Federal Court of Appeal  Cour d'appel fédérale

Date: 20200311

Docket: A-128-18

Citation: 2020 FCA 60

CORAM: **WEBB J.A.**
NEAR J.A.
MACTAVISH J.A.

BETWEEN:

APOTEX INC. and
APOTEX PHARMACHEM INC.

Appellants

and

ADIR and SERVIER CANADA INC.

Respondents

Heard at Toronto, Ontario, on February 4, 2020.

Judgment delivered at Ottawa, Ontario, on March 11, 2020.

PUBLIC REASONS FOR JUDGMENT BY: MACTAVISH J.A.

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

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PUBLIC REASONS FOR JUDGMENT

This is a public version of confidential reasons for judgment issued to the parties. The two are identical, there being no confidential information disclosed in the confidential reasons.

MACTAVISH J.A.

[1] Following a trial in 2008, the Federal Court held that a patent owned by the respondent ADIR relating to a drug known as perindopril was valid and had been infringed by the appellants. The judgment permitted the respondents to claim either an accounting of the

appellants' profits from their sales of perindopril, or damages for the losses sustained by the respondent Servier Canada Inc. (who exploited ADIR's patent in Canada) because of the appellants' infringing activities. The respondents elected to recover the profits earned by the appellants through their infringing activities.

[2] Further hearings were held by the Federal Court with respect to the quantification of the appellants' profits over a two-year period. In a decision reported as 2018 FC 346, 156 C.P.R. (4th) 200 (*Profits* #2), the Court determined that the appellants' profits should not be reduced based on the non-infringing alternative defence.

[3] The appellants contend that the Federal Court erred in law in the framework used to determine whether, in a hypothetical world, the appellants would have acquired non-infringing perindopril from any of three proposed suppliers. The appellants further assert that the Federal Court committed a palpable and overriding error in finding that it was more likely than not that the appellants would have declined to acquire non-infringing perindopril from any of the three proposed suppliers.

[4] For the reasons that follow, I have concluded that the Federal Court did not err as alleged. Consequently, I would dismiss the appeal.

1. The Parties

[5] The respondent ADIR is the owner of Canadian Patent No. 1,341,196 (the 196 Patent) which claims the drug perindopril, which is primarily used in the treatment of hypertension and cardiac insufficiency. The other respondent, Servier Canada Inc., is a corporate affiliate of ADIR. The respondents will be collectively referred to in these reasons as "Servier".

[6] The appellant, Apotex Pharmachem Inc. (Pharmachem), manufactures and supplies drugs in Canada. In or around 2006, Pharmachem began manufacturing a generic version of perindopril in tablet form in Canada. In addition to making export sales of perindopril itself, Pharmachem's generic perindopril tablets were sold to the appellant, Apotex Inc., which sold the tablets in Canada and abroad. The appellants will be collectively referred to as "Apotex" in these reasons.

2. The History of this Proceeding

[7] This is the third time that this case has come before this Court. In order to put the issues raised by Apotex into context, it is necessary to have an understanding of the lengthy history of this case.

i) The Liability Trial

[8] In 2006, Servier commenced an action against Apotex for infringement of the 196 Patent. Apotex did not explicitly deny that its perindopril products fell within the claims of Servier's patent, but counterclaimed, asserting that the 196 Patent was invalid.

[9] In a decision reported as 2008 FC 825, 332 F.T.R. 193 (the liability judgment), the Federal Court found that the 196 Patent was valid, and that it had been infringed by Apotex through the manufacture and sale of perindopril-containing products in Canada. The liability judgment was affirmed by this Court on appeal: 2009 FCA 222, 392 N.R. 96. The Supreme Court of Canada subsequently dismissed Apotex's application for leave to appeal: [2009] S.C.C.A. No. 403, 405 N.R. 400 (note).

ii) The First Profits Trial

[10] As noted earlier, the liability judgment allowed Servier to claim either an accounting of Apotex's profits from its sale of its perindopril-containing products in Canada, or damages for the losses sustained by Servier because of Apotex's infringing activities. Servier elected an accounting of the profits earned by Apotex through its infringing activities.

[11] As a result of the retirement of the judge who conducted the liability trial, the remedies trial took place before a different Federal Court judge. This judge was required to determine what proportion of the profits earned by Apotex between July of 2006 and July of 2008 (the infringing period) were attributable to its infringing activities.

[12] Apotex's profits from the sale of perindopril-containing products in Canada were not in issue at the profits trial. Apotex had acknowledged that there was no alternative to infringing the 196 Patent for sales of perindopril in Canada, with the result that it was required to completely disgorge its Canadian profits. What remained in issue were the profits earned by Apotex from its

sales of perindopril-containing products outside of Canada, in particular, sales made to Apotex's affiliates in Australia and the United Kingdom.

[13] Apotex adduced evidence at the profits trial as to the availability of non-infringing perindopril from a number of sources outside of Canada. It further asserted that had it used one of these non-infringing alternative forms of perindopril, the profits that it realized on its export sales would have been lower than the profits it had earned by manufacturing and selling perindopril-containing products in Canada.

[14] In reasons cited as 2015 FC 721, 482 F.T.R. 276 (*Profits* #1), the Federal Court rejected Apotex's claim that its profits from export sales should be adjusted downward to take the availability of non-infringing alternative sources of perindopril into account. The Court came to this conclusion based on its finding that the non-infringing alternative defence was not available to Apotex as a matter of law.

[15] Having rejected the relevance at law of the availability of non-infringing alternatives, the Federal Court nevertheless went on in *Profits* #1 to consider whether non-infringing perindopril had in fact been available to Apotex from certain of the proposed sources. The Court did not, however, assess the viability of three of the proposed sources of non-infringing perindopril, namely Signa, IPCA and Intas.

[16] While Signa was acquired by Apotex in 2011, it was, at the material time, a non-affiliated company located in Mexico that manufactured active pharmaceutical ingredients and intermediates. IPCA and Intas were non-affiliated drug manufacturers located in India.

iii) The Profits Appeal

[17] The judgment in *Profits* #1 was appealed to this Court, and in a judgment reported as 2017 FCA 23, 406 D.L.R. (4th) 572 (the *Profits Appeal*), Apotex's appeal was allowed in part. Amongst other things, this Court concluded that the Federal Court had erred in law in rejecting the relevance of the non-infringing alternative defence. The Federal Court further erred by failing to adequately consider evidence adduced by Apotex as to the ability and willingness of Signa, IPCA and Intas to provide Apotex with non-infringing perindopril.

[18] In coming to this latter conclusion, this Court observed that there was evidence before the Federal Court that, if accepted, could have led it to find that, in the hypothetical world, Apotex would and could have obtained significant quantities of non-infringing perindopril from one or more of these suppliers. Had this been the case, the profits earned by Apotex would potentially have to be adjusted downward accordingly.

[19] Consequently, this Court remitted the matter to the Federal Court for determination of the following question:

> [W]hether Apotex would and could have obtained quantities of non-infringing perindopril from any of Signa, IPCA or Intas and, if so, whether Apotex would and could have used non-infringing perindopril for sales to its affiliates in the United Kingdom and Australia.

[20] Although this Court ordered that the Federal Court decide this question based on the existing record, it nevertheless allowed the Federal Court to receive additional evidence if it was of the view that such evidence would be of assistance and its acceptance would not prejudice the parties opposite.

iv) The Second Profits Trial and the Decision under Appeal

[21] The re-hearing of the profits issue was carried out before the judge who had decided *Profits* #1. No additional evidence was adduced at the second profits trial, which proceeded based on the evidence from the first profits trial, supplemented by the parties' written and oral submissions.

[22] The Federal Court concluded in *Profits* #2 that Apotex could have obtained non-infringing perindopril from each of Signa, IPCA and Intas for sale to Apotex's affiliates in the UK and Australia. However, the Court also found that the supply of non-infringing perindopril would not have been immediately available to Apotex.

[23] That is, after reviewing the situation of each of Signa, IPCA and Intas, the Federal Court concluded in *Profits* #2 that it would have taken approximately one year for these alternate suppliers to overcome certain technological hurdles and obtain the regulatory approvals necessary to allow them to sell non-infringing perindopril. Apotex does not take issue with this finding in this appeal.

[24] What is at issue in this appeal is the Federal Court's finding in *Profits* #2 that while Apotex could have obtained non-infringing perindopril in year two of the relevant two-year period, it had failed to establish that it was more likely than not that it would have acquired non-infringing perindopril from any of Signa, IPCA or Intas. Rather, the Court found that it was more likely than not that Apotex would have done exactly what it had done in the real world: pursue technology transfers in favour of some of its own affiliates outside of Canada rather than purchasing non-infringing perindopril from non-affiliated third-party suppliers. This course of action would have resulted in Apotex not entering the offshore market until after the expiry of the infringing period.

[25] The Federal Court based this latter finding primarily on the testimony of the late Dr. Bernard Sherman, the founder and Chairman of the Board of Apotex. The Court observed that Dr. Sherman had spoken candidly about Apotex's preference for doing everything that it could in Canada, and its resistance to manufacturing products outside of Canada. Where this was not possible, Dr. Sherman discussed Apotex's preference for manufacturing drugs at its own offshore sites, rather than contracting with non-affiliated third parties.

[26] Dr. Sherman further stated that Apotex would likely have refused to use a supplier from Mexico (thus eliminating Signa), as he was "not certain Mexico was ever approved for sale into Europe or Australia". Insofar as IPCA was concerned, Dr. Sherman agreed that this company would have been a potential supplier of non-infringing perindopril. However, he did not think Apotex would have acquired perindopril from IPCA, as there was no reason why Apotex would

not just have manufactured the drug itself at the plant of one of its foreign affiliates such as Apotex Netherlands B.V.

[27] This evidence led the Federal Court to conclude that while Signa, IPCA and/or Intas could have, and would have, manufactured non-infringing perindopril for sale in the UK and Australia during the relevant period, it was more likely than not that Apotex would have refused to use these third-party suppliers to produce its own non-infringing perindopril. The Federal Court found that it was more likely that Apotex would have sent technology transfers to its own affiliates in India to enable them to manufacture non-infringing perindopril, and that this course of action would likely have delayed Apotex's entry into the British and Australian markets until after the infringing period.

[28] Consequently, the Federal Court concluded that there should be no reduction to Apotex's profits over the infringing period to take the availability of non-infringing perindopril into account, and its decision in *Profits* #1 was thus confirmed.

3. The Issues

[29] As noted earlier, Apotex does not challenge the Federal Court's conclusion in *Profits* #2 that its entry into foreign markets would likely have been delayed by a year because of the need of foreign manufacturers to overcome technical and regulatory hurdles. Apotex does, however, challenge the finding that it would not have availed itself of non-infringing perindopril in year two of the infringing period in the hypothetical world.

[30] Apotex submits that the Federal Court erred in law in the framework that it used to determine whether, in a hypothetical world, Apotex would have acquired non-infringing perindopril from any of Signa, IPCA or Intas. The Court further erred, Apotex says, in failing to follow the directions of this Court in the *Profits Appeal*.

[31] Apotex also submits that the Federal Court committed a palpable and overriding error in finding that it was more likely than not that Apotex would not have used a non-infringing form of perindopril during the infringing period because of the company's historical preference for manufacturing drugs in Canada or at its affiliates outside of Canada.

4. Standard of Review

[32] The standards of review applicable to the issues raised on this appeal are those described by the Supreme Court in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. The legal test applied by the Federal Court in determining the availability of a non-infringing supply of perindopril is a question of law that is reviewable on the correctness standard: *Rivett v. Monsanto Canada Inc*., 2010 FCA 207, 325 D.L.R. (4th) 107 (*Rivett* FCA) at para. 19; and *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] S.C.J. No. 65 at para. 37.

[33] This Court has previously held that the question of whether an infringer would actually have used a non-infringing alternative is a question of fact: *Apotex Inc. v. Merck & Co. Inc*., 2015 FCA 171, 387 D.L.R. (4th) 552 (*Lovastatin*) at para. 73, leave to appeal to SCC refused,

36655 (14 April 2016). In accordance with the Supreme Court's decision in *Housen*, above, findings and inferences of fact as to whether, in a hypothetical world, Apotex would have acquired non-infringing supplies of perindopril from outside of Canada are thus to be reviewed on the palpable and overriding error standard.

5. Legal Principles Governing the Non-infringing Alternative Defence

[34] Before examining the legal test that was applied by the Federal Court in *Profits* #2, it is helpful to have an understanding of the law regarding the non-infringing alternative defence.

[35] The *Patent Act*, R.S.C. 1985, c. P-4 allows courts to award two different types of remedy for patent infringement. The first is an award of damages under subsection 55(1) of the Act. The second is an accounting of profits in accordance with paragraph 57(1)(*b*) of the Act, which allows a judge in a patent infringement case to make an order "for and respecting inspection or account". As will be discussed below, the jurisprudence makes clear that this remedy exists as an alternative to damages.

[36] Damages are based on the harm suffered by the patentee, and are intended to compensate the patentee for his or her losses. An award of damages may include compensation for the patent holder's lost profits from sales or lost royalty payments.

[37] In contrast, an accounting of profits is an equitable remedy based on the profit made by the infringer, rather than the amount lost by the inventor: *Monsanto Canada Inc. v. Schmeiser*,

2004 SCC 34, [2004] 1 S.C.R. 902 at para. 100; *Rivett* FCA, above at para. 23. As the Federal Court observed in *Rivett*, an accounting of profits serves two major equitable purposes: a "prophylactic purpose" deterring the infringer and others, and a "restitutionary purpose", restoring to the wronged party profits which have been wrongly appropriated by the infringer: *Monsanto Canada Inc. v. Rivett*, 2009 FC 317, [2010] 2 F.C.R. 93 (*Rivett* FC) at para. 19, citing *Strother v. 3464920 Canada Inc.*, 2007 SCC 24, [2007] 2 S.C.R. 177 at para. 77.

[38] The premise underlying this remedy is that the infringer notionally acted as the agent of the patent holder, and is therefore obliged to account for the profits earned through its infringement: *Beloit Canada Ltd. v. Valmet-Dominion Inc.*, 73 C.P.R. (3d) 321, [1997] 3 F.C. 497 (F.C.A.) at 356; *Apotex Inc. v. Bayer Inc.*, 2018 FCA 32, [2018] F.C.R. 58 at para. 56.

[39] An accounting of profits should be limited to profits that were actually earned by the defendant as the purpose of this remedy is not to punish the infringing party, but to prevent its unjust enrichment: *Imperial Oil Ltd. v. Lubrizol Corp.*, [1997] 2 F.C. 3, 206 N.R. 136 (F.C.A.) at para. 8.

[40] The Supreme Court has observed that where a patentee has elected to receive an accounting of profits, the patentee will only be entitled to that portion of the infringer's profits that is causally attributable to the invention: *Schmeiser*, above at para. 101. This is because a patent does not confer a complete monopoly if a defendant could make or sell a non-infringing version of the patented invention: *Lovastatin*, above at para. 48.

[41] Citing Professor Norman Siebrasse in "*A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms*" (2003) 20 C.I.P.R. 79, the Supreme Court went on in *Schmeiser* to state that the preferred method of calculating an accounting of profits is the "differential profit approach". In accordance with this approach, profits are allocated taking into account the value that was contributed to the defendant's goods by the patented invention. As Professor Siebrassse has noted, awarding profits according to the value added by the patented invention is consistent with the fundamental nature of patents as intellectual property: above at page 92.

[42] A comparison thus has to be made between those profits that are attributable to the invention, and the profits that the defendant would have made using the best non-infringing alternative option: *Schmeiser*, above at para. 102, citing *Collette v. Lasnier* (1886) 13 S.C.R. 563 at page 576.

[43] In *Lovastatin*, this Court identified the framework to be used in constructing the hypothetical "but-for" world in which the infringer does not infringe the patent.

[44] The issue that faced the Court in *Lovastatin* was whether, in determining the damages sustained because of patent infringement in accordance with subsection 55(1) of the *Patent Act*, regard should be had to legitimate competition from an infringer. Subsection 55(1) states that "[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".

[45] After performing a textual, contextual and purposive analysis of subsection 55(1), and after examining the law relating to causation, this Court concluded in *Lovastatin* that the availability of non-infringing alternatives had to be taken into account in assessing damages for patent infringement. This is because the scope of a patent holder's monopoly may be extended if damages for lost profits were calculated without regard to the availability of a non-infringing alternative to the invention.

[46] That is, a patentee could be better off in some cases than they would otherwise have been if a defendant could have lawfully competed in the marketplace by making or selling a non-infringing product, potentially depriving the patent holder of some sales: *Lovastatin*, above at para. 48. Similarly, a defendant could be worse off than they would otherwise have been if the availability of non-infringing substitutes were ignored: *Lovastatin*, above at para. 60.

[47] As a consequence, this Court concluded in *Lovastatin* that "perfect compensation" requires a consideration of what, if any, non-infringing product or products the defendant or other competitors could and would have sold, but for the infringement. Also relevant is the extent to which lawful competition would have reduced the patent holder's sales: above at para. 50.

[48] The Court concluded at paragraph 73 of *Lovastatin*, that in assessing the impact of legitimate competition from a defendant marketing a non-infringing alternative product, a court must 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? and

(iv) Would the infringer actually have sold the non-infringing alternative?

[49] Of necessity, this is a hypothetical exercise, as the Court must reconstruct the market to determine what would have happened in the hypothetical situation where, rather than infringing a plaintiff's patent, the infringer instead chose to compete with the plaintiff using a non-infringing product.

[50] As this Court observed in the *Profits Appeal*, "evidence concerning the hypothetical world is necessarily hypothetical and the Court is free to draw inferences from the evidence as to what would likely have happened 'but for' the breach": above at para. 61, citing *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142, 167 D.L.R. (4th) 577 at 186.

[51] The persuasive burden is on the defendant to establish that, in this hypothetical world, it could have and would have been able to obtain a sufficient amount of the non-infringing product, and that it could and would have used the non-infringing product to compete with the patent holder: *Lovastatin*, above at para. 74.

[52] The issue of a non-infringing alternative arose again in *Pfizer Canada Inc. v. Teva Canada Ltd*., 2016 FCA 161, 483 N.R. 275, leave to appeal to SCC refused, 37262 (19 January 2017) (*Effexor*). While a claim for compensatory damages for patent infringement was at issue in *Lovastatin*, *Effexor* involved a claim for damages under section 8 of the *Patented Medicines (Notice of Compliance*) *Regulations*, S.O.R./93-133. Citing *Astrazeneca Canada Inc. v. Apotex Inc*., 2013 FCA 77, 444 N.R. 254 at paragraph 7, this Court stated in *Effexor* that the overriding principle is the same in both types of cases: namely, that a plaintiff is to be compensated, no more, and no less: above at para. 47.

[53] The Court observed in *Effexor* that this Court held in *Lovastatin* that to succeed with a non-infringing alternative defence, a defendant had to establish that, in the hypothetical world, it would have and could have had access to sufficient quantities of a non-infringing product. The defendant also had to demonstrate that it would have, and could have, used the non-infringing product to compete with the plaintiff's product: *Effexor* at para. 49, citing *Lovastatin*, at paras. 32, 53, 55, 70, 77 and 78.

[54] The Court noted at paragraph 50 of *Effexor* that both the "could have" and "would have" components of the non-infringing alternative defence are important in ensuring that a plaintiff is put in the position that they would have been in, had the infringement not occurred.

[55] Insofar as the "could have" element of the test is concerned, the defendant has to demonstrate that, in the hypothetical world, it would have been possible for it to secure non-infringing product – that is, that it "could have" done so. To satisfy the "would have" component

of the test, a defendant must demonstrate "that events would transpire in such a way as to put them in that position": *Effexor*, above at para. 50. That is, that the defendant "would have" obtained and used the non-infringing alternative.

[56] As this Court observed in the *Profits Appeal*, the significance of the "would have" requirement is that by requiring that a defendant demonstrate that it would have used a non-infringing alternative, it shows that "the value of the patented invention is not such that reliance on alternatives is unlikely or fanciful". That is, even if a non-infringing alternative is available, a defendant must nevertheless show "that there are no impediments to its use": above at para. 42.

[57] The non-infringing alternative defence was also discussed in *Apotex Inc. v. Eli Lilly and Co.*, 2018 FCA 217, 161 C.P.R. (4th) 411, leave to appeal to SCC refused, 38485 (23 May 2019) (*Cefaclor*). There, this Court reiterated that the goal of the non-infringing alternative defence "is to help ascertain the real value of inventions for which a patentee […] was granted a monopoly": above at para. 49.

[58] In considering the impact of legitimate competition from a defendant marketing a non-infringing alternative to the patentee's product, the Court in *Cefaclor* adopted the four-part test from *Lovastatin*. The Court observed, however, that this test was not intended to be exhaustive, and that where the existence of a non-infringing alternative is in issue, a court will be required to consider *at least* the four questions of fact that were identified in *Lovastatin*: *Cefaclor*, above at para. 51 [emphasis added].

[59] The Court went on in *Cefaclor* to note that the following principles may also be relevant to the inquiry:

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

(*Cefaclor* at para. 52, citing *Lovastatin* at para. 90).

[60] With this understanding of the legal principles governing the non-infringing alternative defence, I turn now to address the first issue raised by Apotex.

6. Did the Federal Court Commit a Palpable and Overriding Error in Finding that Apotex Would not have Obtained Non-infringing Perindopril from Signa, IPCA and/or Intas for Sale to its Affiliates in the UK and Australia?

[61] The Federal Court found that Apotex could have obtained non-infringing perindopril from any of Signa, IPCA and/or Intas for the second half of the infringing period. The Court concluded, however, that instead of purchasing non-infringing perindopril from one of these third-party suppliers, it was more likely than not that Apotex would instead have chosen to forgo

a year's sales in the UK and Australia, waiting until non-infringing perindopril was available from one of Apotex's affiliates in India.

[62] This finding was based on what the Federal Court called a "historical preference" on the part of Apotex for manufacturing in Canada, and for dealing with its own affiliates outside of this country.

[63] Apotex says that this finding was the result of a palpable and overriding misapprehension on the part of the Federal Court with respect to the evidence of Dr. Sherman and others. In concluding that it would not have acquired non-infringing perindopril in year two of the infringing period, Apotex says that the Federal Court erred by fastening on a single statement made by Dr. Sherman, and by ignoring other parts of his evidence, as well as the "real world" facts and the evidence of other witnesses.

[64] According to Apotex, this error led the Federal Court to find that, in the hypothetical world, it would have willingly elected to defer its entry into the perindopril market until after the infringing period. In so doing, Apotex would forgo a year's worth of sales to Australia and the UK, and what Apotex says would likely have been tens of millions of dollars in profits.

[65] Apotex submits that it is manifestly clear from a review of the transcript that Dr. Sherman did not make the admissions that the Federal Court attributed to him, and that the overwhelming evidence before the Court was to the contrary. In support of this contention, Apotex points out

that there was testimony before the Court from suppliers of non-infringing forms of perindopril from outside of Canada confirming that they had previously supplied Apotex with products.

[66] Apotex further argues that the trial judge erroneously equated a “preference” with a “restriction” or a “rule”. According to Apotex, a mere preference on the part of the company for manufacturing in Canada and for using its own affiliates outside of Canada does not provide an answer to the question that the Federal Court had to answer: namely, would Apotex have availed itself of sources of non-infringing perindopril if its preferred options were not available?

[67] According to Apotex, Dr. Sherman acknowledged that Apotex had used third-party suppliers when it was unable to manufacture a product in Canada or at one of its offshore affiliates. While Dr. Sherman did indeed state that he preferred to manufacture drugs in Canada or offshore using Apotex’s affiliates, he also testified that Apotex had used non-affiliated third parties outside of Canada for the manufacture of tablets and active pharmaceutical ingredients when it was unable to use affiliated suppliers, or where there were patent concerns in Canada.

[68] Finally, Apotex says that the Federal Court erred in ruling out Signa as a possible source of non-infringing perindopril. According to Apotex, Dr. Sherman’s concern with respect to the lack of approvals allowing drugs originating in Mexico to be sold in European markets related to tablets, and not to active pharmaceutical ingredients. Signa did not produce tablets, but instead manufactured active pharmaceutical ingredients. According to Apotex, the lack of European approvals thus did not pose an impediment to its use of Signa’s non-infringing perindopril.

[69] In light of these errors, Apotex says that the Federal Court's finding that its profits should not be reduced because of the availability of non-infringing perindopril cannot stand.

[70] I do not accept Apotex's argument that the Federal Court erred in this regard.

[71] As noted earlier, findings of fact made by a trial court are reviewable on the "palpable and overriding error" standard. This is a highly deferential standard of review: *Benhaim v. St-Germain*, 2016 SCC 48, [2016] 2 S.C.R. 352 at para. 38, citing *Canada v. South Yukon Forest Corp.*, 2012 FCA 165, 431 N.R. 286 at para. 46.

[72] "Palpable" signifies an error that is obvious, whereas "overriding" means that the error goes to the very core of the outcome of the case. As this Court noted in *South Yukon Forest Corp*., when arguing that a trial judge committed a palpable and overriding error, "it is not enough to pull at leaves and branches and leave the tree standing. The entire tree must fall": above at para. 46.

[73] The Supreme Court of Canada recently reiterated that appellate courts can only intervene if there is an obvious error in the trial decision that is determinative of the outcome of the case: *Salomon v. Matte-Thompson*, 2019 SCC 14, 432 D.L.R. (4th) 1 at para. 33. Citing the decision of the Court of Appeal of Quebec in *J.G. v. Nadeau*, 2016 QCCA 167, J.E. 2016-290 at para. 77, the Supreme Court stated that a palpable and overriding error is "in the nature not of a needle in a haystack, but of a beam in the eye". The fact that another judge could have made a different factual finding by ascribing different weight to the same evidence does not mean that a palpable

and overriding error has been established: *Nelson (City) v. Mowatt*, 2017 SCC 8, [2017] 1 S.C.R. 138, at para. 38.

[74] In this case, Apotex argues that the Federal Court failed to ascribe sufficient weight to parts of Dr. Sherman's evidence (together with the evidence of other witnesses) that it says supported a finding that, in the hypothetical world, Apotex would indeed have utilized a non-infringing form of perindopril obtained from non-affiliated third-party manufacturers. This included evidence that Apotex had purchased active pharmaceutical ingredients and pharmaceutical formulations in the past from the very non-affiliated third-party manufacturers that were in issue here.

[75] Needless to say, it is not the role of this Court sitting in appeal of a judgment of the Federal Court following a long and complex trial to reweigh the evidence and to come to a different conclusion than did the trial judge: *Cefaclor*, above at para. 110.

[76] If the trial judge did err in her factual finding on the "would" step of the non-infringing alternative test, it is my view that this error was not palpable, as the alleged error is not obvious. On my reading of the entirety of Dr. Sherman's testimony, it was not plainly wrong to find that it was likely that Apotex would not have used a non-infringing alternative from one or more of the non-affiliated third-party manufacturers.

[77] Indeed, even though it was contrary to Apotex's interests to do so, Dr. Sherman testified that Apotex likely would not have acquired perindopril from any of the three third-party manufacturers in question, preferring instead to deal with its own foreign affiliates.

[78] As will be explained in the next section of these reasons, it was open to the Federal Court to consider Apotex's intentions and preferences in assessing whether recourse to the non-affiliated third-party manufacturers would have been more likely than not. It was also open to the Federal Court to conclude that these intentions and preferences rendered it unlikely that Signa, IPCA or Intas would have been used by Apotex as sources of non-infringing perindopril.

[79] Dr. Sherman testified that, despite Apotex's rapid international expansion, the company had nevertheless "resisted manufacturing anything outside of Canada for a long time", preferring "to do everything we can in Canada". This preference is borne out by the fact that even though Apotex could have safely manufactured non-infringing perindopril at the facilities of one of its affiliates outside of Canada, it preferred to manufacture the drug in this country for sales in Canada and abroad, thereby running the risk of being found to have infringed the 196 Patent.

[80] Dr. Sherman did acknowledge that there were situations where the company would choose to manufacture drugs outside of Canada, including cases where manufacturing offshore allowed Apotex to take advantage of lower labour costs. He also acknowledged that the existence of unexpired patents in Canada could lead it to manufacture drugs offshore. However, Dr. Sherman testified that in such cases, Apotex preferred to use its own foreign manufacturing

plants, relying on non-affiliated third parties only when "the chemicals themselves are readily available".

[81] Dr. Sherman further testified that he did not think that perindopril was available when Apotex was looking to break into the perindopril market. As a consequence, it had its own chemical plant in Brantford, Ontario develop the drug.

[82] Thus, when read in context, Dr. Sherman's testimony supports the Federal Court's finding that, in the hypothetical world, Apotex would more than likely have done exactly what it ended up doing in the real world, which was to wait for its Indian affiliates to be ready to supply it with non-infringing perindopril.

[83] As this Court observed in *Cefaclor*, what went on in the real world helps to inform our construction of the "but-for" world, and can be very important in assessing what would likely have happened in that hypothetical "but-for" world: above at para. 52. See also *Lovastatin* at para. 90.

[84] In this case, despite Dr. Sherman's avowed preference for manufacturing drugs in Canada, Apotex had nevertheless developed a "Plan B" to allow it to continue to manufacture and sell perindopril (albeit outside of Canada), in the event that it were to lose the infringement trial in Canada. To this end, Apotex had arranged to transfer the necessary technology to APIPL and ARPL — two of its wholly-owned affiliates in India — thereby ensuring that Apotex had access to an uninterrupted supply of non-infringing perindopril for sale in the UK and Australia.

[85] It is also noteworthy that, in the real world, Apotex had initially preferred to manufacture perindopril in Canada (thereby putting its profits at risk) while building manufacturing plants in India for APIPL and ARPL. It did this instead of transferring the technology to existing unaffiliated third-party manufacturers who could potentially have manufactured non-infringing perindopril at a lower cost to Apotex: *Profits* #2, above at para. 85. From this, it is apparent that potential time delays and loss of profits did not trump Apotex's stated desire and historical preference for manufacturing perindopril in Canada or at one of its own sites outside of Canada.

[86] I am also not persuaded that there was any confusion on the part of the Federal Court as to whether Signa manufactured tablets or just the active pharmaceutical ingredient in perindopril. It is evident from paragraphs 43 and 47 of *Profits* #2 that the trial judge understood that Signa was a manufacturer of active pharmaceutical ingredients.

[87] It is also noteworthy that Apotex had in fact transferred technology to Signa in 2004 to allow it to produce the active pharmaceutical ingredient in perindopril. This transfer was, however, aborted. Dr. Sherman explained that this may have occurred "because it was relatively small scale, it may have been decided that it was more appropriate to transfer it to APIPL than to Signa". Once again, this confirms that, in the real world, Apotex preferred to wait an additional two years to transfer the technology necessary to manufacture non-infringing perindopril to one of its Indian affiliates in 2006, rather than allowing Signa to supply it with the necessary active pharmaceutical ingredient.

[88] The findings of fact with which Apotex takes issue were made following a lengthy trial and two sets of written and oral arguments. The Federal Court had the benefit of assessing the evidence of all of the witnesses, including that of Dr. Sherman himself. In addition to providing insight into Apotex's corporate policies and preferences, Dr. Sherman also testified as to what Apotex would and would not have done in the hypothetical world.

[89] The Federal Court's findings on this point are consistent with Dr. Sherman's evidence, and Apotex has not established that the finding that it would not have acquired non-infringing perindopril in year two of the infringing period was tainted by a palpable and overriding error.

7. Did the Federal Court Err in Law in Its Construction and Application of the "Would Have" Component of the Non-infringing Alternative Test?

[90] As previously discussed, the focus of Apotex's appeal is on the "would have" component of the non-infringing alternative analysis. In particular, Apotex takes issue with the Federal Court's finding that Apotex would not have availed itself of non-infringing perindopril from any of Signa, IPCA and/or Intas in the hypothetical world.

[91] Apotex submits that, in coming to this conclusion, the Federal Court erred in law by improperly focussing on Apotex's preferences and its "real world" decision to manufacture perindopril in Canada while it was challenging the validity of Servier's patent. In so doing, Apotex says, the Federal Court failed to properly value the profits that were causally attributable to the patented invention. This had the effect of grossly overvaluing the patented invention, by treating it as a worldwide monopoly.

[92] According to Apotex, the Federal Court further erred in law by failing to appreciate the difference between an assessment of damages and an accounting of profits, and the significance that this distinction has for the jurisprudence relating to the non-infringing alternative defence. The Court also erred, Apotex says, by focussing on whether there was "brazen" infringement in the real world and the "scale of Apotex's infringement".

[93] In addition, Apotex says that the Federal Court erred in law by misinterpreting or disregarding the direction that this Court provided in the *Profits Appeal* as to how to conduct the non-infringing alternative analysis, and, in particular, how to assess the "would have" component of the test.

[94] Apotex observes that this Court had provided clear guidance in the *Profits Appeal* as to the nature of the "would have" component in an accounting of profits case. Nevertheless, Apotex says that the Federal Court elected not to follow this Court's instructions as to how to carry out a "would have" analysis.

[95] Apotex takes particular issue with paragraphs 68 to 70 of the Federal Court's decision in *Profits* #2, where the Court observed that:

> [68] By linking the "would have" branch of the NIA analysis to whether there exists any impediments to the use of an NIA, [the *Profits Appeal*] seems to remove the clutter of considering the infringer's intentions, which was in fact an important part of the "would have" analysis in *Lovastatin* […]. It also seems to limit the legal relevance of NIAs to a purely economic rationale. The logic behind that conclusion would therefore be that if an NIA is economically viable, then the infringer's profit is not causally attributable to the invention.
>
> [69] However, and in my humble view, the notion of impediment — as in obstacle or barrier — should be linked to the "could have" analysis, not the

> "would have" analysis. Restricting the "would have" analysis to an economic rationale would also discard cases where the infringer would not have used its proposed NIA for reasons other than economic ones and thus would not have legally competed with the patentee. All of the infringer's profits in such a scenario come from infringement.
>
> [70] Therefore, I respectfully do not believe that the "would have" analysis made by the Federal Court of Appeal in *Lovastatin* […] was in any way restricted by paragraph 42 of [the *Profits Appeal*].

[96] It will be recalled that in *Lovastatin*, this Court stated that a Court had to have regard to at least the following four questions:

> (i) Is the alleged non-infringing alternative a true substitute and thus a real alternative?
>
> (ii) Is the alleged non-infringing alternative a true alternative in the sense of being economically viable?
>
> (iii) At the time of infringement, does the infringer have a sufficient supply of the non-infringing alternative to replace the non-infringing sales? Another way of framing this inquiry is could the infringer have sold the non-infringing alternative?
>
> (iv) Would the infringer actually have sold the non-infringing alternative? (emphasis in original)

[97] These four questions do not, however, exist in discrete silos, and there will inevitably be some overlap between them.

[98] For example, the question of whether an allegedly non-infringing alternative is truly a substitute for the patented invention and thus a real alternative to it is arguably subsumed in the

question as to whether the infringer could have obtained a non-infringing alternative. That is, if the allegedly non-infringing alternative is a true substitute for the patented invention, a defendant may be able to show that its profits should be reduced because it could have sold a non-infringing alternative to the invention in issue.

[99] Similarly, the economic viability of a non-infringing alternative ties into the question of whether a defendant would have actually sold the non-infringing alternative. That is, even if a true non-infringing alternative was available to a defendant, the fact that the alternative product was very expensive may well have a bearing on whether the defendant would actually have used and sold the non-infringing alternative product in the hypothetical world.

[100] At the end of the day, what is important is that each of the four questions identified in *Lovastatin* are considered and weighed in determining whether an infringer's profits should be reduced because of the availability of a non-infringing alternative to the patented invention.

[101] It is clear from a review of the reasons in *Profits* #2 that the Federal Court did in fact address all of the issues that it was required to consider. Notwithstanding the comments at paragraphs 68 to 70 of *Profits* #2, the Federal Court went on to consider Apotex's intentions and preferences in determining that it had not established that, in a hypothetical world, it would have acquired non-infringing perindopril from any of Signa, IPCA or Intas: above at paras. 83 and 87.

[102] Apotex seemingly recognizes this fact, as it faults the Federal Court for taking the company's preferences into account in assessing whether it would have availed itself of the non-

infringing perindopril that would have been available from Signa, IPCA and/or Intas in the hypothetical world.

[103] Apotex asserts, however, that a mere subjective preference for manufacturing in Canada and for using its own affiliates outside of Canada does not render the invention claimed in the 196 Patent any more valuable than it would otherwise have been. Nor, according to Apotex, does it provide an answer to the question that was before Federal Court, which was whether Apotex would have used the next best available non-infringing alternative, and not its preference amongst unavailable alternatives.

[104] Apotex insists that there would have been no impediments to it using non-infringing perindopril from Signa, IPCA and/or Intas in the hypothetical world. By improperly focussing on Apotex's preferences and its "real world" decision to manufacture perindopril in Canada while challenging the validity of Servier's patent, Apotex says that the Federal Court failed to properly value the profits that were causally attributable to the patented invention. In so doing, Apotex says that the Federal Court grossly overvalued the patented invention, effectively treating it as conferring a worldwide monopoly.

[105] I cannot accept this contention.

[106] The significance of a party's intentions and preferences has been specifically addressed by this Court in the context of the non-infringing alternative defence, and they have been found to be relevant to the "would have" component of the test.

[107] That is, after observing that a defendant has to satisfy both the "could have" and "would have" components of the *Lovastatin* test, this Court went on in *Effexor* to observe that evidence demonstrating that a party could have done something does not prove that it would in fact have done it: above at para. 51. A defendant must, rather, demonstrate "that events would transpire in such a way as to put them in that position": *Effexor*, above at para. 50.

[108] Using the analogy of running a marathon, Justice Stratas, writing for the Court in *Effexor*, described how personal preferences can factor into the "would have" analysis. He observed that while there might be evidence that someone was fit enough to complete a marathon — that is, that they could do it — that did not prove that the individual would in fact have done so. For example, the individual may have preferred to skip the race and attend a baseball game instead: *Effexor*, above at para. 51.

[109] Similarly, this Court observed in *Cefaclor* that the subjective perspective of an infringer may indeed be relevant to the question of whether the infringer would have used the non-infringing alternative: above at para. 72.

[110] From this it is clear that the preferences of a party can be relevant to the "would have" component of the non-infringing alternative test. As a consequence, I am satisfied that the Federal Court did not err in taking the evidence of Dr. Sherman as to Apotex's preferences into account in concluding that Apotex had failed to establish that it would have used a non-infringing alternative form of perindopril in the hypothetical world.

[111] Apotex also contends that the Federal Court erred in law by failing to appreciate the difference between an assessment of damages and an accounting of profits, and the significance of this distinction as it relates to the jurisprudence governing the non-infringing alternative defence.

[112] While recognizing that there are similarities between the two types of remedy, Apotex notes that they fulfill different purposes. As was discussed earlier, while compensatory damages are intended to put a patent holder in the position that they would have been in, but for the infringement, an accounting of profits asks how a defendant has benefited from the taking of the invention.

[113] In order to answer this question, Apotex notes that a value must be ascribed to the intellectual property in issue. This value is arrived at by taking the profit that was actually earned by the infringing party and deducting from that the profit that would have been earned using the best non-infringing alternative. The focus must thus be on the question of causation and the relationship between the wrong and the remedy.

[114] It is true that some of the cases cited by the parties relate to assessments of damages, rather than accounting of profits: for example, *Lovastatin*, *Effexor* and *Cefaclor*. While the two types of remedies do indeed serve different purposes, it is evident from a review of the jurisprudence that similar principles have been applied in considering the significance of non-infringing alternatives in damages and accounting of profits cases. Indeed, in the *Profits Appeal*, this Court specifically stated that similar principles apply in evaluating a non-infringing

alternative defence in an assessment of damages and in an accounting of profits: above, at paras. 34 and 40.

[115] I am thus not persuaded that the "could" and "would" analysis developed in *Lovastatin* is any less applicable to an accounting of profits in cases such as this. Indeed, the *Profits Appeal* confirms that the guidance provided by *Lovastatin* and further developed in *Effexor* was to be followed by the Federal Court in this case.

[116] Finally, Apotex argues that the Federal Court erred by focussing on the alleged "brazenness" of its infringing activities. According to Apotex, "brazenness" in and of itself is not relevant to the value of the patented invention. The relevant inquiry, Apotex submits, is thus not whether the infringement was "brazen", but whether the use of the proposed non-infringing alterative is "unlikely or fanciful", and whether there are impediments to its use.

[117] Moreover, and in any event, Apotex submits that its infringing conduct was not "brazen".

[118] In support of these arguments, Apotex says that the Federal Court erroneously equated intentional infringement with "brazen" infringement, submitting that the two terms are not equivalent. Apotex notes that the liability judgment merely found that Apotex knew that in manufacturing and selling perindopril in Canada, it was infringing the 196 Patent, but that it believed that the 196 Patent was invalid. According to Apotex, this conduct cannot be said to rise to the level of "brazen" infringement.

[119] I cannot accept Apotex's argument on this issue.

[120] First of all, an accounting of profits is an equitable remedy. As such, the remedy will always be subject to the discretion of the Court and the conduct of a party may well be relevant to the exercise of that discretion. The Supreme Court has, moreover, had regard to the conduct of defendants in accounting of profits cases, noting, for example, the defendant's knowing and intentional infringement of Monsanto's patent in *Schmeiser*, above at para. 95; see also this Court's comments in *Rivett* FCA, above at para. 32.

[121] Moreover, as was conceded by Apotex, "there is no articulated standard of 'brazen infringement'". Nothing in this Court's reasons in *Lovastatin* suggests that "brazen" infringement is something more than intentional or wilful infringement. Indeed, the language used in *Lovastatin* to describe Apotex's real-world behaviour (including its likely knowledge that it was being supplied with lovastatin produced through an infringing process) suggests that this Court used the word in its normal, dictionary meaning of "obvious, without any attempt to be hidden": *Cambridge Dictionary*, (Cambridge University Press: Cambridge) sub verbo "brazen", online: *Cambridge Dictionary* <https://dictionary.cambridge.org/dictionary/english/brazen>.

[122] I am also not persuaded that the Federal Court's consideration of the brazenness of Apotex's "real world" infringement impermissibly introduced an element of punishment into the process. The Federal Court did not order the disgorgement of profits that surpassed Apotex's actual profits, nor did it seek to punish Apotex for its conduct.

[123] However, as this Court observed in *Lovastatin*, "brazen" infringement in the real world makes it very difficult for a defendant to prove that it would have deployed the non-infringing alternative in the "but for world": above at para. 90. See also *Cefaclor*, above at para. 51.

[124] This Court observed in *Lovastatin* that Apotex's evidence in that case fell far short of demonstrating that it would have used the proposed non-infringing product. In coming to this conclusion the Court gave considerable weight to, amongst other things, the scale of Apotex's infringement, its likely knowledge that it was using an infringing form of lovastatin and its belief that the patent in issue was invalid: above at para. 93.

[125] As the Federal Court observed in *Profits* #2, many of these same points apply in this case: above at para. 72. The Court noted that the judge had made very clear findings of intentional infringement in the liability judgment, and that this behaviour on the part of Apotex had to be taken into account in deciding whether it was appropriate to order an accounting of profits: liability judgment at para. 509.

[126] The Court further found in the liability judgment that while it was fully aware of the 196 Patent, Apotex nevertheless chose Canada as the manufacturing site for its perindopril products. The Court observed that Apotex could have avoided infringing Servier's patent by making perindopril-containing products outside of Canada, but that it had chosen not to do so. The Court accepted that Apotex was entitled to arrange its business affairs as it saw fit. However, in so doing, Apotex had to bear the consequences of its choices where it was perfectly aware that a patent would be infringed: liability judgment at para. 509.

[127] From this, it is apparent that the behaviour of an infringer should inform the construction of the hypothetical "but-for" world and the Federal Court thus did not err in having regard to the brazen nature of Apotex's conduct.

8. Conclusion

[128] For these reasons, I am satisfied that the Federal Court did not commit a palpable and overriding error in finding that Apotex likely would not have used a non-infringing alternative form of perindopril during the infringing period because of the company's preference for manufacturing drugs in Canada or at its affiliates outside of Canada.

[129] I am further satisfied that the Federal Court did not err in law in its construction and application of the "would have" component of the non-infringing alternative test.

[130] Consequently, I would dismiss the appeal, with costs.

"Anne L. Mactavish"
J.A.

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

"I agree
D. G. Near J.A."

COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-128-18
STYLE OF CAUSE:	APOTEX INC. and APOTEX PHARMACHEM INC. v. ADIR and SERVIER CANADA INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	FEBRUARY 4, 2020
PUBLIC REASONS FOR JUDGMENT BY:	MACTAVISH J.A.
CONCURRED IN BY:	WEBB J.A. NEAR J.A.
DATED:	MARCH 11, 2020

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