Federal Court of Appeal | Cour d'appel fédérale

Date: 20180208

Dockets: A-244-16
A-274-16

Citation: 2018 FCA 33

CORAM: **DAWSON J.A.**
WEBB J.A.
GLEASON J.A.

Docket: A-244-16

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

JANSSEN INC. and
DAIICHI SANKYO COMPANY, LIMITED

Respondents

Docket: A-274-16

AND BETWEEN:

TEVA CANADA LIMITED

Appellant

and

JANSSEN-ORTHO LLC,
JANSSEN PHARMACEUTICALS, INC.,
OMJ PHARMACEUTICALS, INC. and
DAIICHI SANKYO COMPANY, LIMITED

Respondents

Heard at Ottawa, Ontario, on November 28, 2017.

Judgment delivered at Ottawa, Ontario, on January 24, 2018.

REASONS FOR JUDGMENT BY: DAWSON J.A.

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

Federal Court of Appeal  Cour d'appel fédérale

Date: 20180208

Dockets: A-244-16
A-274-16

Citation: 2018 FCA 33

CORAM: **DAWSON J.A.**
WEBB J.A.
GLEASON J.A.

Docket:A-244-16

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

JANSSEN INC. and
DAIICHI SANKYO COMPANY, LIMITED

Respondents

Docket:A-274-16

AND BETWEEN:

TEVA CANADA LIMITED

Appellant

and

JANSSEN-ORTHO LLC, JANSSEN PHARMACEUTICALS, INC., OMJ PHARMACEUTICALS, INC. and DAIICHI SANKYO COMPANY, LIMITED

Respondents

REASONS FOR JUDGMENT
(Confidential Reasons for Judgment Issued January 24, 2018)

DAWSON J.A.

I. Introduction

[1] Levofloxacin is an anti-microbial drug belonging to the class of antibiotics known as respiratory fluoroquinolones. It is marketed in Canada by Janssen Inc. under the brand name "Levaquin". Levaquin is primarily used to treat serious or complicated respiratory tract infections and some types of urinary tract infections.

[2] Daiichi Sankyo Company, Limited, a Japanese-based pharmaceutical company, owns Canadian Patent No. 1,304,080 (080 Patent) which claims levofloxacin. Janssen Inc. (Janssen Canada) is licensed by Daiichi to sell levofloxacin in Canada.

[3] The Federal Court found that claim 4 of the 080 Patent was valid and was infringed by Teva Canada Limited when Teva offered for sale, and sold, products containing levofloxacin in Canada (2006 FC 1234). The Federal Court restrained Teva from selling and otherwise dealing

with products containing levofloxacin in Canada. The judgment of the Federal Court was affirmed on appeal (2007 FCA 217), and leave to appeal the decision of this Court was refused by the Supreme Court of Canada ([2007] S.C.C.A. No. 442).

[4] Thereafter, following a trial lasting ten days the Federal Court determined the quantum of the damages caused by Teva's infringement. For reasons cited as 2016 FC 593, the Federal Court ordered Teva to pay damages to Janssen Canada in the amount of $5,498,270.00, inclusive of prejudgment interest, and to pay damages to Janssen Pharmaceuticals, Inc. (Janssen US) in the amount of $13,342,949.00, also inclusive of prejudgment interest. As explained in more detail below, Janssen US was part of the supply chain which marketed Levaquin in Canada.

[5] For separate reasons cited as 2016 FC 727, the Federal Court later ordered Teva to pay costs jointly to Janssen Canada and Janssen US. These costs were fixed in the amount of $1,000,000.00, inclusive of all fees, disbursements and taxes, unless within a specified period the Janssen plaintiffs jointly elected to have their costs assessed. The Janssen plaintiffs did not make such an election. In these reasons, Janssen Canada and Janssen US are together referred to as Janssen.

[6] Teva now appeals from the judgment of the Federal Court ordering it to pay damages and from the order of the Federal Court ordering it to pay costs. The appeals were consolidated by order of this Court. In accordance with the consolidation order, a copy of these reasons shall be placed on each Court file.

[7] As will be seen, Teva asserts a number of errors on the part of the Federal Court. In largest part, the asserted errors challenge the Federal Court's appreciation of the evidence. For the reasons that follow, I have found no error of law or palpable and overriding error of fact or mixed fact and law on the part of the Federal Court. It follows that I would dismiss both appeals with costs.

II. Factual background

[8] The following brief overview is sufficient to situate the issues raised on these consolidated appeals.

[9] At the relevant time there were three respiratory fluoroquinolones available in the Canadian market: Levaquin (levofloxacin), Avelox (moxifloxacin) and Tequin (gatifloxacin).

[10] Sales of levofloxacin and other antibiotics were described at trial to fall into three trade channels. These channels were direct sales to hospitals, direct and indirect sales to drug stores and similar entities, and sales to government and educational entities (reasons, paragraph 85). Of particular relevance to these appeals are sales to hospitals.

[11] Teva launched its generic version of Levaquin on November 29, 2004, under the name Novo-levofloxacin. At approximately the same time concerns began to emerge about the safety of Tequin. Tequin was ultimately withdrawn from the market in June 2006. On October 17, 2006, the Federal Court enjoined the sale of Novo-levofloxacin in Canada. Levofloxacin was the only respiratory fluoroquinolone to be sold in a generic form during the relevant time frame.

[12] At trial, Janssen's expert Dr. Rosenblatt put forward an economic model (Scenario A) that enabled him to formulate an opinion on what Janssen's sales of Levaquin 500 mg and 750 mg tablets would have been in the hypothetical "but for" world.

[13] Scenario A was based on a number of assumptions. The first assumption was that Levaquin competed directly against the two other respiratory fluoroquinolones (Avelox and Tequin) and did not compete directly against other antibiotics (such as the macrolides). Another assumption was that once Tequin was withdrawn from the market in June 2006, Levaquin and Avelox would be equally preferred by prescribing physicians. Thus, if Janssen had continued to promote Levaquin during the period of infringement, Levaquin would have maintained its market share against Avelox by gaining a relative share of the lost Tequin sales.

[14] Dr. Rosenblatt put forward an alternative economic model (Scenario B) which was premised on the assumption that sales of Levaquin would have remained flat during the relevant period. Thus, the average level of prescription volumes sold between 2000 and 2004 would have been sold between 2005 and 2010. This was described by Dr. Rosenblatt to be a very conservative scenario. In his view, it was not a likely scenario.

[15] The major assumption common to both scenarios was that the total number of prescriptions "filled" in the period from June 23, 2009 to December 31, 2010 in the hypothetical levofloxacin competitive market did not change from the number of prescriptions that were actually filled in the real world during the damages period. The "levofloxacin competitive

market" refers to the sales of all units of the following molecules in Canada: 500 mg and 750 mg levofloxacin (i.e. Levaquin and Novo-levofloxacin), moxifloxacin and gatifloxacin.

[16] Teva's experts did not construct an economic model to analyze the relevant market. Instead, Teva's forensic accountant, Mr. Mak, presented a number of damage scenarios, one of which concluded that as a result of Teva's entry into the market Janssen was "ahead by $4 million" (reasons, paragraph 95). More specifically, in his Scenario 1 Mr. Mak opined that, with prejudgment interest, Janssen would have benefitted from Teva's entry into the market by between [redacted] (after the deduction of monies that Teva had already paid to Janssen Canada) (expert report of Mr. Mak, Appeal Book, volume 45, tab 72 at page 017041). The net benefit arose as a result of Mr. Mak's calculation of expenses not incurred by Janssen in the "but for" world.

III. The damages decision of the Federal Court

[17] After setting out the relevant facts and describing the evidence adduced at trial, the Federal Court considered the issue of whether Janssen US had standing to claim damages as a result of Teva's infringement of the 080 Patent. This, in turn, required the Court to consider whether Janssen US was a person "claiming under the patentee" within the contemplation of subsection 55(1) of the *Patent Act*, R.S.C., 1985, c. P-4.

[18] The Federal Court conducted a lengthy review of the relevant jurisprudence (reasons, paragraphs 28 to 43) and then reviewed the relevant evidence (reasons, paragraphs 44 to 58). The Federal Court concluded that Janssen US had standing because "it has the licence or permission,

by acquiescence, of Daiichi, to be involved in the chain of the sale of tablets made in Puerto Rico by Janssen Puerto Rico, through Janssen US to Janssen Canada. It is immaterial whether Janssen US had title, even momentarily, to the tablets in Canada." (reasons, paragraph 61).

[19] The Federal Court then moved to quantify the damages sustained by reason of the infringement. The Court began by reviewing the general legal principles, the parties' positions and the concessions made by the parties.

[20] The Court then reviewed the marketplace as it existed in fact (reasons, paragraphs 75 to 88), the two scenarios posited by Dr. Rosenblatt and the multiple damages scenarios presented by Teva's forensic accountant (reasons, paragraphs 89 to 90). After briefly reviewing the parties' competing views about the "but for" marketplace, the Court set out its findings as to what would likely have occurred in the "but for" world (reasons, paragraphs 104 to 106). The Court's central finding was that Scenario A "best represents what would have happened in the "but for" world." However, the Court concluded that some of the assumptions that underlay Scenario A required change. The required changes related to the period in which damages were to be assessed, the percentage of sales of levofloxacin to hospitals and whether sales to educational institutes/governments should be included with hospital sales.

[21] Of relevance to these appeals are the Court's findings related to the period in which damages were assessed and the percentage of sales to hospitals. With respect to the damage period, the Court found that losses due to prescription (retail) sales would terminate approximately two months after the patent expired (August 31, 2009), and that losses due to

sales to hospitals would terminate approximately one year after the patent expired (June 30, 2010) (reasons, paragraph 112). The Court rejected Teva's assertion that there should be a one month time lag at the beginning of the period in which damages were calculated (reasons, paragraphs 113 to 115).

[22] With respect to hospital sales, the Court allowed Janssen's claim for damages as a result of having to suppress its selling price to hospitals by [redacted] when Teva entered the marketplace, and found that Janssen could not raise the prices after Teva was later forced to withdraw from the market (reasons, paragraphs 116 to 118). The Court also found that the percentage of indirect sales to hospitals was [redacted]. Janssen's expert had calculated a figure of [redacted], while Teva's expert calculated a figure of [redacted] (reasons, paragraphs 125 to 131).

[23] Finally, after reviewing the relevant legal principles and the evidence as to what Janssen actually did during the relevant period, the Court rejected Teva's claim that Janssen had failed to mitigate the damages it incurred.

[24] In order to implement into the damages award the changes the Court made to some of the assumptions underlying Scenario A, the Court sent a copy of its draft reasons to counsel for each of the parties and asked that they, working with their experts, prepare an agreed set of figures that resulted from the Court's changes. Counsel did so and those figures are reflected in the judgment of the Federal Court. Unfortunately, it does not appear that the calculations used to calculate the agreed figures form part of the record. Had this Court found it necessary to intervene in the damage award this absence could have negatively affected this Court's ability to

vary findings that related to counsel's calculations. We simply do not know how various amounts were calculated.

IV. The costs decision of the Federal Court

[25] In response to the Court's request that the parties provide submissions on costs, Janssen submitted a draft bill of costs which, including fees, disbursements and taxes, totalled $1,458,751.00. Teva took issue with virtually every item in the draft bill of costs and requested that costs be assessed. Teva also asked that the Court give directions to the assessment officer.

[26] In response, the Federal Court noted that an assessment of costs would be difficult and tedious in view of the many challenges raised by Teva. The Court envisioned that excessive resources of the Court, and the parties, would be spent pursuing the many issues that would have to be considered on an assessment (reasons, paragraph 5).

[27] In the result, the Court ordered that costs fixed as a lump sum be paid to Janssen in the amount of $1,000,000.00. The Court considered this to be "the most reasonable amount in the circumstances." However, the Court gave Janssen the option, to be exercised within 20 days from the date of the order, to have the costs assessed by an assessment officer having regard to the directions given by the Court (reasons, paragraphs 6 to 7). As explained above, Janssen did not elect to have its costs assessed.

V. The issues

[28] As adverted to above, the appellant raises a number of issues on these appeals, many of which raise a number of sub-issues. I would restate the issues to be decided to be:

i. Did the Federal Court err in finding that Scenario A best represented what would have happened in the "but for" world?

ii. Did the Federal Court err in finding that Janssen had taken appropriate steps to mitigate its loss?

iii. Did the Federal Court err in its quantification of lost sales to hospitals in the "but for" world?

iv. Did the Federal Court err by finding that Janssen US was a person claiming under the patentee in Canada?

v. If the Federal Court did not err in finding that Janssen US was a person claiming under the patentee in Canada, did the Federal Court err by:

   a. awarding permanent lost market share damages to Janssen US;

   b. failing to apply a one-month delay or lag to the commencement of Janssen US's damages; and,

   c. failing to deduct a royalty payment that was contractually required.

vi. Did the Federal Court err by awarding an excessive amount for costs?

VI. The standard of review

[29] The standard of review applicable to the issues raised in this case are as described by the Supreme Court in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. The standard of

review to be applied to questions of law is correctness. 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 such error is reviewed on the correctness standard.

[30] Where required, the standard of review will be discussed in greater detail in the context of the analysis of each issue asserted by the appellant.

VII. Consideration of the issues

A. Did the Federal Court err in finding that Scenario A best represented what would have happened in the "but for" world?

[31] As I understand Teva's submission on this issue, it alleges two broad errors on the part of the Federal Court. First, Teva alleges that the Court erred in principle by stating that it was to, in effect, mete out rough justice by application of a "broad axe". Second, the Federal Court is said to have erred by finding Scenario A to best represent what would have likely happened in the hypothetical "but for" world in circumstances where the factual assumptions that underpinned Scenario A either were not supported by any evidence or were rejected by the Federal Court.

1. The asserted error of principle

[32] I begin my analysis with Teva's asserted error of principle. Teva's complaint arises from paragraphs 69 to 71 of the Court's reasons which discuss the general approach to quantifying damages. There, the Federal Court quotes with approval Lord Shaw's comment in *Watson,*

Laidlaw & Co. Ltd. v. Pott, Cassels, and Williamson (1914), 31 R.P.C. 104, at pages 117 to 118, to the effect that:

> … In the case of damages in general, there is one principle which does underlie the assessment. It is what may be called that of restoration. The idea is to restore the person who has sustained injury and loss to the condition in which he would have been had he not so sustained it. In the cases of financial loss, injury to trade, and the like, caused either by breach of contract or by tort, the loss is capable of correct appreciation in stated figures. In a second class, of cases, restoration being in point of fact difficult, as in the case of loss of reputation, or impossible, as in the case of loss of life, faculty, or limb, the task of restoration under the name of compensation calls into play inference, conjecture, and the like. This is necessarily accompanied by those deficiencies which attach to the conversion into money of certain elements which are very real, which go to make up the happiness and usefulness of life, but which were never so converted or measured. The restoration by way of compensation is therefore accomplished to a large extent by the exercise of a sound imagination and the practice of the broad axe. It is in such cases, my Lords, whether the result has been attained by the verdict of a jury or the finding of a single Judge, that the greatest weight attaches to the decision of the Court of first instance.
>
> (underlining added)

[33] The admonition to apply sound imagination and brandish a broad axe is said to be contrary to the decision of this Court in *Apotex Inc. v. Merck & Co., Inc.*, 2015 FCA 171, [2016] 2 F.C.R. 202 (Lovastatin) where, at paragraph 42, the Court noted that because "over-compensation of an inventor chills potential competition" "perfect compensation" is required.

[34] In my view, Teva takes this Court's comments in Lovastatin out of context. The Court's comment about "perfect compensation" was made in the context of discussing the purpose of an award of damages for patent infringement — compensation. The Court noted that the concept of compensation rejects both under-compensation and over-compensation. In the circumstances then before the Court, this required consideration of both: (i) what, if any, non-infringing product

the defendant or any other competitors could and would have sold "but for" the infringement; and, (ii) the extent lawful competition would have reduced the patentee's sales.

[35] The Court then went on to note at paragraph 55 the hypothetical and theoretical nature of the exercise of quantifying damages for patent infringement:

> … a patentee claiming damages is required to reconstruct the market to project economic results that did not occur. This is a hypothetical enterprise. To "prevent the hypothetical from lapsing into pure speculation" courts require sound economic proof of the nature of the market and the likely outcomes with infringement factored out of the economic picture. Within this framework, patentees are permitted to present market reconstruction theories showing all of the ways in which they would have been better off in the "but for" world. A fair and accurate reconstruction of the "but for" world must also take into account relevant, alternative actions an infringer foreseeably could and would have undertaken had he not infringed.
>
> (underlining added)

[36] The "but for" world is of necessity a hypothetical and theoretical construct. It is not a world where, in the words of Lord Shaw, "the loss is capable of correct appreciation in stated figures." It follows that the Federal Court did not err in principle by quoting Lord Shaw or by referring in its reasons to a "broad axe". On a fair reading of its reasons, the Federal Court did not proceed on the basis that what was required was "rough justice". The Court looked to economic proof of the nature of the levofloxacin market and the likely outcomes in that market when Teva's infringement was factored out.

2. The asserted factual errors

[37] I now turn to the three factual assumptions that underpinned Scenario A that Teva asserts were unproven or rejected by the Federal Court. They are that:

a. Levaquin competed directly against the other two respiratory fluoroquinolones, and did not compete directly against other antibiotics.

b. The competitive market was highly promotion sensitive.

c. Levofloxacin and moxifloxacin would have been preferred equally by prescribers during the years 2005 to 2010.

[38] It is well-settled law that for any weight to be given to an expert's opinion, the facts upon which the opinion is based must be proven (see, for example, *R. v. J.-L.J.*, 2000 SCC 51, [2000] 2 S.C.R. 600, at paragraph 59). In the present case, this required Janssen to prove the factual assumptions that underlay Scenario A.

[39] However, for the following reasons I have not been satisfied that the Federal Court erred by relying on unfounded or rejected assumptions as Teva asserts.

(a) Levaquin competed directly against the other two respiratory fluoroquinolones

[40] At paragraph 105 of its reasons the Federal Court found that:

- Once Tequin disappeared from the market "most doctors would have switched to levofloxacin or moxifloxacin but some may have switched to other products such as CIPRO or one of the macrolides".
- The relevant comparator market is the respiratory fluoroquinolone class.

[41] Teva asserts that the first finding is incompatible with the second finding because the first finding rejects a major assumption of Scenario A — that the competitive market for levofloxacin was a "closed, zero-sum market involving only levofloxacin, gatifloxacin and moxifloxacin" (paragraph 33, Teva's memorandum of fact and law).

[42] I begin my analysis by rejecting the premise of Teva's argument. Scenario A is not based on the assumption that doctors who would have prescribed Tequin would only prescribe Avelox or Levaquin in its stead, and would not prescribe other alternatives such as Cipro or one of the macrolides. The only zero-sum aspect to Scenario A is that any increases in sales Levaquin could obtain in the "but for" world could only come from the share of actual prescriptions issued in respect of the other respiratory fluoroquinolones, Avelox or Tequin.

[43] Scenario A assumes that "but for" Teva's infringement Levaquin would have maintained its level of prescription volume "and would have also captured a proportion of the growth in AVELOX® prescriptions" after Tequin was removed from the market (expert report of Dr. Rosenblatt, Appeal Book, volume 13, tab 31, at paragraph 49). Whether other drugs would have captured some of Tequin's market share is irrelevant to this assumption. It follows that the two findings of the Federal Court are not incompatible with one another.

(b) The competitive market was highly promotion sensitive

[44] Dr. Rosenblatt's opinion was premised on the assumption that because Levaquin was prescribed as an acute, rather than chronic, treatment, every prescription was considered a "new" prescribing decision and these decisions were significantly impacted by the promotional efforts

of pharmaceutical sales representatives (expert report of Dr. Rosenblatt, Appeal Book, volume 13, tab 31, at paragraph 42). Teva points to the Federal Court's findings, at paragraph 105, that:

- Visits by sales representatives to physicians promoting a drug have an effect at the initial launch stage of a product, but a lesser effect later.
- Doctors' prescribing practices are significantly affected by "what they are familiar with and seems to work best for their patients."

Teva argues that in light of these findings Dr. Rosenblatt's opinion was based upon an unfounded assumption. Put another way, prescribing decisions were not significantly impacted by promotional efforts.

[45] In my view, Teva's argument parses Dr. Rosenblatt's opinion and its reliance on the role of the promotional efforts of pharmaceutical sales representatives.

[46] Virtually all promotion of a branded drug stops when a generic version of the branded drug enters the market. This is because pharmacies substitute the generic product for the branded product. Dr. Rosenblatt's comment about promotional efforts was given in the context of explaining how, notwithstanding declining growth in 2004 in the volume of prescriptions issued for Avelox, Bayer's continued promotion of its drug Avelox contributed to increase the sales of Avelox at a time when there was no competitive promotion from Levaquin or Tequin.

[47] This does not detract from the assumption in Scenario A that had Janssen continued its pre-infringement promotion efforts it would have, at a minimum, maintained Levaquin's pre-damages market share of the pre-damages period Avelox and Levaquin market, and would likely

have increased its total prescription volume. As Dr. Rosenblatt had previously noted in his opinion at paragraph 37, during the time frame between 2000 and 2004, while Janssen was continuing to promote Levaquin, the number of prescriptions issued for Levaquin was not materially impacted by the entry of Avelox and Tequin into the competitive market.

(c) Levaquin and Avelox would have been preferred equally by prescribers during the years 2005 to 2010

[48] Teva argues that the only evidence to support Dr. Rosenblatt's assumption that Levaquin and Avelox would have been equally preferred was that of Dr. Chan. Dr. Chan's evidence is said to be flawed for a number of reasons, including the Federal Court's comment that it would "treat Dr. Chan's evidence with caution." (reasons, paragraph 16). Teva also argues the Court ought to have accepted the evidence of its expert, Dr. Simor, who the Federal Court found gave his evidence "in a straightforward and candid manner." (reasons, paragraph 20).

[49] I reject these submissions for the following reasons.

[50] First, in cross-examination Dr. Rosenblatt testified that he too had come to the independent opinion that Levaquin's pre-damages period market share was the appropriate measure to use in calculating loss in the "but for" world. At the time of infringement Levaquin had maintained 51.8% of the combined levofloxacin/Avelox market (expert report of Dr. Rosenblatt, Exhibit 5, Appeal Book, volume 13, tab 31, at paragraph 56). Thus, it is not correct to say that Dr. Rosenblatt's opinion rests solely on the evidence of Dr. Chan.

[51] Second, it was open to the Federal Court to prefer the evidence of Janssen's experts over that of Teva's experts. Teva has not shown the Federal Court to have misapprehended the evidence tendered before it about physician prescribing practices.

[52] Finally, having heard Dr. Chan's testimony, the Federal Court accepted that he was qualified to opine as "a medical doctor with a specialist certification in respiratory medicine and expertise regarding respiratory tract diseases, antiinfectives, and prescribing practice including expertise on the Canadian antibiotic guidelines." (reasons, paragraph 16). While Dr. Chan's lengthy answers and apparent umbrage at having his opinions challenged on cross-examination may have led the Federal Court to view his evidence with caution, this falls far short of a finding that any aspect of his evidence was not credible.

B. Did the Federal Court err in finding that Janssen had taken appropriate steps to mitigate its loss?

[53] I begin by setting out the legal principles that underlie the concept of mitigation and then consider the errors asserted by Teva.

1. The concept of mitigation

[54] The concept of mitigation may be succinctly expressed: a plaintiff is not entitled to recover compensation for loss that could have been avoided by taking reasonable action. Pursuant to this concept, any loss is disallowed when the loss flows from the plaintiff's inaction, as opposed to the defendant's wrong.

[55] What constitutes reasonable action is in every case a question of fact, depending on the particular circumstances of the plaintiff and the case. This said, as is the case with the concept of remoteness, a finding that a plaintiff ought to have mitigated its loss is not a simple question of fact because it also involves a legal conclusion.

[56] The burden of establishing the failure to mitigate is on the defendant. The defendant must show both that the plaintiff failed to make reasonable efforts to mitigate and that mitigation was possible (*Southcott Estates Inc. v. Toronto Catholic District School Board*, 2012 SCC 51, [2012] 2 S.C.R. 675, at paragraph 24).

[57] In case of doubt, a plaintiff will generally receive the benefit of the doubt on the ground that a defendant should not be overly critical of a plaintiff's good-faith effort to avoid difficulties caused by the defendant's wrongful act (S. M. Waddams, *The Law of Damages*, looseleaf (Toronto: ON: Thomson Reuters Canada, 1991) at paragraph 15.140). In *Banco de Portugal v. Waterlow & Sons, Ltd.*, [1932] A.C. 452 (H.L.), Lord Macmillan expressed this concept as follows (at page 506):

> Where the sufferer from a breach of contract finds himself in consequence of that breach placed in a position of embarrassment the measures which he may be driven to adopt in order to extricate himself ought not to be weighed in nice scales at the instance of the party whose breach of contract has occasioned the difficulty. It is often easy after an emergency has passed to criticise the steps which have been taken to meet it, but such criticism does not come well from those who have themselves created the emergency. The law is satisfied if the party placed in a difficult situation by reason of the breach of a duty owed to him has acted reasonably in the adoption of remedial measures, and he will not be held disentitled to recover the cost of such measures merely because the party in breach can suggest that other measures less burdensome to him might have been taken.
>
> (underlining added)

[58] This principle applies equally to cases of patent infringement. A plaintiff's conduct is not to be weighed against a single standard of objective reasonability.

2. The reasons of the Federal Court

[59] After correctly reviewing the applicable legal principles, the Federal Court turned to the evidence of what Janssen actually did to mitigate its loss. The Court then wrote, at paragraph 146, that:

> This is what was actually done. There is no evidence from Teva as to what ought to have been done. There are only assertions by Teva's lawyers in argument as to what ought to have been done and when. The Court has no evidence from any marketing person from Teva or any other evidence to suggest that the steps actually taken by Janssen were too late or inadequate.

[60] At paragraph 147 the Federal Court concluded that it could not find that the steps taken by Janssen were insufficient to mitigate the damages incurred.

(a) The asserted errors

[61] Teva now argues that the Federal Court's analysis was flawed in that the Federal Court:

a. Misapprehended the evidence by finding that once Janssen regained market exclusivity for Levaquin it could not raise prices charged to hospitals "as it was bound by an existing contract." (reasons, paragraph 143).

b. Erred in law or committed a palpable and overriding error when it concluded at paragraph 146 that there was "no evidence from Teva" on the issue of mitigation.

c. Erred in law by referring in its mitigation analysis to the date that leave to appeal the liability decision to the Supreme Court of Canada was refused.

[62] In my view, the Federal Court did not err as asserted; in substance Teva impermissibly asks this Court to re-weigh the evidence. I reach this conclusion for the following reasons.

(b) The prices charged to hospitals

[63] Teva argues that Janssen did not prove the existence of any contract that precluded a price hike once Novo-levofloxacin was removed from the market, and that Janssen's witness Mr. Stewart admitted that Janssen could have raised the prices it charged to hospitals once it regained market exclusivity. Mr. Stewart was a Business Unit Director at Janssen Canada who testified about Janssen's marketing strategy and business decisions in respect of the sale of Levaquin in Canada.

[64] While the Federal Court's reference to a contract was unfortunate, this error was not material to the Court's analysis — the Federal Court understood that as a practical matter Janssen would not raise prices to its customers and that there were business reasons to support this approach. That the Federal Court understood these matters is reflected in paragraph 117 of its reasons where the Federal Court quoted at length the testimony of Mr. Stewart on these points:

> Q. Did the presence of Novopharm in the market have an effect on Janssen hospital pricing?
>
> A. Yes, to the extent that, once you have lost all your opportunity to partner with the hospitals and specialists, you don't have anything left except a generic strategy. The only thing you have left to try to leverage to try to hold on to your business is lower your price and compete on price.
>
> In [redacted] of [redacted], we lowered our hospital prices another [redacted] percent universally across the board so all hospitals had an opportunity to save money because we also had no resources to go out and differentiate between the hospitals on a pricing standpoint. This was a blanket drop in the price as a result.

Q. Before Novo-levofloxacin came to the market, did Janssen intend to lower its hospital prices?

A. There was no plan to implement that [redacted] percent reduction across the board strategy.

…

Q. In the period after Novopharm left the market, did that have an effect on Janssen's hospital prices for LEVAQUIN?

A. There was no change to our hospital pricing.

Q. How come?

A. You have established relationships and listings based on the hospital prices that have been offered for the last two years plus. We are not going to rock that boat and change it on these customers. It is not the way we operate.

…

Q. Your [*sic*] told Mr. Wilcox when he was asking you about the price drops in the hospitals -- pardon me, Mr. Markwell -- that after you had lowered the hospital prices in 2006 when you regained the market, you didn't want to raise them because you didn't want to rock the boat, yes?

A. Yes.

Q. By that, you meant you could alienate customers and they would buy the product from someone else?

A. We were coming into the market with other hospital antiinfectives that was the future of our antiinfective franchise at the time. Why would you want to upset the customer by nickel and diming then [*sic*] on one when you want to come in later then asking them to list enough?

(underlining added)

[65] Teva has not shown any palpable and overriding error on the part of the Federal Court with respect to Janssen's ability to raise the price charged to hospitals for Levaquin.

(c) Teva's evidence on mitigation

[66] Teva complains that the Federal Court failed to consider evidence relevant to mitigation and erred by stating that there was "no evidence from Teva". Teva points to the following evidence on mitigation, which it characterizes to be "ample" to establish that Janssen failed to mitigate its loss (Teva memorandum of fact and law, paragraph 55):

- Dr. Chan's evidence in cross-examination that had Janssen started to market Levaquin again in October 2006, it could have grown its market share (Appeal Book, volume 3, tab 18, page 635, lines 7-14).
- Dr. Rosenblatt's evidence on cross-examination that it would be reasonable for Janssen to promote Levaquin in 2006 when it regained market exclusivity (Appeal Book, volume 1, tab 15, page 381, line 25 to page 382, line 6).
- Dr. Grootendorst's testimony that if the market was as sensitive to promotion as suggested by Drs. Chan and Rosenblatt, Janssen "had every incentive to promote Levaquin upon regaining exclusivity in October 2006" (expert report, Exhibit 52, Appeal Book, volume 47, tab 78 at paragraph 164).

[67] I begin my analysis of Teva's submission by observing that Teva takes out of context the Federal Court's statement that there was "no evidence from Teva as to what ought to have been done … only assertions by Teva's lawyers in argument". The Federal Court's comment was a correct observation that Teva had led no fact or expert evidence directed to what would constitute reasonable action on the part of Janssen in the "but for" world. As the presiding Judge observed during oral argument:

> Where is your marketing guy, your guy? You are looking at stray stuff in cross-examination from people who are outside the field and you saying ah-ha. Give me something you can sink your teeth into.
>
> (Appeal Book, volume 4, tab 24, page 1525, lines 15-18)

[68] This is, in my view, a fair characterization of Teva's effort. Given Mr. Stewart's evidence as to what Janssen did and his explanation for why Janssen acted as it did, the above evidence falls short of demonstrating any reviewable error on the part of the Federal Court. Moreover, the following may be said about the specific evidence Teva relies upon.

[69] First, a global comment: none of Drs. Chan, Rosenblatt or Grootendorst were qualified to opine on the reasonableness of Janssen's business decisions. This is particularly true of Dr. Chan whose area of expertise was specialist certification in respiratory medicine and expertise regarding respiratory tract disease, antiinfectives and prescribing practice.

[70] Second, Dr. Rosenblatt's "admission" was significantly qualified. When asked if it "makes sense" for Janssen to promote Levaquin in 2006 he responded:

> A. It could make sense to promote. <u>It could make sense to promote right away. That would depend on the overall strategic decisions that the company is making about where they want to invest and where they don't want to invest, etc.</u>
>
> Q. If you want to generate a return on investment, bring your market back to where you think it should be. It is reasonable to take the steps of promoting if you believe that promotion is effective.
>
> A. You would likely begin promotion.
>
> Q. Likewise, if Janssen was on a fast track to have an injunction issued, they had a case and were on a fast track to get an injunction to drive Novapharm off the market, it would have made some sense, been reasonable, to maintain some level of promotion to maintain the product with the reps before the doctors if they had a reasonable chance of winning?

> A. I can't say "yes" because you need to tell me what timeframes you are looking at, how long, what the likelihood that they would get back on the market, if they would get back on the market in three months or two years.
>
> (underlining added)
>
> (Appeal Book, volume 1, tab 15, page 381, line 25 to page 382, line 18)

[71] Finally, Dr. Grootendorst was qualified as an expert in health and pharmaceutical economics. His evidence that if the market was sensitive to promotion Janssen had "every incentive to promote Levaquin upon regaining exclusivity in October 2006" falls far short of demonstrating Janssen's actions were unreasonable in failing to do so. I agree with the Federal Court's characterization of Dr. Grootendorst's statement:

> That is an assumption rebutting an assumption. I am looking for some meat and potatoes. I am not looking for some stray crumbs under the table.
>
> (Appeal Book, volume 4, tab 24, page 1526, lines 15-18)

[72] Before leaving this issue, Teva endeavored to impugn Mr. Stewart's evidence by pointing to his admission on cross-examination that he was unaware that Janssen had held a Levaquin relaunch meeting in April 2006, and his admission that Janssen could have started to promote Levaquin shortly after October 2006. In my view, Teva overstates the effect of Mr. Stewart's testimony. I reproduce portions of his testimony about Janssen's ability to promote Levaquin:

> Q. Yes. There are other slides, yes. Given that a planning meeting, a SWAT analysis, and so forth had been done in April for relaunching the brand, the brand could have relaunched soon after October 2006; right?
>
> A. Only if they did something about it.
>
> Q. You said it would take time a work up a plan. The plan has already been worked out. All they need to do is assign detailers; right?
>
> A. I am trying to find the plan part. There was an analysis done but no plan built that I can see unless I am missing something. It seems to be focused on the

> 750. It looks like, from the focus on the 750, they were looking at reigniting the promotion of the 750 as discussed earlier to set the stage for the ceftobiprole/doripenem launch and using the knowledge of through the LEVAQUIN marketplace data to better understand the market for those two new brands.
>
> …
>
> Q. It would have been possible to have people who were already detailing physicians to mention that Janssen was back in the market, that LEVAQUIN samples were on the way?
>
> A. Anything is possible.
>
> Q. It wouldn't have cost any addition [*sic*] resources to do that?
>
> A. We have nothing to back up what we told them. We have no samples. Nothing is on order. Nothing is coming in from supply chain. We have no materials.
>
> Q. That could have been arranged for in April?
>
> A. By April.
>
> Q. Could have been arranged for in April of 2006 when the strategy meeting was held?
>
> A. We are not going to do anything to order any supply in a product that is going to get swapped out with a Teva product by the pharmacists until we won the case.
>
> (underlining added)
>
> (Appeal Book, volume 3, tab 18, two extracts: page 952, lines 1-17 and page 953, line 23 to page 954, line 13)

[73] Reading the testimony of Mr. Stewart fairly and in context, Teva has failed to demonstrate any error in the Federal Court's appreciation of the evidence as a whole.

(d) The Federal Court's reference to the date the Supreme Court dismissed the application for leave to appeal from the liability decision

[74] Teva argues that it was an error in law for the Federal Court to refer to the date the leave application was dismissed because Janssen did not suggest that the Levaquin relaunch was delayed because of the leave application.

[75] Teva's complaint stems from paragraph 142 of the reasons of the Federal Court. There, in a paragraph introducing the issue of what steps Janssen actually took to mitigate its loss, the Court recited the procedural history of the litigation dealing with patent validity and infringement. That history included the date on which the leave application was dismissed. Thereafter, the date the leave application was dismissed played no role in the Court's mitigation analysis.

[76] No reviewable error has been shown.

C. Did the Federal Court err in its quantification of lost sales to hospitals in the "but for" world?

1. The reasons of the Federal Court

[77] In order to situate Teva's submissions it is necessary to first review briefly the relevant findings of the Federal Court about hospital sales.

[78] As a matter of law if, as a result of actions of an infringer, a patentee or a person claiming under a patentee must reduce the sale price of a patented ware, a claim for damages may be advanced for price suppression (*AlliedSignal Inc. v. Du Pont Canada Inc.* (1998), 142 F.T.R. 241, 78 C.P.R. (3d) 129, at paragraph 23; aff'd. (1999), 235 N.R. 185, 86 C.P.R. (3d) 324, citing *Colonial Fastener Co. v. Lightning Fastener Co.*, [1937] S.C.R. 36 at page 47). As explained above, the Federal Court accepted Janssen's evidence that it was required to reduce its prices to hospitals by [redacted] when Teva entered the market with its infringing product, and could not later raise its prices after Teva was restrained from selling its infringing product (reasons, paragraph 117).

[79] The evidence before the Federal Court showed that hospitals may acquire drugs directly from a drug company (in this case Janssen) or indirectly from retailers or wholesalers. The Federal Court found that hospitals are demanding about the prices they pay; they generally require drug companies to discount their selling prices. It followed, and the Court accepted, that the higher the volume of sales made indirectly to hospitals, the higher Janssen's profit margin would be; this was so because tablets sold indirectly were tablets Janssen had sold to retailers or wholesalers at a higher price (reasons, paragraph 125).

[80] On the evidence before it the Federal Court found that the competing experts Drs. Rosenblatt and Grootendorst "agreed that there was no precise way in which to determine the percentage of indirect sales to hospitals." Dr. Rosenblatt calculated a figure of [redacted] while Dr. Grootendorst calculated a figure of [redacted] (reasons, paragraph 126).

[81] The Federal Court preferred the opinion of Dr. Rosenblatt who "explained and justified his selection of [redacted]" and his view was said to be substantiated by the testimony of Mr. Stewart and by discovery read-ins (reasons, paragraph 127). By contrast, in cross-examination Dr. Grootendorst "agreed that he was given this [redacted] figure by Counsel for Teva and that his own calculations, at least for the year 2004, would yield a figure of about [redacted]" (reasons, paragraph 128).

[82] Faced with counsel for Janssen's concession in final argument that "the figure of [redacted] was high estimate" the Federal Court stated that it applied the "broad axe" approach. Noting that the median between [redacted] and [redacted] was [redacted], but further noting that based on Dr. Rosenblatt's approach a higher figure was more probable, the Court determined that "an appropriate figure to use" was [redacted] (reasons, paragraphs 129 to 131).

[83] Additionally, a patentee or a person claiming under a patentee is entitled to damages sustained after the patent has expired in respect of losses caused by the infringer's activities which occurred while the patent was in force. Noting that "[p]rescriptions would have to be filled, contracts complied with, and other existing obligations incurred during a period of price suppression when the patent was in force would have to be fulfilled" the Court found that hospital losses would terminate on June 30, 2010, about a year after the patent expired on June 23, 2009 (reasons, paragraphs 107 to 112). This conclusion was also said to result from the application of the "broad axe" principle because the record did not support the dates proffered by either Janssen's or Teva's respective experts. Unsurprisingly, the date proffered by Janssen's expert maximized its loss, while the date proffered by Teva's expert minimized the loss.

2. The asserted errors

[84] Again, Teva asserts a number of palpable and overriding errors of fact and errors of law on the part of the Federal Court when it determined Janssen's damages in respect to sales of Levaquin to hospitals. Broadly speaking, errors are alleged with respect to the Federal Court's finding that Janssen's indirect sales to hospitals in the "but for" world were [redacted] of the total sales in the real world, and with respect to the period in which the Court calculated Janssen's loss. More specifically, Teva asserts that the Federal Court:

a. made a palpable and overriding error of fact in finding that there was "no precise way" to determine the percentage of sales made indirectly to hospitals;

b. made a palpable and overriding error of fact in finding that the assumptions made by Dr. Rosenblatt to calculate indirect hospital sales were based on facts presented at trial while at the same time misapprehending the basis of Dr. Grootendorst's calculations;

c. erred in law in applying a "broad axe" to determine Janssen's indirect sales to hospitals; and,

d. erred in selecting the date on which damages resulting from lost sales to hospitals ceased.

[85] Again, for the following reasons, Teva has failed to persuade me that the Federal Court so erred.

(a) Was there a "precise way" to determine the percentage of sales made indirectly to hospitals?

[86] During oral argument of the appeal, counsel for Teva agreed that neither Dr. Rosenblatt nor Dr. Grootendorst possessed data that would permit a precise method of determining the percentage of indirect sales to hospitals. Teva argued, however, that on discovery Janssen's "fact witness testified that Janssen's Finance Department did have records of all of its hospital sales that could be used to determine the actual quantity of Levaquin sold to hospitals" (Teva's memorandum of fact and law, paragraph 67, referencing Exhibit 61). Teva also submitted that Janssen's accounting expert, Mr. Cohen, admitted in cross-examination that he could have looked at all the claims made to Janssen for sales to hospitals in order to calculate the actual indirect hospital sales made by Janssen, but he did not do so. It follows, says Teva, that once it was clear that Janssen had records that could have been used to quantify the sales, the Federal Court ought to have preferred Dr. Grootendorst's evidence.

[87] There are two answers to this submission in my view.

[88] The first answer is based on the evidentiary record. In cross-examination Mr. Cohen was asked whether he made any independent determination of the percentage of hospital sales that were indirect. He responded:

> A. That is correct. That is impossible to do. Although, I think Mr. Mak might have taken a shot at it by doing the calculation he did.
>
> Q. <u>You say it is impossible to determine the percentage of indirect hospital sales</u>?

> A. Yes, because Janssen doesn't keep specific records as to what the wholesaler did with the product. That was the issue, to try and determine the indirect.
>
> (underlining added)
>
> (Appeal Book, volume 2, tab 16, page 482, line 25 to page 483, line 5)

[89] This is an unequivocal statement that the records Teva says were not produced did not exist. Later, in the passages of his evidence relied upon by Teva, Mr. Cohen spoke of records Janssen did possess relating to certain credits paid to wholesalers who had sold Levaquin to hospitals, and then sought a price reduction from Janssen. When asked if those records could be used to calculate the actual quantity of units sold indirectly to hospitals Mr. Cohen responded:

> A. It may depending on the details that are there on the credits and if they are complete or not. Yes, if the information is on the credit slips or however they do it.
>
> (underlining added)
>
> (Appeal Book, volume 2, tab 16, page 486, lines 4-7)

[90] This evidence falls far short of establishing the existence of records that would allow a precise calculation of the totality of indirect sales.

[91] This is consistent with Mr. Cohen's reply expert report (Exhibit 9) where at paragraph 30(a), he stated "Janssen Canada, in its undertaking responses, indicated that, "*Janssen does not know how many [of its] sales to hospitals were through wholesalers"*." In support of this statement Mr. Cohen cited "Janssen Answers to Undertakings from Day 5 of Examination for Discovery of Mike Park, Item #634, Question 3163 (T-2175-04). Also refer to Mr. Park's

Examination for Discovery dated September 16, 2013 (Questions 433-434), September 17, 2013 (Question 640) and October 21, 2014 (Questions 3333-3337).”

[92] This position is also consistent with Janssen’s counsel’s statement during discovery that finance officials had advised that records of the sort Teva alleged did not exist. This exchange is captured in Teva’s Read-Ins (Exhibit 61, Appeal Book, volume 57, tab 87, page 22522).

[93] The evidence adduced by Janssen about the lack of records relating to hospital sales made by others is more cogent than that relied upon by Teva. In any event, the evidence Teva points to is insufficient to establish any palpable and overriding error in the Federal Court’s appreciation of the evidence.

[94] As to the second answer to Teva’s submission, this Court has not been pointed to any indication that Teva took issue with Janssen’s response to undertakings which denied the existence of records of indirect sales. Nor have we been pointed to any indication that Teva squarely raised the existence of missing or suppressed records before the trial judge. It is too late to raise this issue on appeal.

(b) The experts’ assumptions

[95] Leaving aside Teva’s submission, rejected above, that Janssen possessed documents that could be used to calculate the indirect sales of Levaquin to hospitals, Teva’s complaint with Dr. Rosenblatt’s methodology is that “he was asked to calculate the percentage in reverse by assuming a hospital tablet price given to him by Counsel and using third-party data.” Teva

asserts that Dr. Rosenblatt did not select the third-party data he used, and that he admitted that better third-party data could have been purchased to calculate indirect sales to hospitals (Teva's memorandum of fact and law, paragraph 69).

[96] Dr. Rosenblatt relied upon data provided by a division of IMS Health, an organization that provides information about the sales, utilization and promotion of "virtually all" pharmaceutical products globally to its main customers. The main customers of IMS are pharmaceutical companies, both research-based and generic, the finance and investment community, medical researchers and governments (expert report of Dr. Rosenblatt, Exhibit 5, at paragraph 6). Teva and Janssen obtained this data jointly and shared the cost of acquiring the data.

[97] Reading Dr. Rosenblatt's cross-examination on this issue fairly it is not clear that he acknowledged that better IMS data was actually available — he was told it was not available. Moreover, he testified as to the steps he took to verify the reasonableness of his methodology and the results it produced (Appeal Book, volume 1, tab 15, page 386, line 11 to page 387, line 11).

[98] Given Teva's participation in obtaining the data utilized by Dr. Rosenblatt, Dr. Rosenblatt's evidence as to how he verified the reliability of his methodology and Teva's failure to demonstrate that any additional data was available and that it would have materially impacted Dr. Rosenblatt's calculation, no palpable and overriding error has been demonstrated on the part of the Federal Court in accepting Dr. Rosenblatt's evidence.

[99] Teva complains that the Federal Court also erred by misapprehending Dr. Grootendorst's cross-examination so that it concluded, erroneously, that the percentage of indirect hospital sales applied by Dr. Grootendorst in his report was provided to him by counsel for Teva.

[100] Dr. Grootendorst's expert report, Exhibit 52, recites in Table 12 the number of retail and hospital 500 mg units of Levaquin sold by Janssen from 2000 to 2004. Footnote 43 to his report discloses the source of the data. Footnote 43 states:

> I was provided with the data in Tables 12-14 by Aitken Klee LLP [counsel for Teva]. I calculated the percentages shown in the bottom row.
>
> (Appeal Book, volume 47, tab 78, at page 18018)

[101] On cross-examination Dr. Grootendorst agreed that for his calculation of hospital sales he used data provided by counsel for Teva (Appeal Book, volume 3, tab 21, page 1298 lines 4-7).

[102] While the percentage Dr. Grootendorst calculated was his own, that percentage resulted from Dr. Grootendorst's application of basic, elementary school mathematics to data provided by counsel for Teva.

[103] Teva has shown no material flaw in the Federal Court's understanding of the evidence.

(c) The application of the "broad axe"

[104] Next, Teva complains that the Federal Court failed to follow a principled approach in assessing damages; a judge is not permitted to simply average the numbers in competing expert reports as the Federal Court is alleged by Teva to have done in this case.

[105] Again, Teva has not persuaded me that the Federal Court erred. The Federal Court concluded that "Dr. Rosenblatt explained and justified his selection of [redacted] in his Report" (reasons, paragraph 127). However, in closing argument counsel for Janssen agreed that the figure of [redacted] was a "high estimate".

[106] A court may accept or reject an expert's opinion as it sees fit (*R. v. Abbey*, [1982] 2 S.C.R. 24 at page 43). In the particular circumstances of this case, Teva has not established any palpable and overriding error of fact or extricable error of law in the Federal Court's discount of Dr. Rosenblatt's calculation of the percentage of indirect sales to hospitals based on counsel's concession.

(d) The date on which damages on lost sales to hospitals ceased

[107] As explained above, damages may continue to accrue after the expiration of a patent if the loss flows from the actions of an infringer committed while the patent was in force. Teva argues, however, that the Federal Court erred by selecting June 30, 2010, as the end date for hospital damages. It argues that once the Court found "no reasonable basis" to support either Janssen's claim to damages up to December, 2010, or Teva's proffered dates based on the expiry of the patent or a few months thereafter, it was not open to the Court to arbitrarily choose June 30, 2010 as the end date, particularly when this date was based on contracts or obligations not established in evidence.

[108] Paragraph 110 of the Court's reasons contains the passage that gives rise to this argument:

> In this case, it would be reasonable to presume that some time would extend beyond the date that the patent expired. Prescriptions would have to be filled, contracts complied with, and other existing obligations incurred during a period of price suppression when the patent was in force would have to be fulfilled.

[109] The Federal Court, without further analysis, then went on to find that losses due to prescription (retail) sales would end about two months after the patent expired, while losses based on sales to hospitals would terminate about a year after the patent expired.

[110] It is the phrase "existing obligations incurred during a period of price suppression when the patent was in force would have to be fulfilled" that is relevant to the end date of hospital losses.

[111] As set out in detail above at paragraph 72, Mr. Stewart testified, and the Federal Court accepted, that once Janssen was required to reduce its prices to hospitals by [redacted] it could not later reverse that price reduction. This loss, which occurred while the patent was in force, was therefore in effect a permanent loss that will continue for so long as Janssen sells Levaquin to hospitals. At the time of the trial, Levaquin remained on hospital formularies (cross-examination Dr. Simor, Appeal Book, volume 4, tab 23, page 1468, line 1 to page 1469, line 5).

[112] In this circumstance, I see no reviewable error in the Federal Court effectively cutting off such future loss in the "but for" world one year following the expiry of the patent.

D. Did the Federal Court err by finding that Janssen US was a person claiming under the patentee in Canada?

[113] As explained above, the Federal Court concluded that Janssen US was a person claiming under the patentee because it had "the license or permission, by acquiescence, of Daiichi, to be involved in the chain of the sale of tablets made in Puerto Rico by Janssen Puerto Rico, through Janssen US to Janssen Canada." (reasons, paragraph 61).

1. The asserted errors

[114] Teva asserts that the Federal Court erred:

a. In law in its interpretation of the jurisprudence that has considered subsection 55(1) of the *Patent Act*. Properly interpreted, this jurisprudence is said to require a claimant to demonstrate that it acquired rights to engage in what would otherwise amount to infringing conduct. As Janssen US failed to demonstrate that it had acquired title to, or ownership of, the tablets sold in Canada it failed to demonstrate that it engaged in conduct which would amount to infringement. It followed that the Federal Court erred in finding Janssen US to be a person claiming under the patentee.

b. In law and in fact by finding that Janssen US had the permission of Daiichi to be involved in the Levaquin supply chain. Teva asserts that to reach this conclusion the Federal Court reversed the burden of proof. As a matter of fact, Teva asserts that Janssen US failed to demonstrate that it had a license or permission from Daiichi to exploit the 080 Patent.

[115] For the reasons that follow, Teva has failed to establish any reviewable error on the part of the Federal Court.

2. The interpretation of subsection 55(1) of the *Patent Act*

[116] Subsection 55(1) of the *Patent Act* provides:

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.
(underlining added)	(soulignement ajouté)

[117] In *Armstrong Cork Canada Ltd. v. Domco Industries Ltd.*, [1982] 1 S.C.R. 907, the Supreme Court interpreted the phrase "persons claiming under the patentee" to include both exclusive and nonexclusive licensees. At page 919 the Court held: "[i]t is the infringement of the patent which gives rise to a liability. If that infringement causes damage to the patentee or to any person claiming under him, the infringer must compensate for the damage sustained by reason of the infringement of the patent. A licensee relying on this subsection is not claiming against the infringer for infringement of his rights under the licence, he is claiming for the damage he has sustained in consequence of the infringement of the patent."

[118] In *Signalisation de Montréal Inc. v. Services de Béton Universels Ltée*, [1993] 1 F.C. 341, 147 N.R. 241 this Court stated that the purpose of subsection 55(1) is to discourage patent infringement and to provide redress to those who have a right which may be traced back to the

patentee and who suffer a wrong as a result of the infringement (decision, page 369). A person claiming under the patentee is (decision, pages 356-357):

> … a person who derives his rights to use the patented invention, at whatever degree, from the patentee …. When a breach of that right is asserted by a person who can trace his title in a direct line back to the patentee that person is "claiming under" the patentee. It matters not by what technical means the acquisition of the right to use may have taken place. It may be a straightforward assignment or a license. It may, as I have indicated, be a sale of an article embodying the invention. It may also be a lease thereof. What matters is that the claimant asserts a right in the monopoly and that the source of that right may be traced back to the patentee.
>
> (underlining added)

[119] Courts have interpreted the phrase "persons claiming under the patentee" broadly (see, for example, *Apotex Inc. v. Wellcome Foundation Ltd.*, [1998] F.C.J. No. 382, 145 F.T.R. 161, at paragraph 360).

[120] In the present case, at paragraph 43 of its reasons, the Federal Court concluded that for the Court to find that a party is a "person claiming under the patentee":

- the person must be one who, as a user, an assignee, a licensee or lessee has a title or a right that can be traced back to the patentee (*Signalisation*);
- it does not matter whether a licensee is exclusive or non-exclusive (*Domco*);
- the licence must be proved but it need not exist in writing (*Jay-Lor*);
- the claim must be one in respect of a use in Canada and not elsewhere in the corporate chain (*Servier*).

[121] Teva has not shown any error in this articulation of the law.

[122] Teva relies heavily upon the decision of the Federal Court in *Laboratoires Servier, Adir, Oril Industries, Servier Canada Inc. v. Apotex Inc.*, 2008 FC 825, 67 C.P.R. (4th) 241 to argue that Janssen was required to demonstrate that it had actual ownership of the tablets in Canada or that it otherwise engaged in conduct which would amount to infringement in Canada.

[123] In my view, the Federal Court correctly distinguished *Servier*. In *Servier* the Federal Court found, at paragraph 81, that none of the foreign plaintiffs manufactured, offered for sale or imported any of the compounds claimed in the patent at issue into Canada. There was, therefore, no basis for finding that the foreign plaintiffs were affected by the infringement of the Canadian patent or that they suffered any loss as a result of its infringement. Instead, each affiliate promoted, marketed and registered the product in its specific jurisdiction.

[124] In contrast, in the present case the Federal Court found at paragraph 54 that:

> Exhibit P38 shows that Johnson & Johnson [J&J] is the parent company of Janssen Puerto Rico, Janssen U.S. and Janssen Canada. It shows that Daiichi supplies levofloxacin to Janssen Puerto Rico who manufactures finished levofloxacin tablets in Puerto Rico (Gurabo), and ships them directly to Janssen Canada. <u>However, the paperwork flow showing the sales transactions is one wherein Janssen Puerto Rico sells these tablets to Janssen U.S. who then sells them to Janssen Canada. The price at which Janssen U.S. sells to Janssen Canada is sometimes referred to as the transfer price. Janssen US's claim for damages is based on alleged loss of sales to Janssen Canada at the transfer price</u> less costs such as payments to Janssen Puerto Rico for the product and other expenses.
>
> (underlining added)

[125] It follows from these findings that once infringing sales of Novo-levofloxacin supplanted sales of Levaquin by Janssen Canada, that Janssen US also suffered loss. None of the *Servier* foreign plaintiffs were similarly harmed.

[126] Finally, to conclude on this point, I reject Teva's submission that Janssen US was required to demonstrate that it engaged in conduct in Canada that would otherwise amount to infringement.

[127] As explained above, the purpose of subsection 55(1) of the *Patent Act* is to provide redress to those who have a right which may be traced back to a patentee and who suffer damage as a result of infringement of the patent. A party need only establish that they enjoy rights under a patent in order to be a person claiming under the patentee.

[128] It follows that Janssen US was not required to demonstrate that it held title in Canada to the Levaquin tablets it sold to Janssen Canada.

3. Permission from the patentee Daiichi

[129] I begin my analysis of this issue by rejecting the notion that the Federal Court erred in law by reversing the burden of proof, so as to require Teva to prove the lack of a license between Daiichi and Janssen US. At paragraph 61 of its reasons the Federal Court found that "Janssen US has proven to my satisfaction that it has the licence or permission, by acquiescence, of Daiichi, to be involved in the chain of the sale of tablets". This passage reflects a proper application of the burden of proof.

[130] I now turn to whether this finding of fact is tainted by any error.

[131] As the Federal Court explained at paragraph 45 of its reasons, Daiichi entered into a written license agreement with Johnson & Johnson which permitted Johnson & Johnson to manufacture finished products containing levofloxacin and to sell such products in Canada. Article 2.3 of the license agreement (set out in full at paragraph 45 of the decision of the Federal Court) also granted Johnson & Johnson the right to grant sublicenses to its subsidiaries. However, Johnson & Johnson was required to "obtain DAIICHI's prior written consent on the contents of such sublicense agreement". No evidence of Daiichi's written consent to the grant of a sublicense to Janssen US was adduced at trial.

[132] Teva therefore argues that the Federal Court erred in concluding that Daiichi acquiesced in Janssen US's involvement in the Levaquin supply chain. It also argues that to reach this erroneous conclusion the Federal Court erred by accepting an affidavit that was based on hearsay and by drawing an impermissible inference from the absence of any objection by Daiichi to Janssen US's claim for standing.

[133] I will deal first with the last two points: the arguments about hearsay and an unfounded inference.

[134] With respect to the objection to the affidavit of Mr. Lim, at paragraph 51 the Federal Court noted that the affidavit was "largely hearsay and of little assistance". The Court therefore attached "little weight" to the affidavit. Evidence of "little assistance" given "little weight" is not the stuff of palpable and overriding error. When the reasons of the Federal Court are read fairly, particularly the evidence referred to by the Court at paragraphs 48 through 50 of its reasons, the

Lim affidavit was not material to the Court's conclusion that Daiichi acquiesced in Janssen US's involvement in the sale of Levaquin in Canada.

[135] As to the alleged inference, the passage Teva complains of is contained in paragraph 66 of the reasons of the Federal Court. There, the Federal Court distinguished the facts of this case from the facts of another case. Daiichi's lack of objection did not play a part in the Court's conclusion that Daiichi knew of, and acquiesced in, Janssen US's involvement.

[136] What was material to the Court's analysis was the exchange of emails quoted at length at paragraphs 48 and 49 of its reasons, and the evidence of Mr. Smith that, in the words of the Federal Court, employees of the Johnson & Johnson organization "had frequent meetings and communications with Daiichi in Japan and the United States, and that Daiichi was well aware as to how the [Johnson & Johnson] organization was making and selling levofloxacin finished products through one or more of its related companies." (reasons, paragraph 50).

[137] This evidence amply supports the factual finding of the Federal Court. No palpable and overriding error has been shown.

[138] As I have found that the Federal Court did not err by finding that Janssen US was a person claiming under the patentee, it is necessary to consider the three errors asserted in respect of the award of damages to Janssen US.

E. Did the Federal Court err in quantifying Janssen US's damages?

1. The asserted errors

[139] Teva asserts that the Federal Court erred in quantifying Janssen US's damages. The specific errors are said to be:

a. awarding permanent lost market share damages to Janssen US;

b. failing to apply a one-month delay or lag to the commencement of Janssen US's damages; and,

c. failing to deduct a royalty payment that was contractually required to be paid.

(a) Lost market share

[140] In its second amended statement of defence Teva pleaded that any claim brought by Janssen US was statute barred in respect of any infringement that occurred prior to December 19, 2005. At trial, Janssen US accepted this (reasons, paragraph 74(2)). Teva argues that because the Federal Court awarded damages to Janssen US on the basis of Scenario A, Janssen US was awarded the same permanent lost market share as Janssen Canada. This is said to be in error because the Federal Court failed to address causation or to find the facts required to support a causal link between Teva's presence in the market as of December 19, 2005 and Janssen US's permanent loss of market share.

[141] I see no error in the analysis of the Federal Court.

[142] Janssen US's damages were based upon its lost profits on the lost sales of Levaquin that, but for Teva's infringement, would have been necessary for Janssen US to supply Levaquin to Janssen Canada to fill Janssen Canada's lost sales from December 19, 2005 onward (expert report of Mr. Cohen, Exhibit 7, Appeal Book, volume 15, tab 33, at paragraph 31).

[143] It follows that Janssen US's damages were necessarily caused by Teva's infringing sales of Novo-levofloxacin.

(b) Additional one-month delay

[144] As described above, all of the Levaquin sold in Canada was manufactured in Puerto Rico and shipped directly to Canada where it was warehoused before being shipped by Janssen Canada to wholesalers, pharmacies and hospitals. The experts agreed that in the "but for" world three months would elapse from the time Janssen Canada ordered Levaquin to the time it was delivered in Canada. It followed that Janssen US's damages began to accrue three months after December 19, 2005.

[145] Teva's expert opined that an additional time lag beyond the three months was required in order to account for the shipment of Levaquin from the warehouse to the wholesaler, pharmacy or hospital.

[146] The Federal Court rejected this argument at paragraphs 114 and 115 of its decision:

> Janssen's expert, Cohen, agrees that there is a lag when you follow the product, but says that prescription sales are a good surrogate for *ex-factory* sales because they match closely (see Chart 1 on page 11 of his Reply report, Exhibit P9). Even

> though the same physical tablet is not being sold immediately from the factory to the patient, the numbers match well enough that they can be used for economic modeling. Cohen says there is therefore no need to build this lag into the model even when TRx data is used.
>
> I am persuaded by Cohen's analysis for to say otherwise would be to create a one month window in the middle of Janssen's exclusivity period where they effectively have no sales. Further, because the TRx data matches *ex-factory* sales closely, it is a reasonable surrogate for the "broad axe" approach.
>
> (underlining added)

[147] Teva now argues that the time lag applies to Janssen US. It asserts that no party argued that the additional one-month lag would create a "window" in the middle of Janssen's period of exclusivity and that Janssen's expert, Mr. Cohen, agreed that in the real world a lag occurs between the time Janssen Canada sells Levaquin and a prescription is filled at a pharmacy. Thus, Teva submits that the Federal Court made a palpable and overriding error of fact by awarding damages "on the basis of a legal fiction, and a 'counterfactual' finding of fact" (Teva's memorandum of fact and law at paragraph 103).

[148] In his reply expert report (Exhibits 9 and 10) Mr. Cohen explained why the additional one-month delay proposed by Teva's expert, Mr. Mak, was unnecessary and how it shifted certain lost sales volumes to a time prior to Teva's market entry. At paragraphs 34, 37 and 38 of his report he wrote (omitting the charts referred to in these paragraphs):

> 34. We do not dispute that there is a delay from the time a unit is sold to the time when it is dispensed as a prescription. However, this delay does not translate into an overall 'lag' as the Mak Report identified. Ex-factory and TRx volumes are typically similar for participants in established markets and there is usually only a notable 'lag' in the TRx of participants when they are entering a market. The Mak Report's observations and measurement of TRx lag were based entirely on Teva's experience, which is different from the conditions that existed for Janssen and from the conditions that would have existed in the "but for" world

> (i.e., Teva entering the market as compared to Janssen which was already established in the market at the time).
>
> …
>
> 37. While ex-factory sales typically exceed TRx volumes following the launch of a new product, once a product is established in the market, ex-factory sales and TRx volumes will often be very similar with no ascertainable TRx lag, reflecting that respective levels of sales and prescriptions are more or less in balance with each other. As the following chart shows, Janssen's monthly ex-factory and TRx volumes for LEVAQUIN® were closely comparable in the years prior to infringement and remained consistent in terms of their respective quantities and erosion patterns following Teva's market entry in December 2004: …
>
> 38. In contrast, the following chart shows that if Janssen's monthly TRx volumes for the same period were time-shifted by four months, as suggested in the Mak Report, the resulting distribution shows virtually no correlation to the ex-factory sales pattern: …
>
> (underlining added)

[149] It was open to the Federal Court to accept this evidence and no palpable and overriding error has been demonstrated. Teva has not explained why a different result should pertain to Janssen US.

(c) Royalty payment

[150] Janssen-Ortho LLC (Janssen Puerto Rico) was a party to a sublicense with Johnson & Johnson which required Janssen Puerto Rico to pay a royalty to Johnson & Johnson in respect of all Levaquin produced in Puerto Rico for sale in Canada. In the real world, Janssen Puerto Rico did not make the royalty payments until 2010, and then the payments were not made to Johnson & Johnson. Rather, they were paid to a subsidiary of Johnson & Johnson.

[151] The Federal Court declined to debit royalty payments in the "but for" world until 2010 on the basis that these royalties were not paid in the real world (reasons, paragraph 132). Teva argues that the Federal Court erred in law by ignoring the contractual provision that required Janssen Puerto Rico to pay royalties for Levaquin sales.

[152] In my view, it was open to the Federal Court to infer that conduct in the real world was probative of conduct which would have occurred in the "but for" world. Teva has failed to demonstrate that Janssen Puerto Rico would have acted differently in the "but for" world. The Federal Court did not err as alleged.

F. Did the Federal Court err by awarding an excessive amount for costs?

[153] Teva does not assert any error in the Federal Court's decision to award costs on a lump sum basis. Nor does it submit that the $1 million lump sum award is in and of itself excessive. Instead, Teva asserts that the award is excessive when compared to the amount an assessment officer would have awarded had the Janssen plaintiffs elected to have their costs assessed.

[154] The Federal Court possesses "full discretionary power over the amount and allocation of costs" (Rule 400(1) of the *Federal Courts Rules*).

[155] The Supreme Court has affirmed that "costs awards are quintessentially discretionary" and that they should only be set aside if the court below "has made an error in principle or if the costs award is plainly wrong" (*Sun Indalex Finance, LLC v. United Steelworkers*, 2013 SCC 6, [2013] 1 S.C.R. 271, at paragraph 247).

[156] Teva has not pointed to any authority to support the premise of its argument that a lump sum award must necessarily correspond to the amount an assessment officer would assess. To the contrary, in *Apotex Inc. v. Merck & Co.*, 2005 FCA 23, [2005] F.C.J. No. 65, this Court held that an amount awarded as a lump sum would not necessarily correspond with an amount assessed by an assessment officer.

[157] The Federal Court's award of costs followed a trial that lasted ten days. The trial raised a number of issues, many of which were complex issues. The trial resulted in judgments totaling in excess of $18.8 million. Teva has failed to demonstrate any error in principle or that the award is plainly wrong.

VIII. Conclusion and costs

[158] For the above reasons I have found all of the issues raised by Teva to be without merit. It follows that I would dismiss each appeal with one set of costs.

[159] As for the quantum of the costs, if not agreed I would direct that the costs be assessed at the top of Column IV of the table to Tariff B. While Rule 407 provides that unless otherwise ordered, costs are to be assessed in accordance with Column III, this award reflects the number of issues, some of dubious merit, that Teva chose to put in play and keep in play after receiving Janssen's responding memorandum of fact and law. The award also reflects the fact that Teva succeeded on none of the many issues and sub-issues it required Janssen to respond to.

[160] Finally, these reasons are being released on a confidential basis to allow the parties to make submissions as to what confidential information must be redacted from the reasons before they are released publicly. Counsel's attention is particularly drawn to paragraphs 22, 64, 78, 80, 81, 82, 84, 105, and 111. Such submissions should be served and filed within seven days of the date of these reasons.

"Eleanor R. Dawson"
J.A.

"I agree.
Wyman W. Webb J.A."

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

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-244-16
STYLE OF CAUSE:	TEVA CANADA LIMITED v. JANSSEN INC. and DAIICHI SANKYO COMPANY, LIMITED
AND DOCKET:	A-274-16
STYLE OF CAUSE:	TEVA CANADA LIMITED v. JANSSEN-ORTHO LLC, JANSSEN PHARMACEUTICALS, INC., OMJ PHARMACEUTICALS, INC. and DAIICHI SANKYO COMPANY, LIMITED
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	NOVEMBER 28, 2017
REASONS FOR JUDGMENT BY:	DAWSON J.A.
CONCURRED IN BY:	WEBB J.A. GLEASON J.A.
DATED:	FEBRUARY 8, 2018

APPEARANCES:

Marcus Klee Jonathan Giraldi	FOR THE APPELLANT
Peter Wilcox Stephanie Anderson Benjamin Reingold	FOR THE RESPONDENTS JANSSEN INC. JANSSEN PHARMACEUTICALS INC.

SOLICITORS OF RECORD:

Aitken Klee LLP Ottawa, Ontario	FOR THE APPELLANT
Belmore Neidrauer LLP Toronto, Ontario	FOR THE RESPONDENTS JANSSEN INC. JANSSEN PHARMACEUTICALS INC.