kyong Bo and Lupin 1 cefaclor in the products it started to sell in January 1997 (see paras. 12, 13 above; Liability Decision at para. 828);

h) Before entering the market, Apotex knew that Lilly had entered into an agreement to supply Pharmascience Inc. [Pharmascience], another generic drug manufacturer and Apotex's competitor, with cefaclor products should any other generic drug manufacturer enter the market with infringing cefaclor (Exhibit TX-1684, Appeal Book, vol. 69, tab 343 at pp. 21033-86). Pharmascience, which had an NOC since 1995, did enter the market at about the same time as Apotex did in January 1997 (see Liability Trial Transcript, vol. 39 at pp. 37-39, Appeal Book, vol. 80, tab 398 at p. 24218; Facts Agreed to by the Parties at p. 3, Appeal Book, vol. 2, tab I at p. 550);

i) Apotex did not try to design around the patents at issue until years after having been advised that there were no other commercially viable processes for making cefaclor. Sometime in July 1997, Ms. Fouillade, Apotex's in-house counsel since 1996, was asked to look into the matter by Dr. Bernard Sherman, the then Chairman and Chief Executive Officer of Apotex. She concluded in September and October 1997 that both Lupin 1 and Kyong Bo cefaclor were made with processes which infringed the Lilly and Shionogi patents (Liability Decision at paras. 787-91, 831);

j) Despite Ms. Fouillade having concluded that Lupin 1 and Kyong Bo cefaclor were infringing, Apotex continued to forcefully deny any infringement of the patents before the Federal Court (Liability Decision at para. 710);

k) In her correspondence with Lupin and its representatives, Ms. Fouillade consistently noted that it was urgent to find a solution. Still, no order was placed for Lupin 2 cefaclor before March 1998 (see e.g. Exhibit Glopec-20 (Confidential), Appeal Book, vol. 57, tab 250 at p. 17173; Exhibit Glopec-23, Appeal Book, vol. 73, tab 353 at pp. 22171-73; Exhibit Glopec-26, Appeal Book, vol. 67, tab. 324 at pp. 20790-31; Exhibit Glopec-27, Appeal Book, vol. 67, tab 325 at pp. 20792-93).

l) Although Apotex had what it believed to be non-infringing cefaclor (Lupin 2 cefaclor) available to it as of June 1998, it continued to use infringing material until it had almost exhausted its stock of infringing material in 1999. No product was formulated with Lupin 2 cefaclor before December 1998;

m) Albeit in the context of Apotex's counterclaim against Lilly and Shionogi (where it alleged to have suffered damages because Shionogi had assigned its patents to Lilly in 1995), Dr. Sherman, who took all the important decisions regarding which products Apotex would put on the market, testified that in a "but-for" world where no such assignment had taken place, the "most likely scenario" would have been that Apotex

would have used cefaclor made according to the Shionogi patents (like Kyong Bo) without first obtaining a licence. This assignment was served on Apotex in January 1997 (Liability Decision at para. 750);

n) As mentioned, Lupin and Apotex entered into the 1998 Agreement for the production of 7,500 kg of Lupin 2 cefaclor. Although the Agreement does not include cefaclor's price, it was made on the basis that Apotex was willing to pay a very high premium (at least a 40% increase on the cost of Kyong Bo and Lupin 1 cefaclor, the only active pharmaceutical ingredient (API) in its products; but see Lilly's Day-Book for Re-Hearing, tab 15, Exhibit RX-142, Appeal Book, vol. 36, tab 155 at p. 10742). The prices paid were as follows: Kyong Bo cefaclor was $860.00 U.S.; Lupin 1 cefaclor was $1,050.00 U.S.; and Lupin 2 cefaclor was $1,500.00 U.S.;

o) In fact, the 646 Patent, whose teachings were among those which Lupin was bound to use at step VI of the process to produce 7-ACCA, did not expire until 2004. The infringement of this patent was not before the Federal Court in the liability phase, as this patent was not included in the action at the time of trial. Throughout this trial, Lilly's position was that the Lupin 2 process could not have been used because it was too inefficient to be commercially viable (Liability Decision at paras. 245-46);

p) During the liability phase, Dr. Sherman and Apotex always maintained that they were entitled to assume that Lupin had abided by the terms of the 1998 Agreement in using the new, allegedly non-infringing Lupin 2 process for the production of cefaclor (see e.g. Liability Decision at para. 234). Indeed, Dr. Sherman expressly said that it was not his practice to enter into a contract with a supplier, but that he found it appropriate to do so here;

q) It appears that Apotex maintained this position during the reference phase because, when cross-examined, Apotex's expert, Mr. Roy Weinstein (who was dealing with the rate of royalties), acknowledged that he was told to assume that Lupin 2 process was non-infringing (Damages Trial Transcript, vol. 82 at pp. 88-91, Appeal Book, vol. 54, tab 239 at p. 16361; Exhibit RX-207, Appeal Book, vol. 53, tab 220 at p. 15292; Damages Decision at para. 100);

r) Ultimately, for a variety of reasons (such as the higher price of Lupin 2 cefaclor, rate of exchange and amount of free goods granted by the competition, particularly Pharmascience), Apotex lost more than $5,000,000.00 on the sale of its products made using Lupin 2 cefaclor (Exhibit RX-142, Appeal Book, vol. 36, tab 155 at pp. 10739-43). There was contradictory evidence as to whether or not Apotex could have expected to incur such a loss at different points in time, including June 1998, January 1999 and April 1999. Apotex filed expert evidence to contest the calculations of Dr. Cockburn in regard to the commercial viability of products made with Lupin 2 cefaclor which were based on the actual results achieved on sales of products made with Lupin 2 cefaclor that did not start before 1999. Schedule 14 of the report of Apotex's expert included seven different scenarios (Expert Report of Andrew Harington, Appeal Book, vol. 41, tab 170, at pp. 12401-09); and

s) In any event, Apotex's main position was that such calculations would have been irrelevant to its decision to enter the market in January 1997, given that it never conducted a cost-profit analysis before entering. Dr. Sherman did not testify during the reference phase as to why it was important for Apotex to come to market with cefaclor. However, he had acknowledged at the liability phase in 2008 that in the mid and late 1990s the demand for cefaclor was in fact in decline and the drug was not a major product for Apotex (Damages Decision at paras. 12, 808). Apotex relied solely on the testimony of Mr. Gordon Fahner, who was Director of Finance at the relevant time and became Vice-President – Finance sometime in 2003, to establish that under the leadership of the late Dr. Sherman, Apotex as an organization did not conduct profit analysis for its individual products; rather, it made its business decisions (i.e. Dr. Sherman's decisions) with the objective of having the largest portfolio of products possible in mind (see Damages Trial Transcript, vol. 80 at pp. 194-96, Appeal Book, vol. 54, tab 237 at p. 16251; Damages Decision at para. 68: "as many pharmaceutical products in the marketplace as possible"). Various experts debated the application of concepts such as the "first mover effect" (timing of entry and known presence of Pharmascience) in this case as well as the economic value of the portfolio approach with respect to cefaclor.

[45] It is against this backdrop that I now turn to the issue of the NIA defence.

B. *Did the Federal Court err in finding that no NIA defence was available to Apotex?*

[46] As mentioned, the Federal Court did not have the benefit of this Court's most recent jurisprudence on the issue of the NIA defence before releasing its decision. Thus, as in *Lovastatin*, I find that the Federal Court erred when it concluded that the NIA defence was not available in Canada. However, as was also the case in *Lovastatin*, I conclude that this error is not determinative because, on the evidentiary record before it, the Federal Court could not but conclude that the defence was unavailable in this case.

(1) General principles regarding the NIA defence

[47] *Lovastatin* may well have been the first case where an NIA defence was accepted in the context of a claim for damages resulting from patent infringement (as opposed to an accounting of profit). But our Court's acceptance of the NIA defence was based on general principles of Canadian common law (see e.g. *AlliedSignal Inc. v. Du Pont Canada Inc.* (1998), 78 C.P.R. (3d) 129 at pp. 140-41 (F.C.T.D.) [*AlliedSignal*], aff'd (1999) 86 C.P.R. (3d) 324 (F.C.A.)), as they had been applied by the Supreme Court in *Monsanto Canada Inc. v. Schmeiser,* 2004 SCC 34 (see also for the discussion on the burden of proof: *Rainbow Industrial Caterers Ltd. v. Canadian National Railway Co.*, [1991] 3 S.C.R. 3).

[48] I underline the roots of our conception of the NIA defence because it is important to understand that our Court did not simply import an American law concept in a wholesale fashion. The Court in *Lovastatin* may indeed have referred to American authorities in order to better ground the concept. But one must be careful not to construe references to American jurisprudence lending support for the NIA defence as a blind incorporation of, or strict adherence to, the reasoning adopted by American courts. American courts view the purpose of their patent legislation differently, and emphasize the promotion of strong competition. Further, American statutes provide for "treble damages" (as a punitive award) when, among other things, infringement is committed with knowledge of the existing patent (see 35 U.S.C. § 284). These factors may result in a more lenient approach in the application of the NIA defence. In effect, the threat of a treble damages award certainly curtails potential abuses.

[49] With this in mind, I underscore that the objective of the NIA "defence" is to help ascertain the real value of inventions for which a patentee such as Lilly was granted a monopoly.

Inasmuch as overcompensation is inappropriate in our law, so is undercompensation. Thus, the goal is not to enable an infringer to breach the bargain made on behalf of the Canadian public when a patent is issued. Nor is the defence a means by which one can infringe at the lowest possible cost. This is particularly important to keep in mind when one assesses the rate of royalty that would apply when this defence is accepted. In my view, it is only when an appropriate rate is set that one can consider that accepting such a defence does not amount to a compulsory licence system in disguise.

[50] The rationale of just compensation underpins why the infringer bears the burden of establishing all facts required before a court considers the effect of legitimate competition on the calculation of damages resulting from infringement.

[51] Some of the facts which the infringer must establish were identified in *Lovastatin* as follows:

> **[73]** When considering the effect of legitimate competition from a defendant marketing a non-infringing alternative, a court is required to consider <u>at least</u> the following questions of fact:
>
> > i) Is the alleged non-infringing alternative a true substitute and thus a real alternative?
> >
> > ii) Is the alleged non-infringing alternative a true alternative in the sense of being economically viable?
> >
> > iii) At the time of infringement, does the infringer have a sufficient supply of the non-infringing alternative to replace the non-infringing sales? Another way of framing this inquiry is could the infringer have sold the non-infringing alternative?
> >
> > iv) Would the infringer actually have sold the non-infringing alternative?
>
> [Emphasis added.]

[52] Notably in *Lovastatin*, Apotex, which sought to rely on the NIA defence, had conceded some principles that our Court found relevant to mention because of their general application, namely:

> 1) the real world informs our construction of the "but-for" world;
>
> 2) conduct in the real world is "very important" to what would have happened in the "but-for" world;
>
> 3) findings of fact from the liability decision are relevant to constructing the "but-for" world; and
>
> 4) "brazen" infringement in the real world makes it very difficult to prove that the defendant would have deployed the non-infringing alternative in the "but-for" world.
>
> (*Lovastatin* at para. 90)

[53] Interestingly, Apotex relied on these four principles to support its argument in the case at bar. Apotex also acknowledged at the hearing before us that the findings made by the Federal Court in the Liability Decision, including those made when rejecting its counterclaim, were relevant when constructing the "but-for" world.

(2) Application of the general principles to the case at bar

(a) *Legitimate NIA*

[54] Armed with these principles, I now turn to the very first issue to be considered by any court when determining whether an NIA defence is available: "Is the alleged NIA a true alternative to the inventions at issue?" In non-pharmaceutical cases, this is a very important question that usually turns on whether the product at issue would be considered a true substitute

by the consumer. However, in pharmaceutical cases where generic products are bioequivalents of the original product, this aspect is not an issue.

[55] Until this appeal, the lawfulness of an NIA on which a defendant was relying had never been at issue at the reference stage. That is not to say, however, that it is not an issue that may be validly raised. It goes without saying that to be a real alternative, an NIA must be lawful, that is to say, non-infringing. This applies to more than just the patent(s) in suit in the proceedings.

[56] An unusual feature of this case is that, as mentioned, it was never argued at the liability phase that the Lupin 2 process infringed the patents in suit. Indeed, Lilly always maintained that such a process could not have been used as a matter of fact: because the process was so inefficient, it could not have been used by Lupin to make the 7-ACCA required to fulfil the 1998 Agreement. Thus, the only thing the Federal Court determined in the Liability Decision is that neither the Lupin 1 process nor the Kyong Bo process were in fact used to make the cefaclor supplied under the 1998 Agreement, and that Lilly had not established that the Lupin 2 process infringed on the patents in suit (Liability Decision at paras. 228-29).

[57] Still, at the reference phase of these proceedings, Lilly argued that Apotex had failed to establish that the Lupin 2 process was a lawful process. Its argument was two-fold:

> 1) Apotex had failed to establish that the Lupin 2 process was effectively used, and that it did not infringe the patents at issue; and
>
> 2) *prima facie*, the Lupin 2 process (at Step VI) infringed the 646 Patent referred to in Appendix A to the 1998 Agreement, which was incorrectly believed to have expired.

[58] The Federal Court dealt with only the first part of this two-part argument at paragraph 61 of the Damages Decision. I agree with the Federal Court that it was not open to Lilly to seek to reopen the question of whether the Lupin 2 process infringed on the patents in suit. Such an issue had to be raised and determined at the liability stage, and the burden to do so rested on Lilly.

[59] However, it appears that the Federal Court did not find it necessary to deal with the second part of the argument in light of its findings that the NIA defence was not available in law. It also did not have to do so in the "but-for" world (causation) in light of its factual finding as to when Apotex would have entered the market.

[60] Nor did the Federal Court at the liability phase in 2008-2009 ever have to address Lilly's argument regarding whether the Lupin 2 process infringed another patent (the 646 Patent), because it did not constitute part of the allegations underlying the action. The Federal Court then simply did not have jurisdiction to determine this issue.

[61] Now, at the hearing before us, Apotex failed to provide any meaningful response to the argument regarding the Lupin 2 process and the 646 Patent even though the matter was expressly raised. Yet, knowing that Apotex's counsel rarely leave any stone unturned, I carefully reviewed Apotex's Outline of Argument – Part III, as well as its memorandum of fact and law and the written submissions before the Federal Court, to see if it had been addressed therein. It was surprising to find that this issue – which is essential to the consideration of the Lupin 2 process as legitimate competition – is only mentioned at the last bullet on the last page of the aforementioned outline. It is worth reproducing the bullet in its entirety:

> […] Lilly presented no credible basis for this purported "infringement" – Lilly rests on the evidence of Apotex's expert *economist*, Mr. Weinstein, who was asked in cross-examination to assess infringement of an organic chemistry process patent.
>
> (Apotex's Outline of Augment – Part III at p. 7)

[62] I agree that Lilly could have done more to drive the issue home; the 646 Patent itself is not even in evidence except for the cover page showing the relevant date at which it was in force. However, I do not believe that it was incumbent upon it to do so insofar as the NIA defence is concerned. Lilly did not have the burden of establishing that a process, which it believed could not possibly have been used until Mr. Satpute's testimony was accepted by the Court in the Liability Decision, in fact infringed the 646 Patent.

[63] Furthermore, I do not accept that Lilly relied solely on the evidence of Mr. Weinstein as Apotex alleges in its outline quoted above. Lilly only used the opportunity of this witness's cross-examination to point out to the Federal Court that the factual assumption on which this expert opinion was based had not been established, and that this would undermine the value of his evidence. This point was in fact accepted by the Federal Court (Damages Decision at para. 100).

[64] That said, I agree that the process described in the 1998 Agreement (Lupin 2) does, on its face, appear to infringe the 646 Patent.

[65] Again, because of another unusual circumstance of this case (namely the terms of the 1998 Agreement), the issue of the legitimacy of the Lupin 2 process was clearly at play based on

the evidentiary record before the Federal Court. Indeed, Apotex expressly dictated what process Lupin was bound to use by reference to patents which Ms. Fouillade appears to have incorrectly assumed to be all expired. Thus, as soon as it was established that the 646 Patent was still in force until 2004, the legitimacy of the process set out in Appendix A of the 1998 Agreement, which Apotex and its expert assumed to have been used, became an issue. Apotex had to explain or produce evidence explaining why, despite the reference to this unexpired patent, the NIA on which it sought to rely on was in fact lawful.

[66] Even though it appears that Apotex advised Lupin's representative that it had yet to be sued on October 1, 1997 (see Exhibit Glopec-27, Appeal Book, vol. 67, tab 325 at pp. 20792-93), it is clear from the correspondence that the 1998 Agreement was drafted by Apotex with knowledge that it would be used as part of its defence in the present proceedings. In effect, in her correspondence, Ms. Fouillade insisted that only processes covered by expired patents should be used. For example, even if the improvement patents referred to by Lupin would have increased the yield (Step III-B), she maintained in Appendix A that only the teachings of the main patent (Canadian Patent 1,056,372 or 372 Patent) could be used in the 1998 Agreement. Without cogent explanations from Apotex, it makes little sense to refer to a process patent such as the 372 Patent or 646 Patent (entitled "Deesterification to Acids") if the process covered by such patent(s) was not the one to be used.

[67] So, what exactly is meant by the reference to the "teachings" of the 646 Patent? Could it be referring to information that would not necessarily imply *de facto* infringement of the unexpired patent?

[68] Recall that Apotex strived to control precisely what steps would be used by Lupin to make 7-ACCA. It even named the reagents Lupin was authorized to use. In this context, the reference to the 646 Patent could not be considered as simply referring to unspecified general information mentioned in the said patent. The 646 Patent process covers the same chemical process that had to be performed at Step VI of the overall process leading to the 7-ACCA. *Prima facie*, this process would be infringing on this unexpired patent.

[69] Hence, in the absence of evidence as to how the reference to the 646 Patent in the Appendix would have been understood by Apotex and Lupin as referring to something other than the process covered by the said patent, the Federal Court would not have been in a position to conclude that the Lupin 2 process was established as a true alternative: a legitimate NIA.

[70] Before concluding on this issue, I ought to close the loop by noting that no inference could, in my view, be made from the fact that Lilly never sued Apotex over the 646 Patent. By the time the Liability Decision was issued, more than six years had elapsed since the Lupin 2 cefaclor was imported and used by Apotex. Before that date, Lilly believed – and probably still does – that the Lupin 2 process was not used as Apotex had alleged.

[71] Bearing this in mind, the unlawfulness of the Lupin 2 process was not Lilly's main argument. Both parties focused their efforts on the other aspects relevant to the availability of an NIA defence. I will now address those other aspects. I will first comment on the economic viability of an NIA, and then on whether, in October 1997 or July 1998, the Lupin 2 process,

instead of the infringing Kyong Bo or Lupin 1, could and would have been used by Apotex to enter the market.

(b) *Economic viability of the NIA*

[72] The economic viability of the Lupin 2 process was the subject of much debate before the Federal Court and again before us. In my view, economic viability is not something that is assessed solely from the subjective perspective of an infringer such as Apotex. But obviously, the subjective perspective of the infringer may be relevant to the question of whether the infringer "would" have used the NIA.

[73] However, as I noted earlier, the court's goal is to assess the real value of the patented invention(s). Such value cannot be assessed on a purely subjective basis. Evidently, the court must be satisfied that the NIA invoked was *objectively* an economically viable substitute at the relevant time. To say otherwise would mean that the value of a patent could be artificially reduced by an infringer who behaves in an unorthodox manner, or whose adoption of a substitute is motivated by reasons other than economic ones.

[74] Such a consideration could not be relevant to the assessment of damages under subsection 55(1) of the Patent Act. If it were, a patent would have little value, and it would be an incentive to keep one's invention secret.

[75] In *Grain Processing Corp. v. American Maize-Products Co.*, 185 F. 3d 1341 (Fed. Cir. 1999), a case on which Apotex relied heavily in *Lovastatin* and before us, the question of

whether a substitute process was available was raised in respect of a process that increased the cost by only 2.3%. In the present matter, the increased costs were raised by at least 40%, if not more (see Exhibit RX-142, Appeal Book, vol. 36, tab 155 at p. 10742).

[76] As mentioned, at the reference phase, there was contradictory evidence before the Federal Court as to what Apotex could have "expected" in terms of profitability at various dates. The best scenarios were presented by Apotex's expert, Mr. Harington, in schedule 14 of his report (Exhibit RX-157, Appeal Book, vol. 41, tab 170 at pp. 12402-09; also summarized at p. 12085). For our purposes, the most relevant scenarios are scenarios 4 (June 4, 1998) and 5 (January 1, 1999) (at pp. 12405-06).

[77] In scenario 5, it is clear that Apotex would have expected losses on all of its cefaclor products, given that the price on entry at that time was 70%, and that it could not have broken even on any of its products. In scenario 4, Apotex would have expected to lose money on its 500 mg capsules and 375 mg suspensions, and pursuant to Mr. Harington's figures, it would barely have broken even on its 250 mg capsules and suspensions.

[78] I note, however, that, in this last scenario, the regulated price used by Mr. Harington was disputed. He used a price pegged at 75% of the original's price, whereas in May 1998, an amendment to the applicable regulations had been published in The Ontario Gazette setting the price of the first generic in the market at 60% and, later on, in November 1998, at 70%. Mr. Fahner and Apotex's experts testified that in June 1998 Apotex could nevertheless have expected to be allowed 75%. Importantly, none of these calculations included any free goods. Although

there was a dispute as to the amount of free goods that could be expected versus those actually introduced into the market because of Pharmascience's aggressive marketing, Mr. Fahner did not specify what quantity of free goods would be customary. Thus, even on the best scenario, it is unlikely that products made with Lupin 2 cefaclor would have been viewed as commercially viable *per se*. I understand that most if not all the experts agreed that, unless there were other valid economic reasons to market this product, a rational generic drug manufacturer entering a market where this drug had not been genericized – and where another three years remained before one of the patented processes in suit could be used – would not view the Lupin 2 cefaclor as commercially viable.

[79] In effect, when its reasons are read in the context of the evidentiary record, it is implicit that the Federal Court was not satisfied that Apotex's decision could have been based on the economic viability of its products made with Lupin 2 cefaclor. It just was not an attractive substitute. Instead, the Federal Court referred to the explanation given by Mr. Fahner to determine if, in the "but-for" world, there would be enough incentive for Apotex to enter the market using Lupin 2 cefaclor. As mentioned earlier, the Federal Court found that this was not so, and found – as a fact – that Apotex would not have entered the market on that basis.

[80] Finally, the only thoroughly objective evidence regarding the commercial viability of the Lupin 2 process stems from Lupin itself. As a manufacturer and international supplier of cefaclor, Lupin had tried the routes which Ms. Fouillade included in the 1998 Agreement at Step V-A and B, and concluded that they were not "practical and feasible" (Exhibit Satpute-2, Appeal Book, vol. 57, tab 254 at p. 17183). I note that this was so even when Lupin did not include the

additional 10% loss in yield at Step III, on which Ms. Fouillade insisted by referring to the 372 Patent in the 1998 Agreement.

[81] In these circumstances, I am not satisfied that there was sufficient evidence for the Federal Court to conclude that Lupin 2 cefaclor was an objectively commercially viable substitute. It follows that the Federal Court would not have been justified in considering its effects in the context of an NIA defence.

(3) Could a defence based on Lupin 2 be otherwise available as a matter of fact?

[82] Assuming for the purpose of this exercise that the Lupin 2 process was lawful as well as an economically viable substitute, I turn to the issue of whether an NIA could have been available in October 1997, the first date put forth by Apotex.

[83] The Federal Court found that when infringement first started, it was not established on the evidence that the Lupin 2 process "could" have been used to provide the amount of material necessary for Apotex to enter the market (Damages Decision para. 100). It also noted that, at the relevant time, Lupin 2 was not known to either party (Damages Decision at para. 102).

[84] First, Apotex has not persuaded me that the Federal Court made a palpable and overriding error in concluding as it did. Second, I am satisfied that the evidentiary record was also insufficient for the Federal Court to conclude that Lupin could have produced the Lupin 2 cefaclor required for Apotex to enter the market in October 1997.

[85] There was little, if any evidence that addressed the actual capacity of Lupin to produce the required amount of cefaclor in 1996 and 1997. There were only two witnesses from Lupin, the only supplier from which any evidence was adduced as to the ability of using a process other than the patented ones. Both were heard during the liability trial. Mr. Rejeev Patil worked in the regulatory department at Lupin, and had no knowledge or information with respect to this issue (Liability Decision at paras. 44-45). Mr. Vilas Satpute worked at the relevant time (1996 to 1999) at the Lupin facilities in Ankleshwai, where four compounds were produced – ethambutol, vitamin B-6 and two intermediate compounds known as 7-ADCA and 7-ACCA. As stated, 7-ACCA was the key intermediate compound to make cefaclor (Liability Decision at paras. 46-48).

[86] As Apotex included in its compendium some extracts of Mr. Satpute's testimony to support its position, I have re-read the transcripts of his testimony, which I had heard first-hand during the liability phase of this proceeding. My review confirms that Mr. Satpute had no real memory of what quantities of 7-ACCA were actually produced on-site between 1996 and 1999. He only remembered Apotex's order that required about 6,000 kg of 7-ACCA (to produce about 7,500 kg of Lupin 2 cefaclor) because it was one of the biggest orders Lupin had ever received, and because it required a change in the process for making 7-ACCA, before and after that order was completed. He only had some vague memory of some batches being made before March 13, 1998, either in January or February.

[87] It was thus open to the Federal Court to conclude that this evidence was insufficient to establish that Lupin could have produced Lupin 2 cefaclor much earlier than it actually did. There was no evidence as to the number of orders on hand at the time and the capacity of the

plant to produce both for Apotex and for its other clients. This is especially a concern if a different process would have been required to produce the 7-ACCA on order for other customers (the Lupin 2 process was to be used only for Apotex; see also Liability Decision at para. 233).

[88] Furthermore, cefaclor itself was manufactured at a different Lupin plant: the Mandideep facility, where four APIs were manufactured. There was no evidence whatsoever as to this plant's level of occupation or its capacity to produce an additional 7500 kg in 1996 and 1997. A finding in favour of Apotex would require making an inference that the Federal Court did not appear to have been willing to make. It is certainly not one that I believe could be made on the basis of this record and the representations made before us.

[89] Apotex also argued that the NIA could and would have been available to it as of July 1998. This is essentially the same period that the Federal Court reviewed under the heading "V-When would Apotex have entered the Market" (see particularly Damages Decision at paras. 59, 63). Indeed, the reference to July 1998 is simply a refinement of Apotex's argument submitted before the Federal Court (June 1998). It takes into account that, in addition to having received some cefaclor at that time, Apotex would have required an additional three weeks to formulate its product in order to enter the market.

[90] That said, I agree that, based on the quantities of Lupin 2 cefaclor produced by Lupin in the actual world, it would have been open to the Federal Court, as the trier of fact, to conclude that Apotex had met its burden regarding its capacity to obtain Lupin 2 cefaclor to enter the market (i.e. "could" have done so by July 1998). However, as mentioned earlier, the Federal

Court found as a fact that Apotex "would" not have entered the market at that time with Lupin 2 cefaclor (Damages Decision at para. 70).

[91] I have not been persuaded that this essential finding of fact, which will be discussed in more detail in the next section of my reasons, is tainted by a reviewable error. This is especially so considering that it was undisputed that Apotex had the burden to establish this preliminary fact in order to benefit from an NIA defence.

[92] In conclusion, I find that the Federal Court was ultimately correct to conclude that the NIA defence was not available to Apotex in this case.

C. *Did the Federal Court err in determining when Apotex would have entered the market?*

[93] As mentioned earlier, the Federal Court made it very clear that its task was to determine the amount of all the damages sustained by the patentee by reason of the infringement. This is in effect what subsection 55(1) of the Patent Act requires – no more, no less (Damages Decision at paras. 11, 16).

[94] To do so, the Federal Court used the approach set out by the Supreme Court in *Clements* and appropriately referred to the "but-for" world as a legal fiction. As noted by the Federal Court, it is in this fictional world that the Court had to determine the following question: "But for the infringing product being on the market, what would the patentee's position have been?" (Damages Decision at para. 20). The Federal Court made the most significant difference of opinion as to the specific characteristics of this "but-for" world equally clear: the debate centred

on whether Apotex was entitled to raise an NIA defence in order to reduce the loss in respect of sales, even where the infringer had not employed the NIA in the actual world (Damages Decision at par. 21).

[95] As we know, the Court rejected that defence. Hence, it needed only to apply the general principles it had previously set out.

[96] In regard to the burden of proof and the approach to be taken in doing so, the Federal Court stated at paragraph 33:

> Apotex is correct in saying that Lilly must prove the causal connection between its lost sales and the infringing sales made by Apotex. It must prove on the balance of probabilities that but for the sales of the infringing product, it would have made additional sales; and it must prove the number of those additional sales and the profit that it would have realized on them. I also agree with the submission of Apotex that damages for lost profits have been denied where the causal link between the infringement and the lost sales has not been established…

[97] As I stated earlier, the Federal Court could have described in more detail all the evidence that was before it regarding the actual world, as well as the expert evidence produced in relation to the "but-for" world. Instead, the Federal Court focused its attention on what it considered to be more determinative issues. With this in mind, I find it appropriate to quote the following statements of our Court in *Pfizer Canada Inc. v. Teva Canada Limited*, 2016 FCA 161, which are particularly apposite:

> **[68]** Faced with an allegation that a first-instance court did not apply proper principles, an appellate court must assess what the first-instance court did by reviewing in a holistic, organic and fair way the reasons offered by the court against the record it was considering. Often first-instance courts do not describe the principles that bear upon a case in a perfectly precise or encyclopedic way. Yet, in many such cases, a holistic, organic and fair review of their reasons against the record shows they brought to bear all correct principles.

> **[69]** It must be remembered that judges' reasons—particularly after long complex trials involving many issues—are often the product of synthesis and distillation. When it comes time to draft reasons in a complex case, trial judges "are not trying to draft an encyclopedia memorializing every last [relevant] morsel." Rather, they are trying to "distill and synthesize masses of information, separating the wheat from the chaff," in the end "expressing only the most important…findings and justifications for them": *Canada v. South Yukon Forest Corporation*, 2012 FCA 165, 431 N.R. 286 at para. 50.

[98] With the objective of performing a holistic, organic and fair review of the Federal Court's reasons, my reading of the Damages Decision indicates that the Federal Court accepted Lilly's theory and expert evidence in deciding that entering a non-genericized market is not the same as deciding to remain in a market that has *already* been genericized (Damages Decision at para. 63).

[99] To my mind, it is also clear that, based on the weight it gave to the evidence in the record regarding Apotex's actual behaviour before it entered the market in January 1997, the Federal Court felt that more compelling evidence would have been required from Apotex to convince it that Apotex would have actually developed the Lupin 2 process before it entered into the market in June 1998, as opposed to January 1997.

[100] As noted by the Federal Court, when Apotex made the decision to enter the market in January 1997, it was aware, and indeed should have been mindful of the statement made by Simpson J. in her 1995 NOC decision (see para. 8 above). Furthermore, there was evidence that Apotex was not looking to secure a non-infringing supply source and that it was not really interested in doing so at that stage (Damages Decision at paras. 66-67).

[101] As referred to earlier, Apotex's argument relied on what did happen in the actual world, but only insofar as what happened after its infringement occurred. By then, the genericization of the cefaclor market was well underway and competition with Pharmascience was fierce. In this context, the Federal Court appears to have given little weight to what Apotex did between July 1997 (which marks the beginning of Ms. Fouillade's inquiries) and March 1998. This is so because it accepted that the steps taken toward the eventual decision to order Lupin 2 cefaclor in March 1998, as well as the decision itself, were not a proper proxy for what would have happened in the "but-for" world. Again, for the Federal Court, the decision to maintain one's place in this market was not the same as the decision to enter it. The Federal Court found, as a fact, that Apotex did have an incentive during this timeframe to find a non-infringing alternative, but that this incentive did not exist when it had actually entered the market in 1997 (Damages Decision at para. 64). It is in that context that the Federal Court was looking for persuasive evidence from Apotex to the effect that, had it not used the infringing process in 1997, it would have sought out a non-infringing process *before* June 1998 (Damages Decision at para. 65). The Federal Court found that there was no such persuasive evidence regarding whether Apotex had the desire to enter the market as opposed to remaining in it through lawful means (Damages Decision at para. 68).

[102] It is worth reproducing the part of paragraph 68 of the Damages Decision which deals with Apotex's evidence that it was not motivated by the profitability (and was thus not influenced by the non-profitability) of its cefaclor products:

> […] Apotex offered evidence that it does not conduct a profitability analysis on its individual products before marketing them, so entering the market with a legal cefaclor product could not have been motivated by any direct financial incentive. Other than its general desire to have as many pharmaceutical products in the

> marketplace as possible, it offered no evidence that its wish to add cefaclor to its portfolio would have prompted it to seek out a non-infringing method prior to patent expiry.
>
> [Emphasis added.]

[103] I ought to mention that, before us, Apotex argued that the Federal Court accepted Mr. Fahner's evidence (to the effect that Apotex simply sought to expand its portfolio of products) as evidence of Apotex's only motivation in January 1997 or anytime thereafter. I cannot agree that this is so. Mr. Fahner, who was Director of Finance at the relevant time, was not involved in the actual decision to enter the cefaclor market and later to remain in it. He testified as to the general business approach taken by Apotex as an organization. Surely, if the profitability of individual products was never a goal, Apotex's entire portfolio could be worth nothing. We know that this could not be the case. This raises the question as to why Apotex emphasized its cefaclor business, given that the product was at the end of its success cycle and that three years still remained before the patented processes could be (lawfully) used.

[104] In my view, the Federal Court does not speak to the weight it gave to the evidence presented in regard to Apotex's motivations or business rationale; nor does it say whether the evidence was even credible. Rather, I understand the Federal Court to simply say that, even if it were accepted, this evidence does not go to whether Apotex's general business approach would have prompted Apotex to seek out a non-infringing method.

[105] If one takes this evidence as establishing Dr. Sherman's actual motivation when he made the decision to enter the market in January 1997, it certainly was not sufficient to prompt him to seek a non-infringing method before doing so.

[106] Apotex, moreover, argued that the Federal Court made an extricable error by reversing and elevating the burden of proof. In its view, the Federal Court erred by incorrectly seeking persuasive evidence from Apotex when the burden should have rested on Lilly.

[107] Apotex also submitted that the Federal Court made palpable and overriding errors by: 1) giving insufficient weight to Apotex's conduct from September 1997 to June 1998; and 2) failing to properly consider all the evidence it presented. It states that the Federal Court had no basis in the evidence to support the distinction made between a decision to enter and a decision to remain in the market in the particular circumstances of this case. Relying mostly on the evidence of Mr. Fahner and Dr. Aidan Hollis, Apotex argues that, but for its fundamental error in respect of the burden of proof, the Federal Court could only have concluded that Apotex would have entered the market in June 1998 with Lupin 2 cefaclor.

[108] I have not been persuaded that the Federal Court made an extricable error of law. I agree that, when read on its own, the phrase "the burden remains on Apotex to prove on the balance of probability that it would have come to market with non-infringing cefaclor prior to the expiry of the patent" seems problematic (Damages Decision at para. 62). But these words have to be read together with the Federal Court's express mention that Lilly *did* in fact bear the burden of establishing its loss in the "but-for" world (causation). The problem lies with the structure of the relevant portion of these reasons rather than its substance. It would have been clearer for the Federal Court to restate that the burden rested on Lilly, and that it accepted Lilly's view and evidence regarding whether it would have been the sole player in the "but-for" world's cefaclor market (Damages Decision at paras. 63-64, 71). It is then that the burden shifted to Apotex to

establish that it would have come to (entered) market in June 1998, a time at which it did not in fact enter the market with Lupin 2 cefaclor (in the actual world).

[109] Additionally, in my view, the issue of who had the burden in the "but-for" world's framework of causation could not have played any significant role once the Court accepted as a fact that the decision to enter the market was different from the one taken by Apotex when it entered into the 1998 Agreement and remained in the market with Lupin 2 cefaclor at some point in 1999. This is a fact that the Federal Court clearly accepted.

[110] I now turn to the next argument, which directly challenges this last finding. I have carefully considered all the arguments and evidence put forth by Apotex in the many pages of its outline (Part II) devoted to establishing palpable and overriding errors by the trier of fact. I have also considered the evidence referred to by Lilly. Of course, this evidence was considered while keeping in mind the factual background referred to in my reasons and reflected in the Liability Decision. I have come to the conclusion that Apotex is simply asking us to reweigh all the evidence and become the trier of fact. It is worth repeating that this is not our role, and I am fully satisfied that there was sufficient evidence supporting the Federal Court's findings of fact.

[111] I note that Apotex included in its outline an argument that it did not submit to the Federal Court. According to Apotex, the Federal Court should have considered that, when Apotex added its suspension products in 1998, it in fact made a decision akin to a decision to enter the market. One could hardly fault the Federal Court for not expressly engaging with this argument given that it had not been presented to it. As mentioned recently in another patent case, *Bombardier*

Recreational Products Inc. v. Arctic Cat, Inc., 2018 FCA 172 at paragraph 94, a party must put their best foot forward before the trier of fact; it is inopportune to formulate fresh views of the evidence on appeal.

[112] I now come to Apotex's last argument, which it also did not make as such before the Federal Court, except for the portion grounded on the language of the Liability Decision. In Apotex's view, it is an error of law to award damages for sales displaced by non-infringing products because such sales are beyond the scope of the Patent Act, are too remote, and are not contemplated in the Liability Decision.

[113] I am unmoved by Apotex's attempt to characterize the damages granted in respect of certain sales as damages resulting from non-infringing acts. As mentioned above, the Federal Court correctly set out its task as identifying the loss suffered by the patentee by reason of the infringement, and its conclusions are meant to represent all the damages suffered by reason of the infringement within the meaning of subsection 55(1) of the Patent Act.

[114] I understand Apotex's strategy insofar as the characterization of this argument is concerned; i.e. it was meant to provoke the natural reaction of any patent law jurist to forcefully defend anyone's right to use non-infringing products before or after the expiry of a patent. But once the initial, almost emotional reaction wanes, all these jurists will agree (including those representing Apotex) that, in Canada, there are instances where legal sales are indeed captured by damages because they result from illegal sales. In effect, the loss of certain sales can be claimed as a loss within the meaning of subsection 55(1) of the Patent Act – even if they are

sales of non-infringing products (the ramp-up or springboard effect) or sales of non-infringing components of products – where the court finds that, as a fact, those lost sales arose as a result of the sales of infringing products or because of infringing components (see e.g. *Colonial Fastener Co. Ltd. v. Lighting Fastener Co. Ltd.*, [1937] S.C.R. 36 at p. 41; *Beloit Canada Ltd. v. Valmet-Dominion Inc.*(1997), 73 C.P.R. (3d) 321 at p. 366 (F.C.A.); *Bourgault Industries Ltd. v. Flexi-Coil Ltd.* (1998), 80 C.P.R. (3d) 1 at para. 183 (F.C.T.D.), aff'd (1999) 86 C.P.R. (3d) 221 (F.C.A.), leave to appeal to S.C.C. refused, 27273 (March 23, 2000); *Jay-Lor International Inc. v. Penta Farm Systems Ltd.*, 2007 FC 358 at para. 198; *Merck & Co., Inc. v. Apotex Inc.*, 2013 FC 751 at paras. 200-05 [*Merck*], aff'd 2015 FCA 171, leave to appeal to S.C.C. refused, 36655 (April 14, 2016)). There is no absolute bar in Canada with respect to damages for sales of non-infringing products or components.

[115] As mentioned, Apotex does not dispute that this is so, but it nonetheless seeks to distinguish the cases cited above by saying that they were consistent with the principle of remoteness, whereas the present case is not.

[116] At the hearing before us, Apotex focused particularly on an American case: *DSU Med. Corp. v. JMS Co., Ltd.*, 296 F. Supp. 2d 1140 (N.D. Cal. 2003) [*DSU*], affirmed in the appellate decision affirming the final trial decision, including the evidentiary rulings, 471 F. 3d 1293 (C.A. Fed. Cir. 2006).

[117] I note that Apotex acknowledged that, despite its exhaustive search of American case law, *DSU* was the only piece of jurisprudence that it could find to support its view. It was agreed that this case had never been referred to or cited for the specific proposition advanced by Apotex.

[118] In *DSU*, the U.S. District Court declared inadmissible an expert opinion because the proffered methodology requiring *inter alia* "hypothesized terms in hypothesized contracts was not grounded on an established legal principle and was far too remote factually to be within the line drawn for legally compensable patent injury". It found that a future long-term contract, which expressly contemplated the purchase of a true non-infringing substitute (another type of injection needle), could not result in a compensable loss.

[119] In Apotex's view, the same line should be drawn here as a matter of policy. According to it, the Federal Court should have excluded all sales lost to sales of Lupin 2 cefaclor products on the basis of their being too remote to be compensable.

[120] But, as noted earlier at paragraph 112, Apotex never raised any issue relating to remoteness before the Federal Court. Instead, it relied on the fact that, in the Liability Decision, the Federal Court referred to sales *directly* lost as a result of Apotex's infringement. It underlined that, in a similar situation which prevailed in *Merck*, the Federal Court had set aside all non-infringing sales, stating that the matter had been dealt with at the liability stage (see *Merck* at para. 117).

[121] The Federal Court reviewed this argument at paragraph 15 of its reasons. I agree that the argument based on a literal interpretation of the wording used in the Liability Decision (see para. 652) has no merit. The Federal Court at the liability stage did not have jurisdiction to restrict the scope of the damages set out at subsection 55(1) of the Patent Act. It was simply not its task. The words used had to be construed in the context of what the Court had to decide and the fact that it was left to the reference stage to determine what sales were lost by reason of the infringement. I simply cannot accept the interpretation proposed by Apotex.

[122] That said, the Federal Court is presumed to be fully cognizant of the legal principles applicable to the assessment of damages in patent infringement actions. Indeed, here, it is evident that it was so cognizant. For example, the Federal Court expressly referred to page 452 of a leading British case, *Gerber Garment Technology, Inc. v. Lectra Systems Ltd.*, [1997] R.P.C. 443 (C.A. Civ.) [*Gerber*], which sets out the principles that also apply in Canada, including that of remoteness. *Gerber* is a well-established authority that has been referred to in legal doctrine and case law. It expressly deals with convoyed goods (*Gerber* at pp. 453-55) which are also accepted in Canada as potential damages resulting from the infringement despite the fact that they are not *per se* within the monopoly granted by the patent.

[123] In patent cases, especially those in the pharmaceutical field, foreseeability and, more generally, remoteness, are rarely an issue. Thus, when remoteness is an issue, it should be raised as soon as possible. Otherwise, one could conclude that this was not a live issue or that the argument was waived.

[124] Furthermore, inasmuch as remoteness involves a question of law, it is informed by and intrinsically linked to the facts of each case. The legal conclusion is dependent on the court's findings of fact. It is those facts that help determine how close to the centre the claimed loss falls inside the ripple effects of the wrongful conduct.

[125] To my mind, the effect here (considering that no sale of Lupin 2 product would have occurred before July 2000) is direct and well within the bounds of the wrongful conduct's consequences.

[126] Again, I highlight that the circumstances of this case are quite singular. This is why I stated at the very beginning of my reasons that, in my view, it would be unwise to attempt to draw a line in the sand and define a policy more precise than that already developed by the Supreme Court. Therefore, I do not intend to comment further on *DSU,* for I do not think that this case should be relied on to solve the problem before us.

[127] In the unusual circumstances of this case, I cannot conclude that the Federal Court erred by granting damages that are too remote to be compensable. Considering the Federal Court's findings of fact, the granting of damages for those sales effectively lost by reason of the infringement was fair and proportionate with regard to the wrongful conduct.

D. *Did the Federal Court err in determining the reasonable royalty rate?*

[128] I now turn to the issue regarding the royalty rate.

[129] It appears from the post-trial computation provided to the Federal Court (Appeal Book, vol. 83, tab 418) that Lilly was granted royalties on 1,147 kg of bulk cefaclor at the rate of $1,500 CAN/kg, amounting to a total royalty award of $1,720,000.00. The total award was based on the Federal Court's acceptance of calculations by Mr. Harington, the forensic accounting expert presented by Apotex, regarding the amount of cefaclor which would be subject to a royalty. This amount was composed of the total volume of infringing material imported and accepted by Apotex prior to April 19, 2000, minus the deductions made by Mr. Harington in his report, such as product allotted to experimental use (187 kg) (see Exhibit RX-157, Appeal Book, vol. 41, tab 170 at p. 12068).

[130] Having reviewed Mr. Harington's report, it is not clear to me what the material subject to royalties would exactly encompass. According to Apotex's representations at the hearing before us, this amount would include 344 kg of cefaclor exported by Apotex, as well as cefaclor imported but somehow never accounted for as a lost sale because of wastage and other reasons, many of which remain unclear. Nonetheless, I do not find it relevant to comment any further on the debate that took place before us in that respect, as it is unnecessary for a determination of this appeal (Appeal Book, vol. 83, tab 418 at p. 25572 (confidential)).

[131] As mentioned, the parties were in agreement – and this was well understood by the Federal Court – that a patentee is entitled to a reasonable royalty in regard to sales made by the infringer that the patentee would not have made. In that respect, the statutory tort created pursuant to section 55 of the Patent Act is akin to the tort of trespass: even if the owner of the property (here the incorporeal intellectual property established by the granting of the patent) may

not be able to establish that it actually suffered a loss, it is entitled to a form of compensation sometimes referred to as a user fee (see e.g. *Stoke-on-Trent City Council v. W & J Wass Ltd.*, [1988] 3 All ER 394 at pp. 398-99 (C.A. Civ.)).

[132] It is in the context of determining the reasonable royalty rate that a court needs to contemplate fictional negotiations between the parties. The fictional licensing negotiation, which to some extent mimics the real world negotiations, is a one-time negotiation that takes place before the first act of infringement (*Merck* at para. 157).

[133] Apotex argued that, since the negotiation is meant to apply to infringing material that would not have resulted in sales by Lilly, the Court should consider the date of the first infringement to which such royalty would apply, as opposed to the date of the very first act of infringement. At the hearing before us, when asked to find and confirm what date was actually relevant in its view, Apotex acknowledged that the first sale to which the royalty should apply was in January 1997. This is also the period when Apotex first entered the market and made its first sale. There is thus no need to discuss the issue further.

[134] To construct the hypothetical one-time negotiation, it is usually necessary to consider licencing practices and methodologies that are commonly accepted and applied based on the evidence adduced. Though some methodologies have been preferred in different cases, there is no single correct methodology, and the choice of one in particular depends on the specific circumstances of the case and the evidence before the court (see e.g. *General Tire and Rubber Co. v. Firestone Tyre and Rubber Co. Ltd.*, [1975] 2 All ER 173 at pp. 178-80 (H.L.); see also

AlliedSignal at para. 203). It is for this reason that it is not persuasive to argue that the Federal Court erred in law because it did not adopt the same methodology used in another case.

[135] In the present matter, both sides presented expert evidence. Apotex relied on Mr. Roy Weinstein, and Lilly, on Mr. Raymond S. Sims. Mr. Harington's role was more limited, consisting mainly of applying the rate suggested by Mr. Weinstein to the quantities as well as the other calculations of the loss made in his report (see Exhibit RX-157, Appeal Book, vol. 41, tab 170 at p. 12067).

[136] Further, Apotex points to what it qualifies as a fundamental error in the Federal Court's analysis. It argues that the Federal Court did not imbue the parties to the hypothetical negotiations with the knowledge that they were negotiating over infringing sales which Lilly would never make (Apotex's Outline of Argument – Part IV at p. 4). In its view, the fictional negotiation should reflect the fact that an NIA was available to Apotex, such that Lilly would have understood that it was granting a licence to Apotex to make sales of cefaclor that Lilly would not have otherwise made.

[137] I do not agree that the Federal Court made an extricable legal error. Indeed, it is clear from paragraph 99 of the Federal Court's reasons that it knew that it had to consider all relevant facts and circumstances including "the availability of alternatives to the patented process".

[138] Conversely, the Federal Court's ultimate conclusions were based on its evaluation of the evidence before it, including that of Apotex's expert, Mr. Weinstein. At paragraphs 99 and 101

of its reasons, the Federal Court noted that Mr. Weinstein's approach was too simplistic and that it did not take into consideration all the relevant facts and circumstances of the situation at hand. It also rejected this expert opinion on the basis that its conclusion assumed that an NIA was available as of January 1997. As mentioned earlier, the Federal Court was not satisfied that it had been established that such an NIA "could" have been available at that time.

[139] In fact, on the evidentiary record before it, the Federal Court could not have found that Lupin could produce the required amount of Lupin 2 cefaclor at any time before Apotex entered the market. There was simply no evidence in that respect.

[140] Hence, there is nothing that would justify our Court interfering with the Federal Court's assessment of Mr. Weinstein's evidence. Here again, and for reasons already explained in paragraphs 84-91 above, Apotex has not established that the Federal Court made a palpable and overriding error in reaching its conclusion with respect to the capacity of Lupin to make Lupin 2 cefaclor as of January 1997.

[141] The other arguments raised by Apotex in regard to the royalty rate itself all concern the fact that, in Apotex's view, the amount of the royalty does not make economic sense. Essentially, Apotex invites us to reweigh the expert evidence as well as the other evidence that was before the Federal Court. Needless to say – yet again – it is certainly not our Court's role to do so.

[142] As said before, the exercise performed by the Federal Court in order to reconstruct a hypothetical negotiation does not need to be perfect. Indeed, damages in infringement cases are

notoriously difficult to compute; this is particularly so in the formulation of "but-for" worlds which include more than one hypothetical scenario. It is in this context that, to quote a decision of the House of Lords in an early twentieth century patent case, achieving restoration by way of compensation through "the exercise of a sound imagination and the practice of the broad axe" becomes appropriate (*Watson, Laidlaw & Co. Ltd. v. Pott, Cassels and Williamson* (1914), 31 R.P.C. 104 at p. 118 (H.L.); see also this Court's endorsement of the "broad axe" principle in *Teva Canada Limited v. Janssen Inc.*, 2018 FCA 33 at paras. 32-36, leave to appeal to S.C.C. refused, 38033 (November 11, 2018)).

[143] With this in mind, I have not been persuaded that it was not open to the Federal Court to reach the conclusion that it did in the special circumstances of this case. The rate chosen was indeed high, but there was no NIA available at the relevant time, and the premium Apotex appeared to be ready to pay when it ordered Lupin 2 cefaclor in the actual world was equally very high. There was no evidence that Apotex had even tried to negotiate in order to reduce the amount of this premium after it was first suggested by Lupin.

E. *Did the Federal Court err when it held that Lilly was entitled to interest as damages?*

[144] I now tackle the last issue, relating to the granting of interest as a head of damages. As I will explain, this issue was incorrectly decided by the Federal Court. In particular, the Federal Court erred by relying on a presumption that relieved Lilly from proving its loss regarding compound interest *per se*.

(1) Statutory framework

[145] Before dealing with the arguments before us, it is useful to recall the interplay of section 36 of the FC Act and subsection 55(1) of the Patent Act in order to understand the distinction between the findings relating to interest in the Liability Decision and those in the Damages Decision. Subsection 36(2) and paragraphs 36(4)(*b*) and (*f*) of the FC Act, as well as subsection 55(1) of the Patent Act are reproduced in the annex to these reasons.

[146] Section 36 of the FC Act deals with the awarding of prejudgment interest by the Federal Court. Subsection 36(2) governs prejudgment interest awarded for a cause of action arising, as in this case, in more than one province or outside a province. For its part, subsection 36(5) of the FC Act confers discretion on the Federal Court to, "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". However, subsection 36(4) sets out limitations and circumstances in which interest shall not be awarded under subsection 36(2). Particularly, paragraph 36(4)(*b*) provides that a party is entitled to simple rather than compound interest (*Apotex Inc. v. Merck & Co.*, 2006 FCA 323 at paras. 137-144). Paragraph 36(4)(*f*) provides that "interest shall not be awarded […] where interest is payable by a right other than under this section".

[147] These provisions are not unusual. They are almost identical to those found in the various statutes applicable to other courts in Canada, the United Kingdom and Australia. Such provisions were at play in all the cases to which I will refer in my analysis, such as: *Bank of America Canada v. Mutual Trust Co.*, 2002 SCC 43 [*Bank of America*]; *Hungerfords v. Walker*, [1989] HCA 8 [*Hungerfords*]; and *Sempra Metals Ltd. (formerly Metallgesellschaft Ltd.) v. Inland*

Revenue Commissioners, [2007] UKHL 34 [*Sempra*]. As noted in this case law and in the Liability Decision, these provisions are not considered impediments to the granting of compound interest when faced with breach of contract or tort (see e.g. *Sempra* at para. 100; *Parabola Investments Ltd. v. Browallia Cal Ltd.*, [2010] EWCA Civ 486 at para. 54). The interest thus becomes part of the total damages awarded under common law, or, as in this case, under subsection 55(1) of the Patent Act.

[148] At the liability phase of Lilly's action for infringement, the Federal Court was not tasked with assessing the damages; in effect, even Lilly's right to elect its form of compensation was contested. Rather, the arguments focused on Lilly's substantive right to seek compound interest *per se*. However, it was not disputed that interest, compound or otherwise, was available in the context of an accounting of profit (Liability Decision at p. 325, para. 5).

[149] In the context of a bifurcated proceeding, unless it is agreed that the discretion under subsection 36(2) is to be exercised at the reference stage, the Court must exercise this discretion at the liability stage without knowing whether paragraph 36(4)(*b*) applies, as the Court does not know if interest will be awarded as damages. Thus, the Federal Court in the Liability Decision had to at least determine if it was possible at law for interest as damages to be granted in this matter (paragraph 36(4)(*f*)). It was satisfied that, where full compensation requires an award of compound interest under subsection 55(1) (claim for damages), it was open to the Federal Court to include such an award in the Damages Decision.

[150] Thus, when the Federal Court exercised the discretion under subsection 36(2), the award of prejudgment interest on the award of damages (if elected) in the Liability Decision (at p. 325, para. 4) was expressly said not to apply if Lilly was awarded any other interest as part of its damages at the reference stage.

[151] The Liability Decision was not reversed on appeal and is final. In light of this, in my view, it was not open to Apotex to argue that subsection 55(1) of the Patent Act does not allow for the granting of compound interest.

[152] Thus, in the Damages Decision before us under appeal, the Federal Court had to assess whether full compensation required an award of interest as damages arising from the wrongful conduct at issue. Although the Federal Court could conclude that no further interest award was in fact necessary to fully compensate Lilly, it was not limited in any way to award any interest (simple or compound) it felt appropriate on the evidence before it.

(2) The award of interest

[153] To address the aforementioned issue, evidence was presented to the Federal Court in an attempt to justify the claim for interest as damages: two factual witnesses testified for Lilly and expert evidence on both sides (reports and testimonies) was presented, along with voluminous financial data (such as Form 10-Ks filed with the U.S. Securities and Exchange Commission, as well as financial statements). Had the Federal Court granted compound interest as damages solely on the basis of its assessment of the above-mentioned evidence, Apotex may have had a

difficult task to establish that our Court should intervene, as it would have had to persuade us that the Federal Court's assessment was tainted by a palpable and overriding error.

[154] However, this is not what happened.

[155] First, the Federal Court began by stating that, in order to establish Lilly's right to compound interest, it was not required to prove exactly what use it would have made of the profits lost as a result of the infringer's actions (Damages Decision at para. 118). But after adopting a passage from S.M. Waddams in *The Law of Damages*, 3rd ed. (Aurora, Ont.: Canada Law Book, 1997, as cited at paragraph 37 of *Bank of America*), which indicated that there is no reason why, in principle, compound interest should not be awarded, the Federal Court went on to say:

> I would go further and say that in today's world, there is a presumption that a plaintiff would have generated compound interest on the funds otherwise owed to it, and also that the defendant did so during the period in which it withheld the funds.
>
> [Emphasis added.]

[156] I agree with Apotex: this is not the state of the law in Canada, or, for that matter, in other commonwealth countries such as the United Kingdom, Australia or New Zealand.

[157] There may well be a presumption in some cases where equity applies: see e.g. *Whitefish Lake Band of Indians v. Canada (Attorney General)*, 2007 ONCA 744 at paragraph 49. But even if it were so, common law clearly differs from equity on this point. Neither *Bank of America* nor *Sempra* – nor any other case in Canada or elsewhere – has alluded to such a general presumption

regarding compound interest. This is so whether such interest is simply reflecting the time value of money owed or intended to compensate a specific opportunity lost.

[158] On the contrary, it appears clearly from *Bank of America* at paragraphs 53-55 and *Sempra* at paragraphs 94-97, as well as in the jurisprudence before us applying those two cases, that a loss of interest must be proved in the same way as any other form of loss or damage.

[159] The Federal Court may have felt, in view of the numerous statements by courts – notably the highest courts in Canada, the United Kingdom and Australia – that it is unrealistic or even unfair not to grant compound interest in today's world (see *Bank of America* at para. 44; *Sempra* at paras. 51-52; *Hungerfords* (referred to in *Bank of America*) at paras. 36, 39, 41). It was indeed open to the Federal Court to explicitly say so. However, like our Court, the trier of fact cannot simply ignore the law as set out by the Supreme Court. There is no doubt: until the Supreme Court modifies the state of the common law on this question, Lilly has to prove its claimed loss in regards to the time value of the money.

[160] Even if our Court had, in this instance, the benefit of a more exhaustive and diverse body of jurisprudence on the issue than the Federal Court did at the time, the fact remains that, in the absence of any evaluation by the trier of fact of the evidence put forth by the parties, it would be unwise and inappropriate to decide this issue on appeal.

[161] Although the case law features various illustrations as to the type of evidence required in given cases, none of these are, to my mind, conclusive in the context of this case. It will be

incumbent upon the Federal Court to evaluate if there is sufficient evidence to satisfy the burden of proof taking into account all the circumstances including among others the size and type of the companies involved, the relative size of the amount lost for such large corporations, the long delay involved, including its potential impact on the availability of more specific evidence, and what inferences can be drawn, etc. This exercise goes much beyond what an appellate court should do.

[162] I also note that the rate adopted by the Federal Court was challenged before us. The basis on which the Federal Court arrived at this rate, applicable to all damages on the basis of the annual rate of profit on sales of the Canadian plaintiff, is not readily apparent to me. Lilly did not find any clear precedent where a similar rate was used. I fail to understand why this scenario was the most appropriate. As the Federal Court will have to reconsider the portion of the claim relating to the time value of the money in this case, it will be important for it to explain in more detail its finding as to the rate applicable, if any. I note, furthermore, that Apotex has already paid the damages award in full to Lilly. Thus, should the new award be less than the last one, the Federal Court will need to determine the rate of interest applicable to the amount to be reimbursed by Lilly.

[163] Finally, with respect to the tax issue raised by Apotex, I understand that Lilly's position was that tax would be paid on the award. The Federal Court did not make any specific deduction to account for tax because it would have required it to speculate. It also found that failure to make such a deduction for tax would not result in overcompensation in this case (Damages Decision at para. 119). Apotex does not agree and argued that it was not its burden to establish

the impact of taxation. I agree with Apotex that, logically, interest should only be earned on the net amount that could be used by Lilly. But I am not in a position to evaluate if this would effectively result in overcompensation in this case. Also, this may be a moot issue if the Federal Court on reconsideration is not satisfied with the evidence that compound interest should be awarded, absent the application of the presumption on which it relied. In short, the Federal Court, in its reconsideration of the award of interest as a whole, shall give this factor the weight it believes appropriate. I would also expect a fuller explanation as to the role of the burden of proof in this respect.

V. Conclusion

[164] In view of the foregoing, I propose that the appeal be dismissed except with respect to the portion of the award dealing with damages in the form of interest. The matter should be remitted to Zinn J. for reconsideration of this issue only. Considering the result of the appeal, I also propose that each party bear its own costs.

"Johanne Gauthier"
J.A.

"I agree
Mary J.L. Gleason J.A."

"I agree
J.B. Laskin J.A."

APPENDIX

Patent Act, R.S.C., 1985, c. P-4

[…]	**[…]**
Legal Proceedings in Respect of Patents	**Procédures judiciaires relatives aux brevets**
[…]	**[…]**
Infringement	**Contrefaçon**
[…]	**[…]**
Liability for patent infringement	**Contrefaçon et recours**
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

Federal Courts Act, R.S.C. 1985, c. F-7

[…]	**[…]**
Prejudgment interest — cause of action outside province	**Intérêt avant jugement — Fait non survenu dans une seule province**
36 (2) A person who is entitled to an order for the payment of money in respect of a cause of action arising outside a province or in respect of causes of action arising in more than one province is entitled to claim and have included in the order an award of interest on the payment at any rate that the Federal Court of Appeal or the Federal Court considers reasonable in the circumstances, calculated	**36 (2)** Dans toute instance devant la Cour d'appel fédérale ou la Cour fédérale et dont le fait générateur n'est pas survenu dans une province ou dont les faits générateurs sont survenus dans plusieurs provinces, les intérêts avant jugement sont calculés au taux que la Cour d'appel fédérale ou la Cour fédérale, selon le cas, estime raisonnable dans les circonstances et :
(a) where the order is made on a liquidated claim, from the date or dates the cause of action or causes of action arose to the date of the order; or	a) s'il s'agit d'une créance d'une somme déterminée, depuis la ou les dates du ou des faits générateurs jusqu'à la date de l'ordonnance de paiement;
(b) where the order is made on an unliquidated claim, from the date the person entitled	**b)** si la somme n'est pas déterminée, depuis la date à laquelle le créancier a avisé

gave notice in writing of the claim to the person liable therefor to the date of the order.

[…]

Exceptions

36 (4) Interest shall not be awarded under subsection (2)

[…]

(b) on interest accruing under this section;

[…]

(f) where interest is payable by a right other than under this section.

par écrit le débiteur de sa demande jusqu'à la date de l'ordonnance de paiement.

[…]

Exceptions

36 (4) Il n'est pas accordé d'intérêts aux termes du paragraphe (2) :

[…]

b) sur les intérêts accumulés aux termes du présent article;

[…]

f) si le droit aux intérêts a sa source ailleurs que dans le présent article.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE ZINN DATED JANUARY 23, 2015, NO. T-1321-97

DOCKET:	A-64-15
STYLE OF CAUSE:	APOTEX INC. v. ELI LILLY AND COMPANY AND ELI LILLY CANADA INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	SEPTEMBER 17-18, 2018
REASONS FOR JUDGMENT BY:	GAUTHIER J.A.
CONCURRED IN BY:	GLEASON J.A. LASKIN J.A.
DATED:	NOVEMBER 23, 2018

APPEARANCES:

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