Federal Court of Appeal  Cour d'appel fédérale

Date: 20170202

Docket: A-315-15

Citation: 2017 FCA 23

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

BETWEEN:

APOTEX INC. and
APOTEX PHARMACHEM INC.

Appellants

and

ADIR and
SERVIER CANADA INC.

Respondents

Heard at Toronto, Ontario, on September 27 and 28, 2016.

Judgment delivered at Ottawa, Ontario, on February 2, 2017.

REASONS FOR JUDGMENT BY: DAWSON J.A.

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

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] ADIR is the owner of Canadian Patent No. 1,341,196 (196 Patent) which claims the drug perindopril. Perindopril is distributed and sold under the trademark COVERSYL and is used primarily in the treatment of hypertension and cardiac insufficiency. Servier Canada Inc., a

corporate affiliate of ADIR, exploits the 196 Patent in Canada. Together, ADIR and Servier are referred to as Servier in these reasons.

[2] Apotex Pharmachem Inc. (Pharmachem) manufactures and supplies drugs in Canada. Commencing around 2006, it began to manufacture a generic version of perindopril in tablet form in Canada. The generic perindopril tablets were then sold to Apotex Inc. which sold the tablets in Canada and abroad. Pharmachem also made some export sales of perindopril. In these reasons Pharmachem and Apotex Inc. are collectively referred to as Apotex or the defendants.

[3] In 2008, the Federal Court held that the 196 Patent was valid and was infringed by the defendants through the manufacture in Canada and sale of perindopril tablets: 2008 FC 825 (liability judgment). The liability judgment was affirmed by this Court on appeal: 2009 FCA 222.

[4] The liability judgment permitted Servier to elect to claim either an accounting of the defendants' profits or all of the damages sustained by Servier as a result of the defendants' activities which infringed the 196 Patent. Servier elected to recover the profits the defendants earned by reason of their infringing activities.

[5] Thereafter, following a lengthy trial, the Federal Court determined the amount of Apotex' profits which were attributable to the infringing activity. This required the Federal Court to consider the manufacture and sale of perindopril tablets in Canada as well as their sale abroad. Apotex' profits from the sale in Canada of perindopril tablets in Canada are not in issue on this

appeal because at trial Apotex acknowledged that there was no alternative to infringing the 196 Patent for domestic sales of perindopril. It followed that Apotex was required to completely disgorge its Canadian profits. At issue in this appeal are Apotex' profits from the sale of perindopril tablets abroad, particularly sales made to affiliates of Apotex located in Australia (Apotex Australia) and the United Kingdom (Apotex UK).

[6] To determine the profits earned by the defendants on export sales, the Federal Court was obliged to determine a number of issues, only two of which are at issue in this appeal:

i. With respect to export sales, were there non-infringing alternatives to the infringing perindopril Apotex sold, and if so, what were Apotex' profits attributable to its use of the patented invention?

ii. With respect to the export sales made to Apotex' affiliates in Australia and the United Kingdom, was any part of the profit realized attributable to non-infringing services, namely the provision of an indemnity and related legal services Apotex agreed to provide to its foreign affiliates? If so, this profit was not attributable to the sale of infringing perindopril tablets.

[7] The Federal Court, in reasons cited as 2015 FC 721:

i. rejected the argument that Apotex' profits should be reduced by taking into account the availability of non-infringing alternatives; and,

ii. rejected the argument that Apotex' profits should be reduced on the basis that a portion thereof was attributable to non-infringing services it provided.

[8] This is an appeal from the judgment of the Federal Court. On this appeal Apotex asserts that the Federal Court erred in two respects by:

i. failing to reduce the profits Apotex received from infringement by taking into account the availability of non-infringing alternatives; and,

ii. failing to apportion or segregate the profit Apotex earned on the sale of infringing perindopril from the profit it earned from the provision of the indemnity and related legal services Apotex agreed to provide to its foreign affiliates.

[9] For the reasons that follow, I have concluded that the Federal Court erred in law by rejecting the relevance at law of any available non-infringing perindopril and failed to adequately consider the evidence adduced as to the ability and willingness of three suppliers to provide non-infringing perindopril. In light of the factually complex evidentiary record before the Federal Court and the need to assess the credibility of the evidence, I would remit this issue to the Federal Court as described in more detail below. I have further concluded that while the Federal Court committed an extricable error of law in its interpretation of contracts between Apotex and its affiliates, it did not err in its ultimate conclusion that this is not a proper case to apportion Apotex' profit. It follows that except for the single issue I would remit to the Federal Court, I would in all other respects dismiss the appeal.

[10] I begin my analysis by briefly reviewing the decision of the Federal Court as it relates to the two issues on appeal. I then move to consider the standard of review to be applied to the decision of the Federal Court. Each issue is then addressed.

I. The Decision of the Federal Court

[11] After setting out the issues raised on the accounting, the Federal Court moved to consider whether the profit Apotex earned on certain export sales should be apportioned so as to segregate profit earned from the provision of an indemnity and related legal services from the profit earned on the sale of infringing perindopril.

[12] The Federal Court began by setting out the procedural history of this issue: the issue was not raised until shortly before trial when Apotex presented a motion to allow it to file two addenda to the report in chief of its expert witness, Howard Rosen. Mr. Rosen is a chartered accountant with expertise in the quantification of loss and the accounting of profits in intellectual property disputes. The motion to allow the addenda was granted less than a month prior to the commencement of the hearing (reasons, paragraphs 19 and 20).

[13] The Federal Court then expressed its agreement with the general principle that "the provision of foreign litigation services and of an indemnity for liability under foreign patents does not constitute an infringement of the 196 Patent." It followed that the question to be determined was whether the defendants had provided sufficient evidence to prove that a portion of the price paid in respect of the sale of perindopril tablets was on account of the indemnity and non-infringing services (reasons, paragraph 30).

[14] The Federal Court then reviewed the evidence adduced by Apotex, including the written agreements entered into between Apotex and both Apotex UK and Apotex Australia relevant to sales of perindopril (transfer price agreements) (reasons, paragraph 31 to 46). Of relevance to this appeal is that the transfer price agreements drew a distinction between the transfer price to be paid for a "Patent Challenge Product" and that to be paid for a non-patent challenge product. Patent Challenge Products were defined in the agreements. Simply put, they were products viewed to carry a heightened litigation risk in the relevant jurisdiction. The heightened risk was viewed to arise when Apotex' affiliate was the only generic in the market for perindopril, the

patentee had an unexpired patent for perindopril and the patentee sold a branded version of perindopril.

[15] The Federal Court began its analysis of the evidence by rejecting Servier's contention that the transfer price agreements explicitly define the transfer price to be solely in respect of the supply of perindopril tablets. While the transfer pricing agreements between Apotex and its affiliates define the "transfer price" to mean the price to be paid by the affiliate to Apotex "for the supply of the Product", the Federal Court found that the transfer price agreements "must be interpreted in the light of the entire agreement and that the commercial logic behind the formula for two prices does take into account the increased risk of the sale of a Patent Challenge Product" (reasons, paragraph 51).

[16] This said, the Federal Court then rejected the assertion that the higher price paid by Apotex UK and Apotex Australia for perindopril as a Patent Challenge Product "was paid solely on account of the indemnity provision and related litigation services". Thus the Federal Court found the transfer price to be on account only of the sale of the drug perindopril (reasons, paragraph 51). The Federal Court reached this conclusion for the following reasons:

i. The "provisions of the transfer price agreements that deal with the Transfer Price are distinct from those provisions that provide for an indemnity and related services and are severable." It could not be argued "that the higher price is, in full or in part, a consideration for the indemnity if, in case the Transfer Price provisions are found to be invalid or unenforceable, the indemnity provisions will remain in full force and effect." Additionally, the indemnity and related services were offered even if there was no litigation or risk of litigation and the product was sold at the lower non-patent challenge product price (reasons, paragraph 52).

ii. The choice of the higher Patent Challenge Product price was likely triggered, at least in part, by Apotex' desire to enhance its profitability in cases where its affiliate was the only generic in the marketplace (reasons, paragraphs 56-59). The

Federal Court rejected Apotex' contention that the only factor that triggered the higher Patent Challenge Product price was the increased risk of litigation. Rather, the triggering event for the change in price was the presence of one or more generic competitors in the market – a factor which impacted the profitability of the product (reasons, paragraph 54).

iii. The transfer price agreements provided that any awards or settlements received by Apotex' affiliates in litigation were to be shared with Apotex. This was a significant consideration for the indemnity and legal services offered by Apotex to its foreign affiliates (reasons, paragraphs 60-63).

[17] Additionally, the Federal Court expressed the opinion that segregating or apportioning the revenue Apotex received would not be equitable (reasons, paragraph 51). No additional reasons were given for this conclusion.

[18] The Federal Court then moved to consider Apotex' next argument that there were a number of viable, non-infringing alternative sources of both bulk perindopril active pharmaceutical ingredient and perindopril tablets that, if used, would have resulted in lower profits on Apotex' export sales than it received as a result of manufacturing and selling perindopril tablets from Canada.

[19] After surveying the relevant jurisprudence, the Federal Court concluded that in *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 the Supreme Court did not "suggest that in an accounting of profits, courts are bound to always consider [non-infringing alternative] products, options or scenarios, as fanciful as they may be." Rather, the Supreme Court "simply reiterated that 'the inventor is only entitled to that portion of the infringer's profit which is causally attributable to the invention'" (reasons, paragraph 118). The Federal Court went on to reject Apotex' argument that its profits should be calculated taking into account the

availability of non-infringing perindopril for export sales. It did so for the following three reasons:

i. As expressed by the Federal Court at paragraph 119 of its reasons:

> "Tracing causation is a factual endeavour. In some cases, it could almost be as complex as the invention, and it will require factual or expert evidence. In other cases, as the one before me, there is no need for a very sophisticated analysis of the causal relationship between the infringement and the infringer's profits as the defendants merely sold perindopril, the compound covered by the 196 Patent."

ii. To accept the relevance of a non-infringing alternative for export sale would provide infringers with "a perfect shelter against the consequences of any future patent infringement in Canada" (reasons, paragraph 121).

iii. Apotex' argument was akin to the argument advanced by it in *Wellcome Foundation Ltd v. Apotex Inc.*, [1998] F.C.J. No. 1205, 151 F.T.R. 250 when it argued that it could have legally manufactured the infringing product by obtaining a compulsory license from the patentee. This argument was rejected in that case and was not supported by the case law (reasons, paragraph 122).

[20] Having rejected the relevance at law of non-infringing alternatives, it was not necessary for the Court to consider whether, on the facts of the case, non-infringing alternatives were available. However, the Federal Court noted that "as more than half of the time spent at trial was devoted to the evidence pertaining to that question" the Court would "provide a few comments" (reasons, paragraph 128). The Federal Court then in the course of four paragraphs, paragraphs 129 to 132, briefly reviewed the evidence for the purpose of determining "which alternative would, all things considered, most likely have been used" (reasons, paragraph 134).

[21] The Federal Court then provided the following comments:

i. If perindopril was at the relevant time readily available on the international market, why did Apotex choose to manufacture perindopril in Canada where Servier held an unexpired patent (reasons, paragraph 136)?

ii. No explanation was given as to why a technology transfer to a third party, Signa S.A. de C.V. (Signa), was not completed. This technology transfer would have allowed Signa to supply Apotex with perindopril active pharmaceutical ingredient (reasons, at paragraphs 131, 136).

iii. Apotex failed to demonstrate that an entity referred to as Srini could have obtained regulatory approval and manufactured the required quantity of perindopril active pharmaceutical ingredient at the relevant time or at the quoted price (reasons, paragraphs 137, 138).

iv. Apotex failed to demonstrate Apotex Netherlands, also referred to as Katwijk Farma B.V. could have manufactured the required quantity of perindopril tablets at the relevant time (reasons, paragraphs 132, 140).

v. Even if the defendants' affiliates had demonstrated that they could have manufactured the required quantity of perindopril tablets, Apotex had not shown that this would have resulted in it receiving any profit on the sale of the tablets. Rather, "if those profits had made their way to Canada, it would most probably have been through dividends paid to [the affiliates'] mother companies … not to the defendants" (reasons, paragraph 141).

II. Standard of Review

[22] The standard of review applicable to the issues raised on this appeal 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.

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

III. The Issue of Non-infringing Perindopril

[24] Apotex' submissions on this issue may be summarized as follows:

i. A defendant need only disgorge profits which are causally linked to the patentee's invention. Citing *Schmeiser*, if all of the profits claimed by Servier could have been earned without infringing of the 196 Patent, then the profits to be disgorged are nil.

ii. The evidence established that there were several sources of non-infringing perindopril available to Apotex to sell abroad.

[25] I begin my analysis of Apotex' submissions by considering whether the Federal Court erred by rejecting the relevance at law of non-infringing perindopril for export sales. I then consider the Federal Court's assessment of the evidentiary record before it.

A. The legal relevance of non-infringing perindopril when calculating the profits earned by the defendants by reason of their infringing activities

[26] The starting point of this analysis must be the decision of the Supreme Court in *Schmeiser*, cited above at paragraph 19. In *Schmeiser*, 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.R. 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 is 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, 'where profits are allocated according to the value contributed to the defendant's wares by the patent'". 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 and its

earlier decision *Collette v. Lasnier* (1886) 13 S.C.R. 563 at page 576, the Supreme Court explained that a "comparison is to be made between the defendant's profits attributable to the invention and his profit had he used the best non-infringing option".

[27] The need for a comparison between a defendant's profit attributable to the invention and the defendant's profit using the best non-infringing alternative is explained in the Siebrasse article cited by the Supreme Court. There, at page 92, Professor Siebrasse writes:

> The differential profit approach looks to the profits causally attributable to the infringement, while the cost-based approach looks to the costs causally attributable to the infringement, and the whole profits approach and physically based apportionment more generally, looks to the physical changes causally attributable to the invention. The profits are clearly the correct criterion, for two reasons. First, the award is an award of profits, and the causal link must be between the award and the infringement. Secondly, awarding profits according to the value added by the patented invention and opposed to the proportionate cost or physical size, is consonant with fundamental nature of patents as *intellectual* property. What is valuable is the intellectual contribution which is embodied in an invention, not the physical contribution. It may be that even though the patented aspect is only a small part of the wares which are sold, either by physical proportion or by cost, the entire value of the wares is due to the patent. In such a case, which is not uncommon, the differential profit rule will allocate the entire profits to the patentee.
>
> [Italics in the original]
>
> [Underlining added]

[28] Servier argues that *Schmeiser* did not definitively preclude the use by a trial judge of other valuation methods, better suited to a different set of facts and that it was open to the Federal Court to proceed as it did. I acknowledge that in *Schmeiser* the Supreme Court referred to the differential profit approach as the "preferred means" of calculating an accounting of profits – not the only means. However, at bottom is the need to ensure that a patentee only receives that portion of the infringer's profit that is causally attributable to the invention. In this circumstance,

I accept the submission of Apotex that the value of the invention can only be quantified if non-infringing alternatives are considered. This is so because the value of a patent lies in the ability of the patentee to exclude competitors and competition.

[29] Thus, Professor Thomas F. Cotter, an American scholar whose principal research and teaching interests are in the fields of domestic and international intellectual property law, antitrust law, and law and economics, wrote in *Comparative Patent Remedies: A Legal and Economic Analysis* (New York: Oxford University Press, 2013) at pages 189 to 190:

> 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]

[30] In this circumstance I conclude that the Federal Court erred in law by rejecting Apotex' argument that its profits should be calculated taking into account the availability of non-infringing perindopril for export sales and by failing to apply the differential profit approach.

[31] Before leaving this issue, I wish to deal with the three reasons given by the Federal Court for rejecting the relevance of non-infringing perindopril. Those reasons are summarized at paragraph 19 above.

[32] As I understand the reasons of the Federal Court, the first reason for rejecting the relevance of the non-infringing perindopril was that a non-infringing alternative cannot be the patented product itself. To the extent the Federal Court rejected the relevance of non-infringing

perindopril because the defendant sold perindopril, this conclusion is inconsistent with *Schmeiser* where the Roundup Ready Canola sold by the defendant Schmeiser consisted entirely of the patented genes and the differential profit approach was nonetheless applied.

[33] Additionally on this point, the 196 Patent has no extraterritorial reach. Thus, perindopril may be manufactured in jurisdictions where it was never patented. It may also be manufactured in jurisdictions where Servier held a patent, but the patent has been invalidated or has expired. Ignoring perindopril manufactured in such jurisdictions when assessing Apotex' profit would give an extraterritorial reach to the 196 Patent.

[34] The second reason given by the Federal Court was policy based: considering a non-infringing alternative to be relevant would provide infringers with "a perfect shelter" against the consequences of their infringement. This argument was rejected by this Court in *Apotex Inc. v. Merck & Co. Inc.*, 2015 FCA 171, 387 D.L.R. (4th) 552 (*Lovastatin*) at paragraph 71. While *Lovastatin* considered a claim for compensatory damages for patent infringement, the comments have equal application to an accounting for profits. In any event, policy reasons cannot trump the requirement that an infringer's disgorged profit must be only the profit which is causally attributable to the invention.

[35] The final reason given by the Federal Court, based upon the rejection of an argument in *Wellcome Foundation*, cannot stand for the reason that it is contrary to the application of the differential profit approach applied by the Supreme Court in *Schmeiser*.

[36] Having concluded that the existence of non-infringing perindopril was legally relevant, it is necessary to consider what the evidence established as a matter of fact.

B. The Federal Court's assessment of the evidence

[37] Apotex advances two arguments in respect of the evidence. First, it submits that the availability of non-infringing perindopril was already determined at the liability stage of the proceeding when the trial judge wrote at paragraph 509 of the liability judgment:

> Apotex could have avoided all of the manufacturing infringement by making perindopril - containing products outside of Canada. This is not just speculation. As acknowledged by a number of witnesses for Apotex, Apotex also has manufacturing facilities in India and is in the process of obtaining authorization to produce perindopril from that site.

[38] Second, Apotex argues that to the extent the Federal Court's "comments" on the evidence are found to constitute a finding that Apotex could not have secured non-infringing perindopril for sale to Australia or the United Kingdom, the finding is unsupported by the evidence and based upon palpable and overriding error.

[39] Servier responds that the trial judge made no binding finding of fact in the liability judgment as to the availability of non-infringing perindopril and, in any event, the judge's comment that Apotex was in the process of obtaining authorization to produce perindopril in India falls short of a finding that Apotex could have replaced all of the infringing material. It further responds that the evidence failed to establish that Apotex could and would have replaced all of the infringing perindopril it sold with non-infringing perindopril. Finally, Servier argues

that the Federal Court found none of the hypothetical non-infringing alternative scenarios posited by Apotex would have resulted in any profits flowing to Apotex.

[40] I begin my analysis with the observation that when considering the availability of non-infringing alternatives one enters the world of the hypothetical – in the real world the defendant used an infringing product. This Court considered the nature of the hypothetical world in *Lovastatin*. Notwithstanding that *Lovastatin* concerned a claim for compensatory damages, not an accounting of profits, again I believe that the Court's commentary in *Lovastatin* has equal application to this case. In both situations the Court is to consider a hypothetical world where the infringing conduct did not take place.

[41] In *Lovastatin* the Court found that for a defendant to show that in the hypothetical world it would have been able to obtain a non-infringing product, the defendant must establish that in the hypothetical world it would and could have obtained sufficient quantities of non-infringing product, and that it would and could have used the non-infringing product (*Lovastatin*, paragraphs 49 – 53, 70, 73 and 77-79).

[42] As this Court later explained in *Pfizer Canada Inc. v. Teva Canada Limited*, 2016 FCA 161, 483 N.R. 275, (*Effexor*) at paragraph 50, both the "could have" and "would have" requirements are important. To prove "could have", the defendant must demonstrate that it was possible for it to secure non-infringing product. To prove "would have", the defendant must demonstrate "that events would transpire in such a way as to put them in that position" (*Effexor*, paragraph 50). The importance of the "would have" requirement is that by requiring a defendant

to show that it would have used a non-infringing alternative, the defendant shows that the value of the patented invention is not such that reliance on alternatives is unlikely or fanciful. Put another way, notwithstanding the availability of a non-infringing alternative, the defendant must show that there are no impediments to its use.

[43] Having set out this background, I turn to Apotex' first argument: the availability of non-infringing perindopril was already determined in the liability judgment. I disagree.

[44] The passage Apotex relies upon is found in that part of the liability judgment which considers whether Servier had shown a basis for obtaining the equitable remedy of disgorgement of Apotex' profits. The trial judge's remark was a comment on Apotex' behaviour in choosing to make perindopril in Canada "fully knowing that making perindopril would constitute infringement and that it might be required to disgorge its profits" (liability judgment, paragraph 509). This was not a comment intended to forestall Servier from being able to argue that in the hypothetical world Apotex could not and would not have supplied non-infringing perindopril.

[45] Additionally, I accept Servier's submission that the passage Apotex relies upon falls well short of a finding that Apotex could and would have used non-infringing perindopril for its export sales.

[46] I now turn to the Federal Court's findings on the evidentiary record before it.

[47] Apotex adduced evidence in the Federal Court about the availability of non-infringing perindopril from a number of sources. The findings of the Federal Court on that evidence are summarized above at paragraph 21.

[48] I accept Servier's submission that a judge need not refer to all of the evidence adduced before the court. Reading the reasons of the Federal Court fairly, I am satisfied that the Federal Court found as a fact that neither Srini nor Katwijk could have manufactured the required quantity of non-infringing perindopril at the relevant time. Apotex has not demonstrated any palpable and overriding error in that finding.

[49] Greater difficulty is posed however with respect to three specific suppliers: Signa, IPCA Laboratories Ltd. (IPCA) and Intas Pharmaceuticals Ltd. (Intas).

[50] Evidence adduced with respect to these entities included the following.

(1) Signa (Transcript November 24, 2014, at pages 876 to 936)

[51] Signa's General Manager, Oscar Vivanco, testified that Signa is a producer of fine chemicals located in Toluca, Mexico which manufactures active pharmaceutical ingredients. During the years in issue, 2005 to 2008, it was one of the largest fine chemical producers in the Americas, if not the largest. Signa began its relationship with Apotex in 1994 or 1995, selling active pharmaceutical ingredients to it. In September 2011, Signa joined the Apotex group of companies.

[52] With respect to perindopril, Mr. Vivanco testified that in 2004 Signa received a technology transfer package from Brantford Chemicals (now known as Pharmachem) together with the raw materials required to produce perindopril. The program was never finished because Apotex decided to produce perindopril at a different location. However, had Apotex approached Signa in 2004 or 2005 and asked Signa to finish the program, Signa could have produced 2,000 kg of perindopril in each of 2006, 2007 and 2008.

(2) IPCA (Transcript November 26, 2014, at pages 1297 to 1372)

[53] IPCA's President of the Generics and Head Mission Malaria, Murali Sarma, testified that IPCA is a medium-sized pharmaceutical company listed on both the Bombay Stock Exchange and the National Stock Exchange in Mumbai. To the witness' knowledge, Apotex does not hold shares in IPCA. IPCA manufactures active pharmaceutical ingredients and also formulates tablets. During the relevant period, IPCA sold active pharmaceutical ingredients to a number of researched-based pharmaceutical companies. AstraZeneca, BASF, Bayer, GlaxoSmithKline, Merck, Pfizer, Roche and Sanofi Aventis were all customers of IPCA. IPCA also sold active pharmaceutical ingredients to generic pharmaceutical companies such as Apotex, Actavis and Mylan. About 1% of its business related to Apotex.

[54] During the period from 2005 to 2008, IPCA manufactured small quantities of perindopril for the purpose of regulatory filings and exported this product. While it did not formulate perindopril during this period, IPCA had the capacity to do so. Therefore, had Apotex approached IPCA in 2005 or 2006 and requested that IPCA manufacture between 1,000 and 2,000 kg of perindopril active pharmaceutical ingredient in each of 2006, 2007 and 2008 and

then tablet that perindopril active pharmaceutical ingredient into between 9 and 16 million tablets per month, IPCA would have taken such an order and would have manufactured perindopril for Apotex. At that time IPCA had the necessary regulatory approvals in place in order to send finished dosage materials to the United Kingdom, Australia and the Netherlands.

(3) Intas (Transcript November 26, 2014, at pages 1372 to 1410)

[55] Intas's Executive Vice-President of Global Licensing and Third-Party Sales, Marc Comas, testified that Intas develops, produces and sells generic drugs around the world. It is a privately held company with headquarters in India. Mr. Comas referred to it as a "700 million U.S. dollar company."

[56] Intas produces active pharmaceutical ingredients for internal use only; Intas only produces finished products.

[57] Had Apotex approached Intas in mid-2005 with a view to commercial production on a monthly basis of approximately 16 million tablets of perindopril, Intas would have worked very hard to achieve this production. Intas had the capacity, the necessary Good Manufacturing Practice certificates, and a business team in place looking for this type of business. Mr. Comas saw no reason why Intas would not be able to do so.

[58] While Intas did not produce perindopril during the years 2006 to 2008, in 2010 its wholly owned subsidiary, Accord Healthcare, was granted marketing authorization in the United Kingdom for perindopril, with a right to transfer production to Intas in India. Commencing in

August 2011, Intas supplied perindopril tablets to Accord Healthcare for sale in the United Kingdom and it continues to do so.

[59] The Federal Court made bare mention of these suppliers. The sole mention to the evidence adduced on behalf of Signa was that no explanation was provided as to why Apotex instructed Signa to stop work on the technology transfer project for perindopril (reasons, paragraph 136). While events in the real world inform construction of the hypothetical "but for" world (*Lovastatin*, paragraph 90), the fact the project was stopped is not necessarily dispositive of Signa's capacity in the "but for" world.

[60] The Federal Court's only reference to the evidence of IPAC and Intas was a statement that they "could have formulated the perindopril tablets" (reasons, paragraph 135). It is not clear, however, whether this was a finding of fact or a very short summary of the evidence of Dr. Sherman on behalf of Apotex.

[61] Servier characterizes the evidence summarized above to be speculative and hypothetical. However, 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 (*Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142, at page 186, 167 D.L.R. (4th) 577). An inference is grounded in evidence and so is not speculative.

[62] Servier also objects that no palpable error has been shown on the part of the Federal Court. IPCA never formulated perindopril tablets, and from 2005 through 2008 it only made

small quantities of the active pharmaceutical ingredient perindopril for regulatory filings. Intas did not hold regulatory approval to make perindopril tablets before 2010 and then it only made and sold perindopril tablets in 2011. I reject this argument as well. As set out above, the fact an event does not take place in the real world does not necessarily mean that the event could not and would not have taken place in the hypothetical world.

[63] Signa, IPCA and Intas were at the relevant time, manufacturers of substance in an arm's-length relationship with Apotex. The evidence adduced through them, if believed, could have led the Federal Court to conclude that, in the hypothetical world, Apotex would and could have obtained significant quantities of non-infringing perindopril. It would remain for the Federal Court to consider whether Apotex would and could have used that perindopril for sales to the United Kingdom and Australia.

[64] If the Federal Court intended to conclude on all of the evidence that Apotex could not obtain and would not use non-infringing perindopril, it was a reviewable error for the Federal Court not to explain why it rejected the evidence of Signa, IPCA and Intas. If, instead, in view of its primary finding that the existence of a non-infringing alternative was not legally relevant the Federal Court intended to provide only selective comments on the evidence, in light of this Court's conclusion that a non-infringing alternative is legally relevant, it is necessary for the evidence of Signa, IPCA and Intas to be fully considered. In either event, taking into account the factually complex evidentiary record before the Federal Court and the need to assess the credibility of the evidence, I am of the view that the issue should be returned to the Federal Court for determination.

[65] For clarity, the issue I would remit to the Federal Court is whether Apotex would have and could have obtained quantities of non-infringing perindopril from any of Signa, IPCA or Intas and, if so, whether Apotex would have and could have used non-infringing perindopril for sales to its affiliates in the United Kingdom and Australia. I would confine the issues to these three suppliers because Apotex has not demonstrated any error with respect to any other supplier. The Federal Court is to decide this issue on the record before it, with discretion to receive additional evidence if such evidence would be of assistance and its acceptance would not prejudice the parties opposite.

[66] Three final comments must be made before leaving this issue.

[67] First, it may be that the Federal Court could conclude in the hypothetical world that one or more suppliers would not or could not supply perindopril in time to replace the initial infringing sales. However, this would not end the inquiry as the Federal Court would still have to consider whether at some later point in time a supplier would and could have provided replacement non-infringing tablets.

[68] Second, I am mindful that at paragraph 141 of its reasons the Federal Court found it was not satisfied that if Apotex' affiliates could have manufactured perindopril, any profit would accrue to the defendants. As none of Signa, IPCA or Intas were affiliates of Apotex at the relevant time, this finding is of no assistance to Servier. In any event, I have difficulty understanding the relevance of the finding. The relevant inquiry is if Apotex could have arranged its affairs to provide perindopril tablets from non-infringing activities. If so, the 196 Patent

contributed little or no value to the profits earned by Apotex on foreign sales. How profits were divided within the Apotex group is not relevant.

[69] Finally, should the Federal Court answer the issue remitted to it in the affirmative, it follows that the Federal Court must quantify the impact of that finding on Apotex' profit on sales made to Apotex Australia and Apotex UK. The Federal Court should then consider what, if any, entitlement Apotex has to interest on monies it paid to Servier which are in excess of its obligation as calculated taking a non-infringing alternative into account.

IV. The Issue of Apportionment

[70] Apotex asserts that the Federal Court erred in refusing to apportion the revenue Apotex received under the transfer price agreements for the sale of perindopril to Apotex UK and Apotex Australia. It says that the Federal Court committed a number of errors in its interpretation of the transfer price agreements. Properly interpreted, the higher price paid for perindopril as a Patent Challenge Product reflected the price paid for the indemnity and related legal services Apotex agreed to provide to its foreign affiliates.

[71] For the reasons developed below I reject this assertion. I begin my analysis with a discussion of the causation requirement and conclude that apportionment is not appropriate on the facts of this case because "but for" its infringing activities, Apotex would have earned nothing. While this conclusion is dispositive of Apotex' appeal on this issue, I then consider the standard of review to be applied to the issue of contractual interpretation and the applicable principles of contractual interpretation. Applying those principles I conclude that the Federal

Court's interpretation of the transfer pricing agreements was based on an extricable error of law. This said, applying the required interpretive principles I conclude that Apotex failed to establish that the transfer pricing agreements apportion revenue as it asserts.

A. The requirement of causation

[72] It is a question of fact whether any profits earned by Apotex under the transfer price agreements for the sale of perindopril flowed from something other than the patented invention, and Apotex bears the burden of establishing this fact. The question bears "on the relationship between the profits earned and the appropriation of the patented invention" (*Imperial Oil Limited v. Lubrizol Corporation*, [1997] 2 F.C.R. 3, 71 C.P.R. (3d) 26 (C.A.), at paragraph 9.

[73] As explained in *Beloit Canada Ltée/Ltd. v. Valmet Oy* (1994), 78 F.T.R. 86, 55 C.P.R. (3d) 433 (F.C.T.D.), at page 457:

> There is no question however, that the individual circumstances of a particular case may render an apportionment of profits the only equitable solution. The test in determining if there should be an apportionment is based on the saleability, as a whole, of the product which contains the patented invention. The question for the court is whether the market demand for the defendant's product arose because of the infringed patent or whether it arose by virtue of the product's additional features. In other words, the inquiry is directed to "the value of the patented part to the machine as a whole", to use the words of Lord Shaw in Watson Laidlaw.
>
> This determination is a factual one to be made on the basis of all the evidence. The answer depends entirely on the particular circumstances of each case. The onus is on the defendant to adduce sufficient evidence to satisfy the court that consumer demand for its product arose by virtue of features other than the plaintiffs' infringed patent. If the defendant's evidence in this regard is inadequate, the court will not make an apportionment.
>
> [Underlining added]

[74] While this decision was reversed in part on other grounds ((1995), 184 N.R. 149, 61 C.P.R. (3d) 271 (C.A.)), the trial court's treatment of the apportionment issue was affirmed.

[75] As will be explained in more detail below, the transfer price agreements contemplated a higher price for the sale of perindopril because it was a Patent Challenge Product. The rationale for this was explained at trial by Jeffrey Adams, Apotex Inc.'s Vice-President of International Sales, as follows:

> Around 2006, we were starting to expand internationally. Our expansion efforts were really driven around some of the acquisitions, some of the start-ups that we have been discussing in terms of the U.K., Australia, the Netherlands. In addition to the expansion, there was also a recognition that certain products within our portfolio around that time carried with them a very high likelihood of patent risk. We knew this, and we needed to put a mechanism in place to address the increased risks associated with those products. Bearing in mind that, at the time, the affiliates were quite fragile start-ups, and these small acquisitions did not have a strong financial base and were at risk if we were to lose the patent challenge.
>
> (transcript December 2, 2014, starting at line 16, page 1759)

[76] Mr. Adams explained the steps Apotex took to protect the frailty of its affiliates:

> Generally, in these situations, we provided – let's call it the indemnity transfer price agreement. As the name suggests, there was an indemnity component. The perceived value of the indemnity was quite high in situations like this where there was a potential patent challenge. It also accounted for the anticipated high legal costs and the potential for fairly high damages associated with an event of a negative litigation outcome.
>
> (transcript December 2, 2014, starting at line 19, page 1760)

[77] Mr. Adams also explained that Apotex believed that "where the patent risk was high, that it was reasonable for Apotex to charge a higher transfer price to account for the value of the

indemnity that they were providing but also the damages and the potential legal costs which were quite high" (transcript December 2, 2014, starting at line 1, page 1763).

[78] In the 2006-2007 timeframe discussed by Mr. Adams, the principal product viewed by Apotex to be at patent risk was perindopril.

[79] What drove Apotex' sales of perindopril were the new and useful characteristics of the drug. Had perindopril not been protected by the 196 Patent, there would have been no need for Apotex to provide an indemnity to protect the fragility of its affiliates. "But for" the infringing qualities of perindopril, Apotex would have earned nothing on its sale, whether attributable to the drug itself or to the indemnity required to protect the affiliates. Thus, the profit resulting from the sale of perindopril was entirely causally attributable to the invention. It follows that no apportionment is warranted.

[80] This conclusion is consistent with Apotex' earlier experience with paroxetine in the United Kingdom where Apotex solicited third-party distributors to market and sell the product. Distributors would not "take the product without an indemnity" (transcript December 2, 2014, starting at line 11, page 1761). In consequence Apotex supplied an indemnity. The indemnity was a condition precedent imposed by the distributors in light of the risk of liability for infringement. There was no evidence the purchase price for paroxetine was apportioned in light of the indemnity.

[81] As stated above, the finding that all profits earned from the export of perindopril were causally attributable to the 196 Patent is fatal to Apotex' apportionment argument. However, I reach the same result when the transfer price agreements are properly interpreted.

B. The transfer price agreements

(1) The standard of review

[82] In *Sattva Capital Corp. v. Creston Moly Corp.*, 2014 SCC 53, [2014] 2 S.C.R. 633, the Supreme Court concluded, at paragraph 50, that contractual interpretation "involves issues of mixed fact and law as it is an exercise in which the principles of contractual interpretation are applied to the words of the written contract, considered in light of the factual matrix." It followed that contractual interpretation should be dealt with as a question of mixed fact and law, attracting a deferential standard of review unless an extricable error of law is identified. One example of such an extricable legal error identified by the Court was the application of an incorrect principle. This said, the Supreme Court cautioned that courts should be cautious in identifying extricable questions of law.

(2) Principles of contractual interpretation

[83] *Sattva* also provides useful guidance on the interpretation of contracts. The construction of a contract is to be based on common-sense. It is not to be based on technical rules of construction. The overriding concern is to determine "the intent of the parties and the scope of their understanding" (*Sattva*, paragraph 47).

[84] Contracts are to be read as a whole. Words are to be given their ordinary and grammatical meaning. The meaning is to be consistent with the surrounding circumstances known to the parties at the time the contract is formed. These surrounding circumstances are often referred to as the "factual matrix". While the scope of the factual matrix is broad, it is not without limits. The factual matrix is to be assessed objectively; the factual matrix does not include evidence of subjective intentions.

(3) Application of the standard of review and the principles of interpretation

[85] As discussed above, the Federal Court rejected the assertion that the higher Patent Challenge price "was paid solely on account of the indemnity provision and related litigation services" (reasons, paragraph 51). The Federal Court's reasons for this conclusion are summarized above at paragraph 16.

[86] Apotex asserts that the Federal Court committed a number of extricable errors of law in its analysis. I agree that it was an error of principle for the Federal Court to rely upon a boilerplate severability clause in order to interpret the intentions of the parties.

[87] The severability provision contained in each transfer price agreement provided:

> Any provision herein which in any way contravenes the law or which is invalid or unenforceable, in whole or in part, shall be deemed to not be a part of this Agreement and shall be severable therefrom and the remainder of this Agreement shall remain in full force and effect.

[88] This provision evidences the parties' objective intention to take advantage of the common law doctrine of severance. This doctrine allows invalid parts of the contract to be separated from

the valid parts. Severance contemplates the unintended situation where a term of a contract is found to be invalid. Accordingly, a severance provision does not inform the broader objective intention of the parties and their understanding when they entered into a valid contract.

[89] Servier argues that the Federal Court's reliance upon the severability provision did not dominate its interpretation of the transfer price agreements. However, the remaining reasons given by the Federal Court are not persuasive and are not sufficient to justify its conclusion. I reach this conclusion for the following reasons.

[90] First, Apotex' obligation to indemnify existed irrespective of whether the product was a Patent Challenge Product. Accordingly, this fact by itself does not answer the question of whether the higher Patent Challenge price is attributable to the value provided by the obligation to indemnify.

[91] Next, the Federal Court rejected Apotex' contention that the factor that triggered the higher Patent Challenge price was the increased risk of litigation. The Court instead found that the higher price was triggered, at least in part, by Apotex' desire to enhance its profitability. In rejecting Apotex' contention that the increased risk of litigation triggered the higher price, the Federal Court failed to deal with evidence, some of which is quoted above, relevant to the factual matrix. Perindopril carried with it a high likelihood of patent risk and there was a need to protect the "fragility" of the affiliates. This was well known by the parties at the time the transfer price agreements were entered into and the Federal Court ought to have considered this. This said, the

fact a higher price was imposed is not determinative of the question whether this was the objective intent of the parties.

[92] Finally, the fact Apotex would receive a share of any awards or settlements received by its affiliates is again by itself not an answer to whether the higher Patent Challenge price is attributable to the value provided by the indemnification.

[93] Having concluded that the Federal Court committed an extricable legal error when it interpreted the transfer price agreements, I next consider their proper interpretation.

[94] The transfer price agreement between Apotex and Apotex UK is product-specific to perindopril. In my view, the following provisions shed light on the intention of the parties.

[95] Apotex UK agreed to pay a "Transfer Price" which is defined in the agreement to mean "the price to be paid by Apotex UK to Apotex for the supply of the Product" (clause 5.1(e)).

[96] Recitals B and C of the agreement defined the product to be "the generic pharmaceutical product Perindopril" which is a generic version of the "product developed and manufactured by Servier and/or its affiliates … under the brand name Coversyl".

[97] To determine the Transfer Price one must first determine whether perindopril is a Patent Challenge Product. clause 5.1(c) defines a "Patent Challenge Product":

> "Patent Challenge Product" means a generic pharmaceutical product manufactured by Apotex and supplied to Apotex UK for distribution and sale in Territory during the same time that:
>
> (i) a competitor markets and sells a competitive branded version of the same pharmaceutical product for which the competitor holds a recognized unexpired patent in the Territory; and
>
> (ii) there are no other competing generic versions of the same pharmaceutical product marketed and sold in the Territory.

[98] For a Patent Challenge Product clause 5.2 provides:

> Transfer Price – Patent Challenge Product. During any period that the Product is a Patent Challenge Product, Apotex UK shall pay to Apotex a Transfer Price for each shipment of the Product manufactured and supplied by Apotex to Apotex UK for commercial sale in the Territory equal to the Product's Manufacturing Cost plus ninety percent (90%) of the Product Profit.

[99] For a non-patent challenge product the price was to be set on the terms contained in clause 5.3.

[100] Recital F noted that it "is contemplated that [Servier] may challenge the right of Apotex and Apotex UK to manufacture, market and sell" perindopril for use in the United Kingdom. In that event, the indemnification, control of the defence and entitlement to damages provisions found in clauses 1 to 4 of the agreement applied. Briefly, clause 1 obliged Apotex to indemnify Apotex UK against infringement claims. Clause 2 provided that Apotex should assume control of the defence and would be entitled to a percentage of all settlement or damage amounts resulting in infringement action. Clause 3 allowed Apotex to receive a percentage of any settlement or damage amounts resulting from a patent challenge brought in the United Kingdom, a proceeding which only Apotex could initiate. Clause 4 provided that Apotex was to control any litigation.

[101] The Apotex Australia transfer price agreement is very similar to the Apotex UK agreement except for the following:

i. Apotex' entitlement to settlement or damage amounts was set at a different percentage in Australia.

ii. While the Apotex UK transfer price agreement provides that the entry of other generics into the United Kingdom market would trigger a drop in price, a somewhat different provision prevailed in Australia.

iii. Apotex Australia was to pay a Transfer Price of cost plus a different percentage of profit while perindopril was a Patent Challenge Product.

iv. A different provision applied to determine the non-patent challenge product price.

[102] From these provisions I take the following.

[103] First, the agreements define the Transfer Price to be the price paid "for the supply" of generic perindopril. The Transfer Price is to be paid "for each shipment of the Product manufactured and supplied by Apotex" for commercial sale. While not determinative, it is significant that the transfer price agreements do not state that the price difference between Patent Challenge perindopril and non-patent challenge perindopril is in consideration for the indemnification agreement.

[104] Second, and related to this, Apotex' obligations to indemnify and defend were the same whether perindopril was a Patent Challenge Product or not. This makes it difficult to attribute the increased price to an obligation that existed in any event.

[105] Turning to the factual matrix, I do accept that commercially Apotex needed to receive a larger price where the litigation risk loomed large - as it did with perindopril. However, by itself

the need for a larger price falls short of establishing an agreement that Apotex' affiliates agreed to pay the difference between the Patent Challenge price and the non-infringing patent price solely in exchange for Apotex' ongoing obligation to protect them. Such an agreement would carry a number of consequences, including tax consequences. As transfer price agreements it would have been expected that taxing officials would scrutinize the agreements carefully to ensure the fairness of the sale price. This would suggest that any agreement to apportion the revenue should have precisely set out what was to be paid for what.

[106] For these reasons, I find that Apotex has not demonstrated that the revenues received pursuant to the transfer price agreements was intended to be apportioned between revenue received for the drug and revenue received for the indemnity and defence costs it agreed to bear.

[107] Finally, on the facts of this case I find no air of reality to Apotex' apportionment argument in circumstances where:

i. Apotex' pleadings did not refer to apportionment;

ii. during the discovery process Apotex did not suggest that the transfer prices paid by its affiliates were in respect of anything other than the generic drug perindopril; and

iii. in his initial report Apotex' expert, Mr. Rosen, computed Apotex' profits based on its recorded revenues from its sales of perindopril. He did so because he was of the view that the Patent Challenge price represented the fair market value for the sale of perindopril (transcript November 21, 2014, line 26, page 752 to line 17, page 753).

[108] It is simply not credible that Apotex objectively intended to formally apportion the transfer price (as opposed to simply charging a higher price) in circumstances where this notion

was first floated on the eve of trial by an expert accountant retained by Apotex to calculate its profits.

[109] For these reasons, I would dismiss this ground of appeal.

V. Conclusion

[110] For the above reasons, I would allow the appeal in part. I would remit to the Federal Court a single issue to determine in accordance with these reasons. The issue I would remit is: whether 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. This will require that paragraphs 3 and 4 of the judgment of the Federal Court be set aside.

[111] In all other respects I would dismiss the appeal.

[112] As only two issues were raised on appeal and as success was divided on these issues, I would not award any costs on the appeal.

"Eleanor R. Dawson"
J.A.

"I agree.
Boivin J.A."

"I agree.
Woods J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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APPEARANCES:

H. B. Radomski Nando De Luca Ben Hackett	FOR THE APPELLANTS
Judith Robinson Joanne Chriqui Brian John Capogrosso	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Goodmans LLP Barristers and Solicitors Toronto, Ontario	FOR THE APPELLANTS
Norton Rose Fulbright Canada LLP Barristers and Solicitors Montréal, Quebec	FOR THE RESPONDENTS