Federal Court of Appeal | Cour d'appel fédérale

Date: 20150723

Docket: A-242-13

Citation: 2015 FCA 171

CORAM: **DAWSON J.A.**
STRATAS J.A.
BOIVIN J.A.

BETWEEN:

APOTEX INC. and
APOTEX FERMENTATION INC.

Appellants

and

MERCK & CO., INC. and
MERCK CANADA INC.

Respondents

Heard at Toronto, Ontario, on January 14 and 15, 2015.

Judgment delivered at Ottawa, Ontario, on July 23, 2015.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: STRATAS J.A.
BOIVIN J.A.

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] The principal issue raised on this appeal is whether, when calculating damages for patent infringement, it is relevant to consider the availability of non-infringing alternative products available to the infringer. For the reasons that follow I have concluded that, as a matter of law, the availability of a non-infringing alternative is a relevant consideration. The issue arises in the following context: Apotex has been found liable for patent infringement. On the issue of remedy,

Apotex submits that the damages it is liable for should be reduced because it had available a non-infringing product that it could and would have used. On the evidentiary record before us, I disagree. Therefore, I would dismiss the appeal with costs.

I. Factual Background

[2] Merck & Co. Inc. (Merck & Co.) is the named patentee of Canadian Patent No. 1,161,380. The patent is a product-by-process patent for the anti-cholesterol drug lovastatin (AFI-1 process). The patent issued to Merck & Co. in 1984 and expired on January 31, 2001. Merck Canada Inc. (Merck Canada) or its corporate predecessor has sold lovastatin in Canada under the trade name MEVACOR since 1988 under licence from Merck & Co.

[3] Merck & Co. and Merck Canada are collectively referred to as Merck or the respondents in these reasons.

[4] In 1993, Apotex Inc. applied to the Minister of Health for a notice of compliance that would enable it to market a generic version of lovastatin in Canada. Apotex alleged it would not infringe the patent because it would use a process to produce lovastatin that would not fall within the scope of the patent (AFI-4 process).

[5] A notice of compliance was issued to Apotex on March 27, 1997.

[6] In 1997, Merck commenced an action against Apotex Inc. and Apotex Fermentation Inc. (AFI) (together the appellants or Apotex) alleging infringement of the patent. After a lengthy

trial, a judge of the Federal Court found that the patent was valid and had been infringed (2010 FC 1265).

[7] Specifically, the Judge found the patent to have been infringed in two respects. First, the Judge found that one batch of lovastatin manufactured in or around November 1996 by AFI in Winnipeg (batch CR0157) was prepared using the patented process. Second, in 1997 Apotex transferred production of lovastatin from AFI in Winnipeg to Qingyuan Blue Treasure Pharmaceutical Co. Ltd. (Blue Treasure), a Chinese joint venture company in which AFI held a 42.5% share. The transfer of the AFI-4 process and technology to Blue Treasure was made on the basis that the lovastatin purchased from it by Apotex would be produced exclusively with the AFI-4 process. Notwithstanding, the Judge found that after March 1998 and continuing until around March 2000, 294 batches of lovastatin were produced by Blue Treasure using the patented process.

[8] The Judge characterized this infringement to be significant. Approximately 60% of Apotex' sales made between March 1997 and the expiry of the patent were sales of infringing lovastatin. On a volume basis, approximate 71% of the total amount of bulk lovastatin supplied to Apotex Inc. by AFI (either directly or through Blue Treasure) was infringing material.

[9] The Judge also found that the respondents were entitled to compensatory damages rather than an accounting of profits.

[10] Following the exhaustion of all rights of appeal relating to the liability phase, the Judge embarked on a lengthy inquiry into the quantification of Merck's damages.

[11] Briefly stated, for reasons cited as 2013 FC 751, the Judge found that Merck was entitled to a total damages award of $119,054,327, plus pre-judgment and post-judgment interest. The damages were comprised of:

i) $62,925,126 as lost profits of Merck Canada in respect of pre-expiry replacement sales (as defined in the reasons of the Federal Court);
ii) $51,290,364 as lost profits of Merck & Co. in respect of pre-expiry replacement sales;
iii) $2,696,963 based on a reasonable royalty calculation, for post-expiry infringing domestic sales; and
iv) $2,141,874 based on a reasonable royalty calculation, for infringing export sales.

[12] These damages were calculated on the basis that the Judge rejected the argument advanced by Apotex and AFI that the availability of non-infringing lovastatin should be taken into account in assessing damages.

II. The Issues

[13] In their memorandum of fact and law the appellants asserted that the Judge committed a number of reviewable legal errors, including awarding pre-judgment interest at a rate greater than the Bank Rate. At the hearing of the appeal the appellants advised that they would not pursue the argument that the Judge erred by awarding pre-judgment interest based on an augmented Bank Rate. The remaining issues continue to be live.

[14] As set out above, I have concluded that the Judge erred by rejecting the legal relevance of the non-infringing alternative when computing the compensatory patent infringement damages. However, recognizing the legal relevance of the non-infringing alternative process by itself does not assist the appellants. An additional issue must be determined on the evidence: has Apotex made out its case as a matter of fact?

[15] Thus, I would state the issues to be:

i) Did the Judge err in law by rejecting the legal relevance of non-infringing lovastatin when computing damages for patent infringement?

ii) If the Judge so erred, has Apotex made out its case based upon the existence of non-infringing lovastatin?

iii) Did the Judge err in assessing the royalty rate applicable to pre-expiry infringing sales?

iv) Did the Judge err in assessing the royalty rate applicable to post-expiry infringing sales?

v) Did the Judge err by determining that Merck & Co. had standing to bring a claim for damages by virtue of its exclusive licence agreement with Merck Canada?

III. The Standard of Review

[16] 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.

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

IV. The Decision of the Federal Court

A. *The relevance of non-infringing alternatives*

[18] The Judge dealt with this issue at paragraphs 26 through 121 of her reasons. She began her analysis by briefly setting out the respective positions of the parties.

[19] Merck Canada claimed lost profits in respect of the MEVACOR tablets it would have sold domestically to replace every infringing Apo-lovastatin tablet sold domestically prior to the patent's expiry. The Judge defined these tablets and sales to be the pre-expiry replacement tablets or sales (reasons at paragraph 11).

[20] The appellants countered by submitting that, except for the tablets that formed part of infringing batch CR0157 prepared in Winnipeg, Merck Canada should only be entitled to a reasonable royalty because it could not show that its damage was sustained "by reason of the infringement" as required by subsection 55(1) of the *Patent Act*, R.S.C. 1985, c. P-4 (Act) (reasons at paragraph 32).

[21] This submission was premised on the basis that, commencing in March 1997, as a result of its AFI-4 process Apotex had available a non-infringing alternative. Apotex submitted that the "but for" causation test should take into account that from the day it received its notice of

compliance it had the regulatory approval, capacity and capability to produce all pre-expiry replacement tablets sold in Canada. It followed, in Apotex' submission, that Merck Canada had not demonstrated that its loss was caused by the wrongful use of its AFI-1 process by Apotex. It further followed that Merck Canada's loss should be limited to a reasonable royalty on all pre-expiry replacement sales.

[22] Merck responded that Canadian law did not recognize the relevance of non-infringing alternatives.

[23] Having framed the competing positions, the Judge reviewed the general principles applicable to the assessment of damages under subsection 55(1) of the *Act* (reasons at paragraph 41).

[24] The Judge then considered the compensatory principle of damages and the burden on Merck Canada to show that, but for the infringement, it would have made the sales in question (reasons at paragraph 42).

[25] She rejected the appellants' submission that Merck could not prove that Merck Canada would have sold the pre-expiry replacement tablets in the "but for scenario" because Apotex had access to a non-infringing alternative. In her view, if the appellants had not infringed the patent, Merck Canada would have sold every pre-expiry replacement tablet (reasons at paragraph 56).

[26] The Judge gave four reasons for her conclusion:

i) Causation was adequately considered when she concluded that Merck's lost sales were not recoverable when Apotex used the non-infringing AFI-4 process (reasons at paragraph 52).

ii) The appellants' argument conflated causation with the subsequent quantification of damages (reasons at paragraph 53).

iii) Causation in the context of tort law is directed to the original position of the plaintiff. Therefore, Apotex' own hypothetical action was irrelevant (reasons at paragraph 54).

iv) The Judge distinguished *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142, 167 D.L.R. (4th) 577 relied upon by Apotex. In her view, the case concerned a breach of confidence and involved equitable principles that were not applicable in the context of damages for patent infringement (reasons at paragraph 55).

[27] The Judge then reviewed Canadian and British jurisprudence and concluded that the current state of Canadian law was that the existence of a non-infringing alternative was not relevant to an assessment of damages for patent infringement (reasons at paragraphs 57 to 76).

[28] The Judge went on to reject four arguments advanced by the appellants to support the submission that Canadian law concerning the relevance of non-infringing alternatives had changed or should change:

i) In her view, the Supreme Court of Canada did not alter the jurisprudence in *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902. At issue there was an accounting of profits. Nothing suggested the principles applicable to an accounting of

profits could or should be applied to the assessment of damages (reasons at paragraphs 77 to 82).

ii) While the Judge acknowledged the legal relevance of non-infringing alternatives in American jurisprudence, the American statutory provisions are very different from those of Canada and the United Kingdom (reasons at paragraphs 91 to 97).

iii) Academic writing by Professor Norman Siebrasse was not precedential. Professor Siebrasse merely wished Canadian law recognized the non-infringing alternatives defence. Further, he was acknowledged by Apotex to be the "lone voice in the wilderness" (reasons at paragraphs 98 to 106).

iv) Although non-infringing alternative-type arguments were recognized in the context of the calculation of damages under section 8 of the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133, the approach was not applicable to the calculation of damages under subsection 55(1) of the Act (reasons at paragraphs 107 to 112).

[29] Finally, at paragraphs 113 to 120 of her reasons, the Judge gave four policy reasons for rejecting the legal relevance of non-infringing alternatives:

i) a patentee would be inadequately compensated;

ii) the non-infringing alternative was already taken into account because Merck could not claim lost profits in respect of sales lost to non-infringing Apo-lovastatin;

iii) acknowledging the relevance of non-infringing alternatives would create an incentive to infringe; and

iv) acknowledging the relevance of non-infringing alternatives would be inconsistent with Canada's repeal of the compulsory licensing regime and Canada's international

obligations (specifically article 1709(10) of the *North American Free Trade Agreement* and article 31 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*).

B. *The calculation of a reasonable royalty for pre-expiry infringing sales*

[30] The Judge considered that, if she were wrong with respect to the relevance of the non-infringing alternatives, a reasonable royalty should be fixed for all lost domestic sales where Apotex could have competed without infringing the patent — the pre-expiry replacement tablets or sales.

[31] Without calculating a royalty amount, the Judge proposed a framework for the hypothetical negotiation of a lump sum royalty. Such royalty would be between the appellants' maximum willingness to pay (representing the maximum amount that would leave Apotex better off by taking a licence), and the respondents' minimum willingness to accept (below which Merck would not accept an amount for entry) (reasons at paragraphs 166 to 167).

[32] I have concluded that, while at law a non-infringing alternative is legally relevant, the appellants failed on the evidence to establish they could and would have pursued the non-infringing alternative. Therefore, it is not necessary to consider in any further detail the Judge's reasons on this alternate finding.

C. *The calculation of a reasonable royalty for post-expiry infringing sales*

[33] During the life of the patent, Apotex stockpiled infringing bulk lovastatin and then sold it in tablet form after the patent expired. The parties and the Judge agreed that the appropriate damages award would be based upon a reasonable royalty in respect of these sales (reasons at paragraphs 185 to 189).

[34] The Judge assessed a reasonable royalty based on the methodology advanced by Merck's expert. The royalty was calculated by taking the mid-point of the per kilogram cost savings to Apotex by using the infringing process, multiplied by the weight of the infringing lovastatin sold after the patent expired (reasons at paragraphs 191 and 199).

D. *Lost profits of Merck US*

[35] Merck US claimed damages for lost sales because Merck Canada was required to acquire its bulk lovastatin from it. Apotex argued Merck US was not entitled to any significant damages because in 1992 it entered into an exclusive licence agreement with Merck & Co. In Apotex' view, as a result Merck US was a nominal patentee with no right to "monetize" the patent.

[36] The Judge rejected this submission. In her view, granting an exclusive licence to use the invention did not confer any interest or property in the patent; granting an exclusive licence does not detract from the patentee's ability to claim its own damages if caused by the infringement (reasons at paragraphs 241 to 244).

[37] Having framed the issues and summarized the approach of the Federal Court to the issues, I turn to consideration of the issues.

V. Consideration of the Issues

A. *Did the Judge err in law by rejecting the legal relevance of non-infringing lovastatin when computing damages for patent infringement?*

[38] Patents are said to be creatures of statute (*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625, at paragraph 45 (Sildenafil); and, *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153, at paragraph 37 (AZT)). The statutory basis for a claim to damages as a result of patent infringement is subsection 55(1) of the Act:

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. [emphasis added]	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. [Je souligne.]

[39] The issue to be resolved on this appeal is whether the requirement that damages be sustained "by reason of the infringement" is, as the Judge found, in some way restricted so that a court is required to disregard legitimate competition from an infringer? In the alternative, is potential legitimate competition from the infringer a legally relevant consideration? This is a question of statutory interpretation subject to review on the correctness standard.

[40] To the extent that the text of subsection 55(1) may be seen to permit either interpretation, in my view any ambiguity is settled when the purpose and the statutory context of the provision are considered.

[41] The purpose of an award of damages is to compensate a patentee (or any entity claiming under the patentee) who has suffered loss as a result of patent infringement. The concept of compensation rejects both under-compensation and over-compensation.

[42] The Act as a whole is intended to advance research and development, and to encourage broader economic activity (*Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at paragraph 42). The Act coaxes inventive solutions to practical problems into the public domain through the promise of a limited monopoly for a limited period of time (AZT at paragraph 37). At the heart of this bargain with the inventor, and at the heart of the Act, is the concept of balance between the benefit conferred on the public through the disclosure of a new and useful invention, and the benefit conferred on the inventor through the grant of a monopoly. Thus, in the event of infringement, under-compensation of an inventor discourages research and development, and the disclosure of useful inventions. Equally, over-compensation of an inventor chills potential competition to the extent that a potential infringer is uncertain about the scope and validity of a patent. The balance at the heart of the Act requires perfect compensation.

[43] With this in mind, the inquiry must move to which possible interpretation of subsection 55(1) leads to perfect compensation? By requiring that damages for infringement

must arise “by reason of the infringement”, the Act invokes the principle of causation. Therefore, it is necessary to understand the role of causation in the quantification of compensatory damages.

[44] The Supreme Court has explained causation to be the expression of the relationship that must be found to exist between the wrongful conduct of the defendant, and the injury to the plaintiff which justifies the payment of compensation to the plaintiff by the defendant (*Snell v. Farrell*, [1990] 2 S.C.R. 311 at page 326, 72 D.L.R. (4th) 289). At page 328 of the Supreme Court Reports, the Supreme Court stated that causation need not be determined by scientific precision: it is “essentially a practical question of fact which can best be answered by ordinary common sense”.

[45] The legal test for establishing causation is the “but for” test. A plaintiff must show on a balance of probabilities that “but for” the defendant’s wrongful conduct, the plaintiff would not have suffered loss. This is a “factual inquiry” to be established on the evidence. The “but for” test for causation is to be applied in a “robust common sense fashion” (*Clements v. Clements*, 2012 SCC 32, [2012] 2 S.C.R. 181, at paragraphs 8 and 9).

[46] These principles are not controversial and were accepted by the Judge (reasons at paragraph 49). In applying these principles the Judge accepted that if the defendant could prove that a third-party competitor would have been able to capture some sales of lovastatin, the plaintiff would not be entitled to its lost profits, and instead would be limited to a reasonable royalty (reasons at paragraph 115).

[47] This said, the Judge refused to apply principles of causation to the actions of Apotex, dismissing "a fiction that the defendant could have used a non-infringing alternative (but did not)" and finding it not to be "punitive to compensate Merck for lost profits where the Defendants could have (but did not) use the non-infringing alternative" (reasons at paragraphs 115 and 116). As developed below, in my respectful view, the Judge erred in these passages in her application of the principles of causation. As well, in these passages the Judge erred by conflating the relevance of the non-infringing alternative with the availability of the non-infringing alternative in fact.

[48] The difficulty with the Judge's approach is that if damages for lost profits are calculated never having regard to an available non-infringing alternative, the patentee will sometimes be better off than it would have been in the absence of infringement. This is so for the following reason. Where a defendant can make and sell a non-infringing alternative, the patent does not confer a complete monopoly on the patent holder. Instead, the patent confers a share of market power upon the patentee. In this circumstance, where, instead of using a non-infringing alternative, a defendant infringes, it is a question of fact whether, "but for" the infringement, the defendant would not have competed with it. The defendant's lawful competition in the "but for" world may have deprived the patentee of some sales.

[49] Put another way, in cases where, in the "but for" world, the infringer could and would have made and sold a non-infringing alternative, these sales may well reduce the patent owner's sales. Awarding the patentee full damages for lost profits in every case will, therefore, sometimes over-compensate the patentee.

[50] Perfect compensation requires consideration of: (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.

[51] I find support for this analysis in American jurisprudence and in the decision of the Supreme Court in *Monsanto*.

[52] American jurisprudence tends to apply the "but for" test in a similar way. Under the American law for damages for patent infringement (35 U.S. Code § 284 (2011)), in order to recover lost profits a patent owner must show causation in fact, establishing that "but for" the infringement, the patentee would have made additional profits (*King Instruments Corp. v. Perego*, 65 F. 3d 941 at page 952 (Fed. Cir. 1995)). When a patent owner seeks to recover alleged lost profits on lost sales, the patentee has the initial burden to establish a reasonable probability that it would have made the alleged sales "but for" the infringement. Once the patentee establishes this, the burden shifts to the alleged infringer to establish that the patent owner's "but for" causation claim is unreasonable for some or all of the lost sales (*Rite-Hite Corp. v. Kelley Co. Inc.*, 56 F. 3d 1538 at pages 1544-1545 (Fed. Cir. 1995 (en banc)).

[53] The state of American jurisprudence is that if a non-infringing alternative which a defendant could and would have resorted, but for the infringement, is as good as the patented invention, and would have replaced all infringing sales, the infringement causes the patentee to suffer no damage.

[54] In *Grain Processing Corporation v. American Maize-Products Company*, 185 F.3d 1341 at pages 1350-1351 (Fed. Cir. 1999), Judge Rader (as he then was), writing for the Court, explained the two principal rationales for taking into account the availability of a non-infringing alternative.

[55] First, 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.

[56] Second, only by comparing the patented invention to non-infringing alternatives can a court discern the market value of the patent owner's exclusive right, and therefore his expected profit or reward. Judge Rader quoted with approval from John W. Schlicher, *Patent Law: Legal and Economic Principles* (New York: Thomson West, 1997) to the effect that "unless the law wishes to systemically overreward patented inventions, it is necessary to inquire about the nature and value of the product that the infringer could have made had he not infringed".

[57] Thus, American jurisprudence is clearly to the effect that the "but for" causation inquiry requires consideration of non-infringing alternatives. Otherwise, patentees may be over-compensated.

[58] Before considering *Monsanto*, by way of context I note that the ordinary monetary remedies available for patent infringement are damages and an accounting of profits. While the Act does not explicitly provide for an accounting of profits, it references this remedy in paragraph 57(1)(*b*) which allows a court, in an action for infringement, to make an order "for and respecting inspection or account". The jurisprudence makes clear that this remedy exists as an alternative to damages.

[59] In *Monsanto*, the patentee sued the defendant for patent infringement and sought an accounting of the defendant's profits. In its analysis of the remedy claim, citing *Lubrizol Corp. v. Imperial Oil Ltd.*, [1997] 2 F.C. 3 (C.A.), 71 C.P.R. (3d) 26, the Supreme Court noted that it was settled law that a patentee is only entitled to that portion of the infringer's profit that was causally attributable to the invention. The Court went on to explain that the preferred method of calculating an accounting of profits is the "differential profit" approach. This requires a comparison between the infringer's real world profit and what his profit would have been had he not infringed (*Monsanto* at paragraphs 101 to 105).

[60] The Judge correctly understood that *Monsanto* did not change the existing law as to how the patentee's lost profits are to be calculated. However, the significance of *Monsanto* is that if a court may consider a defendant's resort to a non-infringing alternative when calculating the

infringer's profit, there is no reason in principle to ignore such conduct when calculating the patentee's lost sales. This is particularly so where:

> The problem with computing lost profits without considering the availability of noninfringing alternatives is that […] this practice renders the patentee *better off* than she would have been in the absence of infringement. (Analogously, ignoring noninfringing substitutes when calculating defendant's profits renders defendants worse off than they would have been, but for the infringement.) [Emphasis in the original]

(Thomas F. Cotter, *Comparative Patent Remedies: A Legal and Economic Analysis* (New York: Oxford University Press 2013) at pages 189 to 190).

[61] Before leaving this issue I wish to deal with the Judge's reliance upon *The United Horse Shoe and Nail Company, Limited v. Stewart and Company* (1888), 5 R.P.C. 260 (H.L.), 13 App. Cas. 401, and the policy reasons the Judge found to support rejection of non-infringing alternatives.

[62] In *United Horse Shoe*, the House of Lords held that a non-infringing alternative is always irrelevant. This decision has been subsequently followed by courts in the United Kingdom and some Commonwealth jurisdictions.

[63] It is fair to say that the House of Lords rejected non-infringing alternatives for policy reasons. No Law Lord conducted a causation analysis, and the reasons of each Law Lord reflect the Court's opprobrium of the infringer's conduct. To illustrate, the Lord Chancellor wrote that "[e]very sale of goods manufactured, without licence, by patent machinery, is and must be treated as an illegal transaction in a question with the patentee" (*United Horse Shoe* at page 267).

[64] *United Horse Shoe* has a narrow foothold in Canadian law. Counsel were able to refer us to only two cases that have referred to the decision: *Domco Industries Ltd. v. Armstrong Cork Canada Ltd.et al.* (1983), 76 C.P.R. (2d) 70 at page 73 (Fed. Proth.), [1983] F.C.J. No. 1182, reversed on other grounds, (1986), 10 C.P.R. (3d) 53 (F.C.T.D.), 3 F.T.R. 289; and, *Jay-Lor International Inc. v. Penta Farm Systems Ltd.*, 2007 FC 358, 59 C.P.R. (4th) 228 at paragraph 116.

[65] *Domco* was a reference for the recovery of damages incurred as a result of patent infringement. The Prothonotary rejected the relevance of a non-infringing alternative. The Prothonotary did not provide any detailed analysis, stating the argument "is irrelevant in the light of what actually happened, and tends to obfuscate the main issue of the continued infringement by the defendant" (*Domco*, C.P.R. at page 91).

[66] On appeal, Justice Collier affirmed the rejection of the relevance of a non-infringing alternative. The Judge applied *United Horse Shoe* with little analysis.

[67] In *Jay-Lor* at paragraph 116, the Judge cited *United Horse Shoe* with approval in an *obiter* discussion of general principles.

[68] Neither of these decisions are binding on this Court, and I decline to follow them. In my view, they do not accord with the requirement in subsection 55(1) of the Act that the damages be sustained "by reason of the infringement".

[69] The Judge cited four, what she characterized to be “compelling”, policy reasons for rejecting the legal relevance of non-infringing alternatives (reasons at paragraphs 113 to 120). The first and second reasons were that a patentee would be inadequately compensated and, moreover, the availability of a non-infringing alternative was already taken into account in the liability phase of the trial, when the Judge found that some of Apotex’ lovastatin was made using the non-infringing process.

[70] In my view, these concerns do not withstand scrutiny. As explained above, taking into account a non-infringing alternative that could and would be available perfectly compensates a patentee. Determining which sales were non-infringing is not relevant to the assessment of the damage that resulted from the infringement.

[71] The third policy ground cited by the Judge for not taking a non-infringing alternative into account was that to do so would create an incentive to infringe. In my view, the availability of other remedies at law, such as elevated costs, injunctive relief for the remaining duration of the patent, an accounting of the infringer’s profits, and punitive damages (see, for example, *Eurocopter v. Bell Helicopter Textron Canada Limitée*, 2013 FCA 219, 449 N.R. 111) counterbalance any incentive to infringe.

[72] The final policy ground cited by the Judge was that legal recognition of non-infringing alternatives would violate Canada’s international obligation to eliminate compulsory licensing for patented pharmaceutical inventions. However, reasonable royalty damages are only equivalent to granting a compulsory licence if there is no non-infringing alternative. In such a

case, the infringer would obtain the full benefit of the invention without fully compensating a patentee who would not have willingly licenced the patent. However, where a non-infringing alternative exists, nothing prevents the infringer from using the non-infringing alternative and the patentee could not complain that legitimate competition from the infringer was akin to the infringer acquiring a compulsory licence. Restoring the patentee to this notional position is not equivalent to granting a compulsory licence. Moreover, following a finding of infringement, there will normally be a permanent injunction. The patentee is fully compensated for the infringement and further infringement is punishable by contempt of court.

B. *Has Apotex established the relevance of a non-infringing alternative based upon the existence of non-infringing lovastatin?*

[73] When considering the effect of legitimate competition from a defendant marketing a non-infringing alternative, a court is required to consider at least 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?

[74] As a matter of principle, the burden lies on the defendant to establish the factual relevance of a non-infringing alternative on a balance of probabilities. Indeed, Apotex

acknowledged in oral argument that it bears the persuasive burden, on a balance of probabilities, to prove that it would have used the non-infringing alternative. This is consistent with jurisprudence such as *Rainbow Industrial Caterers Ltd. v. Canadian National Railway Co.*, [1991] 3 S.C.R. 3, 84 D.L.R. (4th) 291.

[75] Before turning to consider the state of the evidence, it is necessary to deal with the Judge's findings, at paragraphs 34 to 37 of her reasons, that:

- It was more likely than not that the defendants would have made and sold non-infringing Apo-lovastatin tablets in place of the infringing tablets.
- Apotex' non-infringing alternative was available in fact.

[76] These findings were made solely on the basis of one paragraph of an agreement in writing made between the parties prior to the trial, which the Judge referred to as the "Streamlining Agreement". At paragraph 19, the parties agreed that:

> 19. The Defendants had the resources and capacity to manufacture and sell non-infringing lovastatin tablets formulated using lovastatin API made using the AFI-4 process at the AFI plant in Winnipeg in sufficient quantities to meet market demand for lovastatin tablets upon receipt of Apotex's NOC on March 26, 1997 and at all times thereafter through actual amounts of lovastatin API made at AFI's Winnipeg Facility and amounts delivered to AFI by Qingyuan Blue Treasure Pharmaceuticals Co. Ltd., as found at the liability trial, and through replacing all infringing sales of Apo-lovastatin tablets under any of the following four scenarios:
>
> […]
>
> For greater certainty, this agreement does not affect or limit the Plaintiffs from arguing or leading evidence that uncertainty existed regarding the ability of the Defendants to meet the market demand for lovastatin with non-infringing lovastatin tablets formulated using lovastatin API made using the AFI-4 process at the AFI plant in Winnipeg.

[77] I agree with the Judge that the parties agreed that from the time Apotex received its notice of compliance, and at all relevant times thereafter, the defendants had the capacity to manufacture and sell non-infringing lovastatin in sufficient quantities. However, as Apotex conceded in oral argument, the Streamlining Agreement did not address the question of what would have happened in the "but for" world. The Judge erred by jumping from a statement as to manufacturing capacity to conclusions as to what Apotex could and would do in the "but for" world.

[78] In my view, based on the evidence adduced at trial, Apotex failed to meet its burden to show that, notwithstanding its manufacturing capacity, it could and would have sold non-infringing lovastatin in place of infringing lovastatin.

[79] Dealing first with whether Apotex could have sold non-infringing lovastatin, Merck argues that the alleged alternative must have been actually available to replace Apotex' infringing sales as they were made. Otherwise, Merck, not Apotex, would have replaced those sales. I believe this submission to be correct both in fact and in law. In *Advanced Building Systems Pty Ltd et al. v. Ramset Fasteners (Aust) Pty Ltd*, [2001] FCA 1098, (2001) 52 I.P.R. 305 the Federal Court of Australia rejected the relevance of a non-infringing alternative, but held that if it was legally relevant, it could only apply "if at the moment of infringement […] there is available on the market instantaneously the appropriate substitute" in the reconstituted market. I agree.

[80] Before leaving *Advanced Building Systems*, I note the Judge there observed that Australia authorities do not adopt the "but for" approach to causation, instead applying a "common sense approach" (*Advanced Building Systems* at paragraph 124).

[81] Merck further argues that Apotex did not have any non-infringing lovastatin available to replace the infringing sales. In this regard, infringing sales of Blue Treasure lovastatin began in October, 1998 and non-infringing sales ended in February, 1999. In the Streamlining Agreement the parties agreed that Apotex would have run out of stock of non-infringing lovastatin on October 28, 1998.

[82] As Merck also argues, to create replacement tablets of non-infringing lovastatin, Apotex would have had to re-activate the lovastatin fermentation operations at the AFI facility. This would have required Apotex to: ferment non-infringing lovastatin; ship commercial grade lovastatin to Toronto; and formulate it into tablets. This would have taken at least three weeks, because at least eleven days was required for fermentation and Dr. Sherman testified that would take between one and two weeks to make tablets from bulk. On this basis, at the time each infringing sale was made, Apotex could not have replaced that sale with non-infringing lovastatin.

[83] At the hearing of the appeal, Apotex argued in reply that its non-infringing alternative was available to it at the time it sold infringing tablets of Blue Treasure lovastatin. It relied upon evidence at pages 554 and 557 of the appeal book to argue that since there were 61.91 kg of non-

infringing lovastatin that Apotex sold in July 1998, this lovastatin was available to replace its infringing sales.

[84] This argument cannot be accepted for the following reasons.

[85] First, the amount of non-infringing lovastatin sold during any period is irrelevant to the issue of Apotex' remaining supply of non-infringing lovastatin. The fact Apotex sold 61.91 kg of non-infringing lovastatin in July 1998 has no bearing on whether it had any more non-infringing lovastatin available to replace infringing sales beginning in October 1998 or later.

[86] Second, July 1998 is the wrong point in time for considering whether there was any remaining non-infringing lovastatin available to replace infringing sales. Leaving aside the agreement of the parties that Apotex would exhaust its supply of non-infringing lovastatin on October 28, 1998, the relevant time frame is the period during which Apotex sold both infringing and non-infringing lovastatin. Based on the data referred to by Apotex, between October 1998, when infringing sales began, and February 1999 when non-infringing sales ended, Apotex sold 60.88 kg of non-infringing lovastatin. In January 1999, Apotex sold 0.49 kg of non-infringing lovastatin and after January 1999, sales of non-infringing lovastatin effectively stopped. The inference to be drawn is that by October, 1998, Apotex had at most 60.88 kg of non-infringing lovastatin available to displace infringing sales. By November 1998, based on its sales, Apotex had at most 29.89 kg of non-infringing lovastatin available. In December 1998, Apotex had at most 5.17 kg of non-infringing lovastatin. And in January 1999, Apotex had only 0.49 kg of non-infringing lovastatin. If Apotex had the entire 60.88 kg of non-infringing lovastatin available in

October 1998, and used all of it to replace infringing sales as they occurred, Apotex' entire supply of non-infringing lovastatin would have been exhausted by mid-November 1998. Whether Apotex could have restocked with non-infringing tablets by December 1998 is a fact that was not proved in evidence.

[87] Finally, all of Apotex' non-infringing lovastatin supply was sold in the real world. The parties agreed, in paragraph 22 of the Streamlining Agreement, that the size of the lovastatin market in both the "but for" world and the real world was the same. As Merck argues, had Apotex diverted any non-infringing tablets to displace infringing sales in the "but for" world, Merck would have captured the diverted non-infringing sales.

[88] I, therefore, conclude that Apotex has failed to establish that it could have replaced all of its infringing sales with sales of non-infringing lovastatin.

[89] While this is dispositive of the appeal on this issue, I also find that Apotex failed to establish that it would have replaced its infringing sales. I reach this conclusion on the following basis.

[90] First, as Apotex conceded in oral argument:

- The real world informs our construction of the "but for" world.
- Conduct in the real world is "very important" to what would have happened in the "but for" world.

- Findings of fact from the liability decision are relevant to constructing the “but for” world.
- “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.

[91] In the liability phase, the Judge found, at paragraph 309 of her reasons (reported at 2010 FC 1265), that if Blue Treasure had been using the non-infringing process to ferment lovastatin, it would have lost significant amounts of money for each kilogram of product it shipped to AFI. However, Apotex knew that once Blue Treasure began to use the allegedly non-infringing process it became profitable. The inference to be drawn is that Apotex knew Blue Treasure was in fact using the infringing process; yet Apotex used that bulk product to prepare and sell its lovastatin tablets.

[92] In this circumstance it is relevant to note that from January 1, 1997 to January 1, 2001 Apotex believed Merck’s patent was invalid.

[93] Apotex’ evidence falls far short of demonstrating that it would have sold the non-infringing product when one considers: the scale of Apotex’ infringement; its likely knowledge that Blue Treasure was supplying it with infringing lovastatin; its belief the Merck patent was invalid; its failure to call a witness from AFI to support its contention that, had it known the product was infringing, it would have resurrected operations at AFI in Winnipeg; and the fact the Judge found that the testimony of Apotex’ only fact witness was, albeit not on this point, unsubstantiated and self-serving.

[94] Even accepting that the parties agreed in the Streamlining Agreement that Apotex had capacity to make the non-infringing lovastatin and that Apotex would have made an accounting profit by producing the non-infringing tablets, Apotex has not established that it would have pursued that alternative in the "but for" world. Specifically, Apotex did not point to evidence that demonstrated the profits that it would have made through the non-infringing alternative would have been greater than value lost in any of the identified scenarios (for example, the research and development activities foregone by repurposing the Winnipeg facility). As such, notwithstanding whether it had the capacity to produce the non-infringing alternative, Apotex has not satisfied its persuasive burden to demonstrate on the facts that it would have produced the non-infringing lovastatin.

[95] To conclude on this point, while in my view, the Judge ought to have considered the relevance of non-infringing alternatives, Apotex has not shown it would have produced non-infringing lovastatin in the "but for" world. It follows that there is no basis for interfering with the Judge's decision concerning the lost profits to be awarded to Merck Canada in respect of pre-expiry tablet replacement sales. It further follows that it is not necessary to consider whether the Judge erred in assessing the royalty rate that would have been applicable to the sales during the patent term had the relevance of the non-infringing alternative been made out.

C. *Did the Judge err in assessing the royalty rate applicable to post-expiry infringing sales?*

[96] As noted above, during the life of the patent, Apotex stockpiled infringing bulk lovastatin and then sold it in tablet form after the patent expired. The parties and the Judge agreed that the appropriate damages award in respect of those sales would be based upon a reasonable royalty.

[97] The Judge assessed a reasonable royalty based on the methodology advanced by Merck's expert. The royalty was calculated by taking the midpoint of the per kilogram cost savings to Apotex by using the infringing process, multiplied by the weight of the infringing lovastatin sold after the patent expired.

[98] At trial, Apotex proposed a *de minimis* royalty rate of 1% on post-expiry sales. The Judge rejected Apotex' proposal in paragraphs 192 to 198 of her reasons.

[99] On appeal, Apotex argues that the Judge misapprehended its position, stating that she failed to appreciate that it would simply have purchased "infringing" bulk lovastatin in the open market after patent expiry, and not use its improperly stockpiled lovastatin. However, the Judge rejected Apotex' "throw-away" scenario on the basis it was unsupported by the evidence. This finding of fact is entitled to deference, and no palpable and overriding error has been demonstrated.

D. *Did the Judge err by determining that Merck & Co. had standing to bring a claim for damages by virtue of its exclusive licence agreement with Merck Canada?*

[100] As explained above, Merck US claimed damages for lost sales because Merck Canada was required to acquire its bulk lovastatin from it. At trial, Apotex argued Merck US was not entitled to any significant damages because in 1992 it entered into an exclusive licence agreement with Merck & Co. In Apotex' view, as a result Merck US was a nominal patentee with no right to "monetize" the patent.

[101] On appeal Apotex again argues that since Merck US had no right to earn revenue from the patent, it also had no right to award of damages.

[102] The Judge carefully considered this argument at paragraphs 239 to 246 of her reasons. Apotex has failed to show any error in the Judge's analysis.

VI. Conclusion

[103] For these reasons, I would dismiss the appeal with costs.

"Eleanor R. Dawson"
J.A.

"I agree.
David Stratas J.A."

"I agree.
Richard Boivin J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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