Federal Court  Cour fédérale

Date: 20180328

Docket: T-1548-06

Citation: 2018 FC 346

Ottawa, Ontario, March 28, 2018

PRESENT: The Honourable Madam Justice Gagné

BETWEEN:

ADIR
AND
SERVIER CANADA INC.

Plaintiffs

and

APOTEX INC.
AND
APOTEX PHARMACHEM INC.

Defendants

JUDGMENT AND REASONS

I. Nature of the Matter

[1] In 2008, the defendants, Apotex Inc. and Apotex Pharmachem Inc. [Apotex], were found liable for infringing ADIR's Canadian Letters Patent No 1,341,196 [196 Patent] by manufacturing and selling perindopril tablets in Canada (*Laboratoires Servier, Adir, Oril*

Industries, *Servier Canada Inc v Apotex Inc*, 2008 FC 825 [Liability Judgment]). The plaintiffs, ADIR and Servier Canada Inc. [Servier], elected to receive an accounting of Apotex's profits and, in *ADIR v Apotex Inc*, 2015 FC 721 [*Perindopril FC*], Apotex was ordered to disgorge its profits attributable to the infringement of the 196 Patent. Apotex appealed and the Federal Court of Appeal granted the appeal in part and sent one issue back to this Court for redetermination (*Apotex Inc v ADIR*, 2017 FCA 23 [*Perindopril FCA*]).

[2] The present reasons are thus directed towards whether any of Apotex's profits from export sales of perindopril could have and would have been realized through use of a non-infringing alternative [NIA]. If so, the profits that it must disgorge to Servier should be reduced accordingly.

[3] For the reasons set out below, I find that Apotex has met its burden of proving that it could have obtained non-infringing perindopril for sale to its affiliates in the United Kingdom [UK] and Australia, but only at a delay of one year from the date of its real world sales.

[4] However, I am of the view that Apotex has not met its burden of proving that, in the hypothetical world, it would have obtained non-infringing perindopril from any of the three proposed non-affiliate suppliers.

II. Issues

[5] The single issue to be determined may be divided into the three following sub-issues:

A. *In the hypothetical world, could Apotex have obtained quantities of non-infringing perindopril from Signa, IPCA and/or Intas for sale to its affiliates in the UK and Australia?*

B. *In the hypothetical world, would Apotex have obtained quantities of non-infringing perindopril from Signa, IPCA and/or Intas for sale to its affiliates in the UK and Australia?*

C. *If questions A and B are both answered in the affirmative, what would be the impact of that finding on the quantification of Apotex's disgorgement of profits to Servier?*

III. Analysis

[6] The parties were offered the possibility to present written and oral submissions on the impact of the *Perindopril FCA* decision on the main issue to be redetermined and to draw the Court's attention to relevant parts of the evidence adduced during the seventeen day trial held in 2014. They filed written representations and compendia of evidence tendered at trial, and a hearing was held for oral submissions.

[7] In *Apotex Inc v Merck & Co, Inc*, 2015 FCA 171 [*Lovastatin FCA*], Justice Eleanor Dawson enunciated in clear terms the test to be used by Canadian courts when asked to consider an NIA defence:

> [73] When considering the effect of legitimate competition from a defendant marketing a non-infringing alternative, a court is required to consider at least the following questions of fact:
>
> > i) Is the alleged non-infringing alternative a true substitute and thus a real alternative?
> >
> > ii) Is the alleged non-infringing alternative a true alternative in the sense of being economically viable?

> iii) At the time of infringement, does the infringer have a sufficient supply of the non-infringing alternative to replace the non-infringing sales? Another way of framing this inquiry is could the infringer have sold the non-infringing alternative?
>
> iv) Would the infringer actually have sold the non-infringing alternative?
>
> [My emphasis.]

A. *In the hypothetical world, could Apotex have obtained quantities of non-infringing perindopril from Signa, IPCA and/or Intas for sale to its affiliates in the UK and Australia?*

[8] In *Lovastatin FCA*, the Federal Court of Appeal referred to the Federal Court of Australia in *Advanced Building Systems Pty Ltd et al v Ramset Fasteners (Aust) Pty Ltd*, [2001] FCA 1098, (2001) 52 IPR 305, which stipulated that an NIA must be instantaneously available on the market at the time of infringement (see *Lovastatin FCA* at para 79).

[9] In *Perindopril FCA*, the Federal Court of Appeal left open the possibility of finding that Apotex could have obtained an NIA from Signa, IPCA and/or Intas in the hypothetical world, even though none of these suppliers had manufactured commercial quantities of perindopril prior to or during the period of infringement:

> [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 UK and Australia.

[10] This real world fact, in my respectful view, adds an additional layer of hypothesis to the consideration of what Apotex could have and would have done, which makes for a more complex determination of what exactly could have transpired in the "but for" world.

[11] Having considered the evidence tendered at trial and the parties' written and oral submissions, I am of the view that Apotex could have used a third-party manufacturer to produce non-infringing perindopril for its sales in the UK and Australia. However, I do not believe that Apotex could have replaced all of its sales made in the real world. The evidence establishes that using a third-party manufacturer to produce perindopril in both Active Pharmaceutical Ingredient [API] and tablet forms would most likely have pushed back Apotex's sales from their real world start dates of July 2006 (the UK) and August 2006 (Australia).

[12] Apotex takes the position that in the hypothetical world, it could have produced non-infringing perindopril via a third-party manufacturer to replace its infringing sales on the same timeline as in the real world. Servier challenges this position as utopic, adding that Apotex's Exhibit D-118, "Timeline of Events as They Could Have Occurred", makes many assumptions that are not supported by concrete evidence.

[13] After reviewing the evidence, I am not convinced that Apotex's proposed timeline is more likely than not to proceed as rapidly as it submits that it could have. In that regard, I agree with Servier that Apotex's proposed timeline is utopic.

[14] I acknowledge that Apotex worked rapidly to get to market in the real world. Graham C. Higson, Servier's European regulatory expert concludes in his expert report: "[I]t is my opinion that Apotex adopted the fastest possible route to regulatory approval in the UK, with the time from the first purchase of perindopril API from Pharmachem for research and development purposes, to MHRA [Medicines and Healthcare products Regulatory Agency] approval, including the 18 months of regulatory agency review, being an impressive 27 months" (Exhibit P-97, para 10.1). I accept that in the hypothetical world, Apotex would likely have worked just as rapidly. Nevertheless, the evidence suggests that there would likely have been numerous delays and setbacks in getting an NIA to market when manufacturing in foreign jurisdictions, pushing back Apotex's proposed timeline. I will discuss the nature of the likely delays below and explain why I do not believe that producing non-infringing perindopril using Signa, IPCA and/or Intas could meet Apotex's D-118 timeline.

[15] Evidence tendered about the hypothetical world is by its nature inexact. Though I am convinced that using a third-party manufacturer would result in delay, the evidence provided is not precise enough to allow me to pinpoint an exact date by which sales to the UK and Australia could have begun in the hypothetical world. Consequently, I propose to apply the "broad axe" principle to conclude that in the hypothetical world, Apotex could have sold non-infringing perindopril at a delay of one year from the date of its real world sales – meaning that in the hypothetical world, Apotex could have sold non-infringing perindopril to the UK and Australia by July 2007 and August 2007, respectively.

[16] The Federal Court of Appeal recently reaffirmed that applying the "broad axe" principle to determine what could and would have occurred in the hypothetical world is entirely appropriate (*Teva Canada Limited v Janssen Inc*, 2018 FCA 33). As Justice Eleanor R. Dawson writes:

> [36] The "but for" world is of necessity a hypothetical and theoretical construct. It is not a world where, in the words of Lord Shaw, "the loss is capable of correct appreciation in stated figures." It follows that the Federal Court did not err in principle by quoting Lord Shaw or by referring in its reasons to a "broad axe." …

[17] Before reviewing the evidence, I will briefly address Apotex's complaint that Servier is "attempt[ing] to cast a new case in its written representations, as opposed to providing the Court with a summary of its position at trial". Apotex takes issue with Servier dedicating much of its new submissions to delays caused by technology transfers and regulatory issues in order to rebut the "could they" branch of the NIA hypothetical world analysis, since those issues were not covered in Servier's initial closing submissions.

[18] I see no problem with Servier's strategy. The state of the law on NIAs has somewhat evolved since 2014. Servier did not include any such arguments in its submissions at trial because the legal relevance of NIAs for computing non-punitive remedies in patent infringement cases where the entire product is found to infringe had not been firmly established at the time. Now that it has been, and that the parties have been permitted to make additional submissions for the purpose of this rehearing, it is both fair and logical to permit Servier to make arguments applying the current law to the trial record.

(1) The "Could They" Framework

[19] The framework to use in order to ascertain whether Apotex could have obtained non-infringing perindopril from Signa, IPCA and/or Intas is the one set out at paragraph 140 of *Perindopril FC*. Apotex has the burden of establishing that its proposed third-party manufacturers can: (a) complete the required technology transfer(s); (b) obtain all marketing approvals; and (c) manufacture the required quantities of perindopril API and/or tablets – all within the relevant timeframe.

[20] In the hypothetical world, Apotex assumes that all R&D is still performed by Pharmachem in Canada between the late 1990s and 2004 and that Apotex still develops the tablet formulation and produces tablets for the purposes of regulatory testing over the course of 2004, as occurred in the real world. In the hypothetical world, Apotex must replace its infringing sales in the UK and Australia, which took place between July 2006 and July 2008. Finally, within that timeframe, Apotex must still receive marketing approvals from the regulatory authorities in the UK and Australia to sell the perindopril manufactured by one or more of its proposed third-party manufacturers.

[21] Apotex advances three separate theories for how it could have obtained non-infringing perindopril from a third-party manufacturer for sale to the UK and Australia. The first theory is that Signa, IPCA and/or Intas are included in its original regulatory applications. The second theory is that they are added in amendments to its pending regulatory applications and the third theory is that they are added in variations to its issued marketing approvals. I will only consider the first theory because it is the fastest means by which Apotex could have obtained non-infringing perindopril in the hypothetical world.

[22] Apotex submits three proposed third-party manufacturers that could supply the UK and Australian markets with non-infringing perindopril on its behalf – Signa (based in Mexico), IPCA (based in India) and Intas (based in India). IPCA is introduced as a supplier of both perindopril API and tablets, Signa as an API supplier and Intas as a tablet supplier.

(2) IPCA as Supplier of Perindopril API and Tablets

(a) *Technology Transfer for API*

[23] Mr. Darren Hall, Vice-President of Global Supply Operation at Pharmachem, testified that Pharmachem had a complete R&D process ready to be transferred to a manufacturing plant by December 2003. He stated:

> Yeah, recall that in earlier testimony I talked that the R&D process would have been available no later than December of 2003. So, at that particular point, we could have initiated a lab to plant transfer of the technology, and that would have been probably the earliest point that we could have done that.
>
> (Trial Transcript Vol 10, page 1595, lines 13-18.)

[24] Mr. Hall further estimated that following the technology transfer, it was his experience that a transferee facility would take about three to four months to complete its first submission batches.

[25] Mr. Higson, Servier's European regulatory expert, testified that someone like Mr. Hall (i.e., someone in charge on the transferring end) would be the most appropriate person to testify as to a transferee's ability to receive and implement a technology transfer package:

> Q. And you would agree with me that the people with the best knowledge about a recipient's ability to receive and implement a tech transfer package of the API would have been those who were involved with such transactions at the relevant time?
>
> A. Not necessarily.
>
> Q. Who would you say had better information than the people that were there?
>
> A. I would say the people who are transferring the package --
>
> Q. Uh-hmm.
>
> A. -- of data are the ones that would be able to assess whether the other manufacturers had the capability to do what they were being asked to do.
>
> (Trial Transcript Vol 14, pages 2144-2145, line 28 and lines 1-13.)

[26] I am therefore of the view that the technology transfer for the production of perindopril API could have occurred as early as December 2003.

(b) *Regulatory Requirements for API*

[27] Mr. Murali Sarma, President of Generics at IPCA, testified that IPCA's Ratlam facility could manufacture perindopril API. The Ratlam facility was Good Manufacturing Practices [GMP] compliant and had been approved by the American Food and Drug Administration [USFDA] from 1989 until at least the date of Mr. Sarma's testimony, and by the European Directorate for the Quality of Medicines [EDQM] from the early 2000s until at least the date of Mr. Sarma's testimony. Mr. Sarma testified that the UK was covered under EDQM approval.

[28] However, while Apotex's Written Closing Submissions at trial stipulate that: "The Ratlam facility was first certified as GMP compliant by the US FDA in 1989, the TGA [Therapeutic Goods Administration] Australia in 1999 and the EDQM Europe in early 2000s, all of which remained in good standing through 2008" (at para 220), Mr. Sarma's testimony does not support the fact that the Ratlam facility had been approved by the TGA. None of Apotex's references to the trial transcript support this point.

[29] It may be that the Ratlam facility's USFDA approval would be considered sufficient GMP compliance for the TGA – an argument that Apotex makes for Signa's API manufacturing facility. However, as discussed below, having the TGA recognize USFDA approval takes several positive steps, a lengthy process that is not accounted for in Apotex's D-118 timeline. Consequently, the regulatory approval stage for IPCA's Ratlam facility is one example of an event that would likely result in delay, affecting Apotex's utopic timeline.

(c) *Ability to Manufacture the Required Quantity of API*

[30] IPCA was already producing small quantities of perindopril API for regulatory purposes from 2005 to 2008. Mr. Sarma testified that had Apotex approached IPCA in 2005 to manufacture the necessary quantity of perindopril API during this time, it could have done so. IPCA's Ratlam facility was only operating at between 66% and 78% of its capacity between 2006 and 2008 and the quantity of perindopril API required by Apotex would have represented less than 0.5% of the facility's available capacity.

(d) *Technology Transfer for Tablets*

[31] Mr. Chetan Doshi, Director of Formulation Development, Solid Dosage at Apotex, testified that Apotex's process for the manufacture of formulated perindopril tablets was ready to be transferred to a third-party by May-June 2004. Mr. Doshi further testified that, upon reception, it will take a facility receiving a technology transfer approximately three to four weeks to formulate finished dosage forms. According to Mr. Sarma, since IPCA had previously worked on formulating other prils, IPCA would have no problem working within this timeline.

[32] Mr. Higson's testimony that someone in charge on the transferring end is the best authority for a transferee's ability to receive and implement a technology transfer package is also applicable for technology transfers related to perindopril tablets:

> Q. And on the receiving end you would agree that the people who are at the intended recipient's [sic] would have relevant information to provide in that process?
>
> A. They would have some information but the same comment applies that I made earlier. It's the person -- it's the individuals who are contracting the work out --
>
> Q. Right.
>
> A. -- are the ones who must check to see whether the group that they are proposing to contract the work to can actually do the work themselves.
>
> Q. So the transferor is best situated --
>
> A. Yes.
>
> Q. -- to assess the viability of the intended recipient?
>
> A. Yes.
>
> (Trial Transcript Vol 14, pages 2146-2147, lines 23-28 and lines 1-10.)

(e) *Regulatory Requirements for Tablets*

[33] Mr. Sarma testified that IPCA's Athal facility could manufacture perindopril tablets. He also testified that the Athal facility was GMP compliant, being approved by the USFDA in 1989 through to at least the date of his testimony, the MHRA in 1997 through to at least the date of his testimony, and the TGA in 1999 through to at least the date of his testimony. I believe that IPCA's Athal facility had all the required GMP approvals necessary to produce perindopril tablets for Apotex in the hypothetical world.

[34] Regulatory approvals for the finished product typically requires stability testing and bioequivalence studies to be completed, with test results submitted in the marketing approval application for each jurisdiction. I find unreliable Apotex's evidence on whether or not IPCA (or any third-party tablet manufacturer) must complete its own bioequivalence and stability studies in order to be included in Apotex's original regulatory submissions to the UK and Australia. The evidence shows that IPCA must either complete its own bioequivalence and stability studies or it may need only complete an equivalence study (a comparative batch analysis) to establish that its tablets are equivalent to those made by Apotex in Canada (which would undergo stability testing and bioequivalence studies as part of the R&D process done within Canada).

[35] Apotex's position is that a comparative batch analysis is all that is required. Dr. Phillip Altman, Apotex's Australian regulatory expert, provides support for this position. In his expert report (Exhibit D-78), he writes:

> 94. Marketing applications for generic products for oral administration from any manufacturer are normally required to be

> supported by a clinical bioequivalence study demonstrating an equivalent rate and extent of absorption of the API into the body. If another manufacturer manufactures the identical generic product (ie, is manufactured in the same way, has the same specifications for the API and finished product and is subject to the same quality control testing procedures including the same *in vitro* dissolution characteristics), then an argument may be presented to waive the requirement to conduct another bioequivalence study on the basis that it is highly likely that the second manufacturer's product will behave similarly in terms of absorption and bioequivalence. It is not uncommon for such waivers to be granted. If Apotex transferred production of perindopril by way of technology transfer to its Indian affiliates or to third-party manufacturers, it is likely that the TGA would have accepted the initial bioequivalence study for the perindopril manufactured at the new location.
>
> (See also Dr. Altman's testimony, Trial Transcript Vol 9, page 1454, lines 7-23.)

[36] Nevertheless, Mr. Angus Cameron, Apotex's European regulatory expert, states the following in his expert report (Exhibit D-83):

> 8.6 …Where alternative sites were to be used for the initial MA [Marketing Approval] applications, comprehensive data on the DS [Drug Substance] and DP [Drug Product], as included in the initial submission made by Apotex Europe in the "real world" to the MHRA in January 2005, would have to have been generated by those alternative DS and DP manufacturers. The CTD [Common Technical Document] would be specific to the manufacturers of the DS and of the DP. Equivalence of the finished DP to that of the originator would have to be demonstrated through a human bioequivalence study conducted using DP manufactured at the new site.

[37] This passage indicates that substantial data on the foreign manufacturing site would have to be included in the marketing approval application to the UK regulatory authority, along with human bioequivalence studies conducted on the perindopril tablets manufactured at the foreign

site. I am therefore left with no firm conclusion as to whether or not stability testing and bioequivalence studies are required from an alternative third-party manufacturer.

[38] A requirement that IPCA carry out stability testing and bioequivalence studies on perindopril tablets manufactured at its Athal facility would take a significant amount of time and would necessarily delay Apotex's regulatory applications to the UK and Australia, further delaying the point at which Apotex could begin sales in these countries. Given that it remains uncertain whether or not the regulatory requirements for a third-party manufacturer would correspond with Apotex's rapid timeline of events in the hypothetical world, I identify this area of the "could they" framework as one that would more likely than not fail to align with Apotex's utopic timeline, resulting in undetermined delay.

(f) *Ability to Manufacture the Required Quantity of Tablets*

[39] Mr. Sarma testified that the Athal facility was operating at either 69% or 77% between 2006 and 2008, so that IPCA would have had considerable spare capacity to make the perindopril tablets for Apotex. Additionally, IPCA was manufacturing lisinopril and ramipril during the 2005-2008 period, two other prils similar to perindopril that would have expedited IPCA's production of perindopril.

(3) Signa as Supplier of Perindopril API

(a) *Technology Transfer for API*

[40] Mr. Hall testified that Pharmachem could have transferred its information on producing perindopril API to a third-party manufacturer by December 2003. The same evidence summarized above regarding IPCA's ability to receive and implement a technology transfer for perindopril API from Pharmachem applies here.

[41] Signa has an existing commercial relationship with Apotex going back to 1994-1995. Mr. Oscar Vivanco, Signa's General Manager, testified that Signa had substantial experience with technology transfers. By the time of his testimony, it had received and successfully implemented over thirty technology transfers, including quinapril for Apotex. Signa had also received a complete perindopril technology transfer package from Apotex in April 2004. It stopped the transfer early at Apotex's request, though Mr. Vivanco testified that Signa could have completed it.

[42] It took Signa eight months to manufacture commercial quantities of quinapril API after receiving a technology transfer. However, Mr. Vivanco testified that he believed it would take Signa just four months to produce the required commercial quantities of perindopril API. This proposed timeline is a result of Signa's previous experience producing quinapril within eight months. That experience would allow for an accelerated perindopril production schedule, given the many shared steps in the production of quinapril and perindopril. Alternatively, Mr. Vivanco testified that Signa could have produced the total quantity of perindopril API within a maximum of five months if it followed the synthetic scheme, a more lengthy process to make perindopril API.

(b) *Regulatory Requirements for API*

[43] The sufficiency of Signa's GMP compliance is another area that does not quite align with Apotex's utopic timeline. There is a dispute between the parties as to whether Signa's USFDA approval would be sufficient GMP compliance for the Australian regulatory authorities and whether the UK regulatory authorities even require GMP compliance for API manufacturing facilities. Apotex argues that Signa's manufacturing facility was GMP compliant during the relevant time period, having been deemed acceptable by the USFDA in 2004.

[44] With regard to Australia, Servier asserts that USFDA approval is not sufficient GMP compliance for the TGA, while Apotex counters that it is. Apotex points to the testimony of its Australian regulatory expert, Dr. Altman, who stated: "By agreement with the Australian authorities and the USFDA, they have agreed that an approval from the USFDA GMP would be recognized by the Australian authorities" (Trial Transcript Vol 9, page 1448, lines 6-9).

[45] Upon reviewing the evidence, I agree with Apotex that USFDA approval is sufficient for GMP compliance in the eyes of the TGA. However, this equivalency is not automatic. It requires making an application to the TGA and receiving their acknowledgement of USFDA approval, a process that necessarily takes time and is not accounted for in Apotex's D-118 timeline.

[46] For example, in the TGA's "Guidelines on Standard of Overseas Manufacturers" that is attached as Appendix A to Dr. Altman's supplementary expert report (Exhibit D-79), it states: "The TGA is aware that the FDA does not issue any document that complies with the TGA

requirements. If a sponsor wishes to use GMP evidence from the FDA, the sponsor may request MAS [the Manufacturer Assessment Section of the TGA] to search the FDA database (fee applies)" (at 7). The document also states: "In the case of FDA inspections outside the USA, the sponsor must provide objective evidence that the scope of the inspection included the relevant API(s). For example, a copy of the Establishment Inspection Report may be provided" (at 7). These guidelines instruct that simply having USFDA approval for a manufacturing site would not be sufficient GMP compliance for the TGA. Signa would need to take several positive steps to have its USFDA approval recognized and it is not clear exactly how long that would take – though it is by no means as immediate as Apotex suggests.

[47] With regard to the UK, Apotex states that the MHRA only inspected and issued GMP certification to finished dosage manufacturers at this time. As an API supplier, Signa would not have needed to obtain any GMP certification from the MHRA. Although I agree with Apotex on this point, its UK regulatory expert, Mr. Cameron, adds that there are still several regulatory steps that need to be carried out for European recognition of an API manufacturer, even when GMP compliance is not required. For example, on page 13 of his expert report (Exhibit D-83), Mr. Cameron writes:

> 8.2.14 Therefore, during the period involved (2004-2008), Apotex could have sourced perindopril tert-butylamine DS from any manufacturer located in any country provided the following conditions were met:
>
> - the manufacturing standards met EU levels of GMP compliance;
>
> - the DS met the specification laid down for perindopril tert-butylamine in the European Pharmacopeia (Ph Eur);

> - written confirmation was obtained from the DS manufacturer to commit to informing Apotex of any modification of the manufacturing process or specifications; and
>
> - the QP [Qualified Person] of the MA holder, and the DP manufacturer were able to sign declarations that the DS manufacturer operated in compliance with the EU detailed guidelines on GMP for starting materials (this would normally be achieved by the QP conducting a detailed site audit of the DS manufacturer).

[48] Mr. Cameron's expert report continues to detail how the MA holder and the DP manufacturer must continue to ensure the API manufacturer's compliance with European regulatory guidelines by auditing the API manufacturing site themselves. Contrary to Apotex's submissions, this process also seems to be quite lengthy and is not accounted for in its D-118 timeline.

(c) *Ability to Manufacture the Required Quantity of API*

[49] I believe that Signa had the required ability to manufacture the required quantity of API, since its manufacturing facility was only operating at between 27-30% during the relevant timeframe.

(4) Intas as Supplier of Perindopril Tablets

(a) *Technology Transfer for Tablets*

[50] Mr. Doshi testified that, upon reception, it would take a facility receiving a technology transfer approximately three to four weeks to formulate finished dosage forms. The same

evidence summarized above regarding IPCA's ability to receive and implement a technology transfer for perindopril tablets from Apotex applies here.

(b) *Regulatory Requirements for Tablets*

[51] Intas' Matoda manufacturing facility had GMP certification from the MHRA since 1999 and the TGA since 1997; it has maintained its GMP certification since that time. I believe that Intas' Matoda facility had all the required GMP approvals necessary to produce perindopril tablets for Apotex in the hypothetical world.

[52] The same uncertainty regarding whether, as a third-party manufacturer, Intas would be required to undergo its own stability testing and bioequivalence studies, as discussed above for IPCA, applies here.

(c) *Ability to Manufacture the Required Quantity of Tablets*

[53] I believe that Intas could have produced the required quantity of perindopril tablets, given that at this time, Intas had implemented the technology to replicate thirty different dosage forms from other companies and its Matoda facility was only operating at 50% capacity during the relevant time period.

(5) Conclusion on the "Could have" Branch

[54] There are further factors that would likely affect Apotex's ability to meet its utopic timeline not properly captured in the framework above. These factors contribute to my overall

conclusion that, while Apotex could have used a third-party manufacturer to produce non-infringing perindopril, it is more likely than not to have been a slower process than the one presented in its D-118 timeline.

[55] For example, Servier points to Intas' experience producing perindopril tablets in 2010-2011 as an indication that the perindopril tablet production process would take far longer than Apotex presents in its D-118 timeline. In early 2010, Intas received a dossier for the production of perindopril tablets for sale to the UK from its wholly-owned subsidiary based in the UK. By August 2011, Intas had shipped its first commercial quantities of perindopril tablets, a process that took approximately a year and a half. Apotex emphasizes that the year and a half includes steps that Intas would not be required to carry out in the hypothetical world, such as carrying out the R&D and preparing marketing approval applications for regulatory approval. These are steps that would be carried out by Apotex itself in the hypothetical world, not by Intas.

[56] I agree with Apotex that Intas' year and a half experience is slightly longer than what would need to happen in the hypothetical world for a third-party manufacturer to produce perindopril tablets on Apotex's behalf. In the hypothetical world, Apotex would be working together with the third-party manufacturer producing its perindopril tablets, facilitating the R&D and preparing marketing approval applications. However, Intas' real world experience does not seem to be that much lengthier than what is likely to have occurred in the hypothetical world. Mr. Marc Comas, Intas' Executive Vice-President of Global Licensing and Third-Party Sales, testified that the timeframe for production of perindopril tablets would have been roughly the

same if it had received a similar dossier from Apotex in 2005, with the caveat that, "maybe we could have done it even faster" (Trial Transcript Vol 8, page 1404, lines 18-19).

[57] A further example is that Apotex's D-118 timeline requires that a comparative batch analysis be carried out on the perindopril tablets manufactured by its third-party manufacturer before the stability testing and bioequivalence studies are completed on the tablets manufactured by Apotex in Canada for R&D purposes. I agree with Servier that this timing is unrealistic, given that the comparative batch analysis requires that tablets produced by the third-party manufacturer be compared against data from the above-mentioned studies. Moreover, there is no evidence tendered by Apotex to indicate that carrying out a comparative batch analysis before the stability testing and bioequivalence studies are complete is common practice or even feasible.

[58] In fact, Ms. Renka Panchal, the Director of International Regulatory Affairs at Apotex, testified that the stability testing and bioequivalence studies need to be complete before the CTD can be compiled for submission to the regulatory authority as part of the marketing approval application – a process that takes around thirty days and which must also include data from the comparative batch analysis. In the D-118 timeline, all of these processes are happening concurrently. In my opinion, the reality of carrying out a comparative batch analysis and preparing the CTD does not match up with Apotex's utopic timeline.

[59] Furthermore, despite Apotex's assertion that it was its primary position that the NIA suppliers could and would have been included in the original submissions, its regulatory expert

for Australia, Dr. Altman, does not seem to have considered this possibility, as seen in his cross-examination below:

> Q. …We know from the evidence, sir, that there was a certain amount of Apotex perindopril tablets that were sold into Australia between October 2006 and July 2008. That is of evidence in this trial. The Court has heard it. You are not in a position to say that any other manufacturer would have made those sales instead. Is that right?
>
> A. I can't say that they would have. What I am saying is given sufficient time, they could have.
>
> Q. You just don't have all the information in order to be able to make that assessment?
>
> A. No. I don't know all the assumptions that would be necessary to be able to say that manufacturer A of the API and tablet manufacturer B of the finished product could have received approval by 2006 in Australia. I just don't have that information.
>
> (Trial Transcript Vol 9, pages 1546-1547, lines 17-28 and lines 1-4.)

[60] Additionally, Apotex's evidence that Signa, IPCA and/or Intas could have produced non-infringing perindopril is heavily based upon testimony from these companies' executives that they could have and would have done so. However, it is worth pointing out that the executives were asked whether their companies could have produced commercial quantities of perindopril if Apotex had approached them in mid-2005. Approaching Signa, IPCA and/or Intas in mid-2005 does not align with Apotex's D-118 timeline. The third-party manufacturers would need to have been approached by mid-to-late 2003 in order to meet the D-118 timeline.

[61] All this to say that, despite Apotex's assertion that one or more third-party manufacturers could have produced non-infringing perindopril for sale to the UK and Australia between 2006

and 2008, the evidence does not bear out their utopic timeline. All events must occur perfectly, without any error or delay, in order for sales of non-infringing perindopril in the hypothetical world to replace sales of infringing perindopril in the real world. Given my review of the evidence, it is unrealistic to conclude that there would be absolutely no error or delay and thus, Apotex's utopic timeline is unlikely to occur in the hypothetical world.

[62] Consequently, it is my opinion that, in the hypothetical world, Apotex could have obtained quantities of non-infringing perindopril from Signa, IPCA and/or Intas for sale to its affiliates in the UK and Australia. However, in the hypothetical world, the infringing sales could only have been replaced at a delay of one year from the date of its real world sales.

B. *In the hypothetical world, would Apotex have obtained quantities of non-infringing perindopril from Signa, IPCA and/or Intas for sale to its affiliates in the UK and Australia?*

[63] I believe that the hypothetical question that must be answered with respect to this branch of the test is: would Apotex have obtained non-infringing perindopril from one of the proposed third-party manufacturers or would it have temporarily left the perindopril market for the UK and Australia? I say temporarily because we know from the evidence tendered at trial that the late Dr. Bernard Sherman had decided to send a technology transfer to two of its own sites located in India – APIPL for the API and ARPL for the tablets, in case Apotex lost the liability phase of its trial against Servier. We also know for a fact that those affiliates only became ready to manufacture perindopril for export sales to the UK and Australia after this Court issued its injunctive relief and prevented Apotex from manufacturing perindopril in Canada. In other words, APIPL and ARPL were not ready to manufacture perindopril at a commercial scale at the

beginning of and during the infringing period; but they were in the process of obtaining all necessary approvals.

[64] In this hypothetical world analysis, I am prevented from considering what occurred in the real world as an option (i.e., infringing by manufacturing in Canada). However, I am not prevented to consider other options that were available to Apotex in the real world, such as delaying its entry to the UK and Australian markets until APIPL and ARPL – or any other affiliate discussed in *Perindopril FC*, were ready to manufacture at a commercial scale.

[65] In *Lovastatin FCA*, the availability of an NIA defence was found to stand because of the causation framework that the Supreme Court of Canada affirmed in *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, via its introduction of the differential profits approach for calculating an accounting of profits. In affirming the causation framework, the Supreme Court created a precedent requiring the inventor to receive only "that portion of the infringer's profit which is causally attributable to the invention" (at para 101), thus requiring courts to segregate the profits made by the infringer or the sales lost by the patentee, attributable to the patent, and leave aside the profits/lost sales resulting from the infringer's fair and legal competition.

[66] In that decision, Justice Dawson disagreed with this Court's finding that, should the NIA defence be available, Apotex had demonstrated that in the "but for" world, it "could have" and "would have" sold lovastatin manufactured using the non-infringing AFI-4 process. At paragraph 89 of her reasons, Justice Dawson finds that the "could have" branch of the test is dispositive of the appeal as, in her view, Apotex failed to demonstrate that the non-infringing product was

available at the time of the infringement. She nevertheless moves to treat the evidence regarding the "would have" issue and finds, for several reasons, that Apotex also failed to meet that branch of the test :

> [90] First, as Apotex conceded in oral argument:
>
> • The real world informs our construction of the "but for" world.
>
> • Conduct in the real world is "very important" to what would have happened in the "but for" world.
>
> • Findings of fact from the liability decision are relevant to constructing the "but for" world.
>
> • "Brazen" infringement in the real world makes it very difficult to prove that the defendant would have deployed the non-infringing alternative in the "but for" world.
>
> [91] In the liability phase, the Judge found, at paragraph 309 of her reasons (reported at 2010 FC 1265), that if Blue Treasure had been using the non-infringing process to ferment lovastatin, it would have lost significant amounts of money for each kilogram of product it shipped to AFI. However, Apotex knew that once Blue Treasure began to use the allegedly non-infringing process it became profitable. The inference to be drawn is that Apotex knew Blue Treasure was in fact using the infringing process; yet Apotex used that bulk product to prepare and sell its lovastatin tablets.
>
> [92] In this circumstance it is relevant to note that from January 1, 1997 to January 1, 2001 Apotex believed Merck's patent was invalid.
>
> [93] Apotex' evidence falls far short of demonstrating that it would have sold the non-infringing product when one considers: the scale of Apotex' infringement; its likely knowledge that Blue Treasure was supplying it with infringing lovastatin; its belief the Merck patent was invalid; its failure to call a witness from AFI to support its contention that, had it known the product was infringing, it would have resurrected operations at AFI in Winnipeg; and the fact the Judge found that the testimony of Apotex' only fact witness was, albeit not on this point, unsubstantiated and self-serving.

[67] In *Perindopril FCA*, Justice Dawson did not analyse the "would have" branch, most probably because I barely deal with the subject in *Perindopril FC*. However, she states the following :

> [42] As this Court later explained in *Pfizer Canada Inc. v. Teva Canada Limited*, 2016 FCA 161 (CanLII), 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.
>
> [My emphasis.]

[68] By linking the "would have" branch of the NIA analysis to whether there exists any impediments to the use of an NIA, *Perindopril FCA* 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 FCA*. 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 FCA* was in any way restricted by paragraph 42 of *Perindopril FCA.*

[71] At paragraph 90 of *Lovastatin FCA*, Justice Dawson writes: "Findings of fact from the liability decision are relevant to constructing the "but for" world; [and] "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." She also writes: "Apotex' evidence falls far short of demonstrating that it would have sold the non-infringing product when one considers: the scale of Apotex' infringement; its likely knowledge that Blue Treasure was supplying it with infringing lovastatin; its belief the Merck patent was invalid …" (at para 93).

[72] Most of those comments apply here. For example, in the Liability Judgment, Justice Judith Snider made very clear findings of intentional infringement. Justice Snider writes at paragraph 135: "The record of this trial contains ample evidence of direct infringement by Apotex" and later elaborates:

> [509] In contrast, the behaviour of Apotex must also be taken into account. Apotex, fully aware of the '196 Patent, chose Canada as the manufacturing site for perindopril products. 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. Indeed, as stated by Dr. Sherman, during his testimony, Apotex had "determined that it would make sense to have the facilities outside of Canada qualified in case it turned out we would lose at trial". I have no problem with Apotex and other related companies arranging their business affairs in any way they see fit. However, they must also bear the consequences of their choices where they are perfectly aware that a patent will be infringed. In this case, Apotex chose to make perindopril in Canada fully knowing that making perindopril would constitute infringement and that it might be required to disgorge its profits.

[73] That said, two recent decisions of this Court confirm that the infringer's intention is still a relevant factor to consider.

[74] In *Airbus Helicopters, SAS v Bell Helicopter Textron Canada Limitée*, 2017 FC 170, Justice Luc Martineau was asked to consider the possible effect of the defendant's legitimate competition from marketing a non-infringing alternative to the plaintiff's patented skid-type landing gear for helicopters. As instructed by *Lovastatin FCA*, he needed to consider at least the following questions of fact:

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

[75] In his reasons, Justice Martineau makes many references to the *Schmeiser* causation framework and the requirement that an NIA be economically viable, while also extensively discussing how intentional infringers cannot take advantage of the benefit of hindsight to argue that they would have used the proposed NIA, when in the real world, the NIA was never actually considered.

[76] With respect to *ex post* facto evidence – a necessity in the hypothetical world – Justice Martineau nevertheless gives some warning:

> [295] The fact that Bell was able to develop the Production gear at some posterior date does not allow the Court to infer that Bell would have done so on the eve of first infringement of the '787 Patent. It would simply be too easy to allow infringers of a valid patent, to retroactively rewrite history to escape their liability to pay damages by bringing out scenarios that were never considered or unrealistic on the eve of first infringement. … In other words, if a look into what transpired in the "real world" is acceptable to a certain point, it must not translate itself in some "hindsight bias", which can be defined as the inclination, after an event has occurred, to see the event as having been predictable, despite there having little or no objective bias for predicting it.
>
> [Citation omitted.]

[77] In *AstraZeneca*, above Justice Barnes also recognizes the importance of the *Schmeiser* causation framework. Like Justice Martineau, he applies the four-step *Lovastatin FCA* test as a framework for structuring his decision and also emphasizes the intentionality of the infringing conduct:

> [31] Initially I did have reservations about the idea that the availability of a NIA can be informed, in part, by the willfulness of the infringement. But as I understand the decision of the Federal Court of Appeal in *Lovastatin* FCA, the idea is no more than this: where an infringer brazenly infringes a valid patent, or substantially courts the risk of doing so, an inference may arise that

> no viable substitute was available. If it were otherwise the rational choice would always be to employ the NIA and not the infringing product.

[78] In my view, full adherence to the NIA analytical framework still requires that the intentions, motivations and preferences of an infringing party be considered.

[79] The "could have" branch is an objective test. It is thus easier to demonstrate that it is met. The "would have" branch is, on the other hand, largely based on subjective components and will require the Court to make inferences from the objective evidence tendered at trial and from what transpired in the real world to determine what would likely have motivated the infringer's conduct in the "but for" world.

[80] I fully agree with Justice Robert Barnes that "…[t]he "could have and would have" evidentiary concerns are […] magnified when the proposed hypothetical NIA(s) were never, at any time, submitted to the relevant regulator for assessment and approval" (AstraZeneca Canada Inc v Apotex Inc, 2017 FC 726 at para 21).

[81] The burden of convincing the Court that the infringer would still have competed using an NIA in the "but for" world lies on the infringer (*Lovastatin FCA* at para 74).

[82] In the present case, having concluded that Apotex could have used Signa, IPCA and/or Intas to obtain non-infringing perindopril for half of the infringing period – and that Signa, IPCA and/or Intas would have manufactured those goods for Apotex – I am of the view that the evidence falls short of establishing that, despite the fact that it was economically viable for

Apotex to do so, it would have used one or more of the non-affiliate manufacturers to obtain perindopril API and tablets.

[83] In my view, as evidence for the "would they" branch of the test, Apotex needed to demonstrate more than the fact that it would have been economically viable to use its proposed NIAs – which it did; the evidence clearly demonstrates that it would have been more profitable to manufacture perindopril using API from India and Mexico, while having the tablets formulated by either Intas or IPCA in India (Exhibit D-52, s 6.18).

[84] Apotex needed to demonstrate that it was more likely than not that it would have temporarily used non-affiliate NIA suppliers, rather than expedite the remaining steps and wait until its Indian affiliates APIPL and ARPL, or any other affiliates discussed in *Perindopril FC*, were ready to manufacture at a commercial scale and approved to manufacture perindopril for the UK and Australian markets.

[85] In assessing whether or not it did, I need to remain mindful of the rational choice Apotex made to manufacture in Canada while it would have made more profit outsourcing the manufacturing to the three non-affiliate NIA suppliers.

[86] Apotex argues that it cannot be penalized for choosing to carry on operations in Canada, rather than exporting jobs outside the country. However, there is reason to doubt this posited pure intention when one considers that Apotex intended and ultimately did move some of its manufacturing activities to its affiliates in India (APIPL and ARPL), and that since the end of the

infringing period, Signa (located in Mexico) became part of the Apotex group of companies; Apotex has now moved part of its manufacturing activities to India and Mexico.

[87] Again, Apotex's actions, motivations and preferences in the real world are instructive in drawing inferences as to what it would have done in the hypothetical world.

[88] Dr. Sherman spoke candidly at trial about Apotex's historical preferences. He explained that Apotex preferred "to do everything [it could] in Canada" and had so far resisted manufacturing "anything outside of Canada" (Trial Transcript Vol 12, page 1884, line 9). He also discussed Apotex's preference for manufacturing products at its own sites, rather than contracting with non-affiliate third parties. He even expressed doubts that Apotex would have used the services of Signa or IPCA, over those of affiliates APIPL, ARPL, Apotex Netherlands and Srini (all members of the Apotex group of companies) (Trial Transcript Vol 12, pages 1896-1900, 1928-1929). He added that they probably would not have used Mexico (thus eliminating Signa) because: "I'm not certain Mexico was ever approved for sale into Europe or Australia" (Trial Transcript Vol 12, page 1896, lines 26-27). I agree with Servier that such admissions as to what Apotex would likely have done underscore the speculative nature of Apotex's arguments.

[89] Rather than pursuing the technology transfer to then third-party Signa, Apotex preferred to continue the work in Canada, despite its infringement, only to then transfer the API and tabletting to wholly-owned affiliates APIPL and ARPL.

[90] The only evidence referred to by Apotex to counter those inferences brings us back to the "could have" analysis and turns around technological and regulatory hurdles. The evidence that an NIA supplier would have supplied the required amount of perindopril if asked cannot counter the lack of evidence that Apotex would have had chosen to call on them to do so. This leaves the Court with little to no evidence that, but for the infringement, Apotex would have turned to the proposed third-party suppliers of its NIA to manufacture the quantities of perindopril sold to Apotex's affiliates in the UK and in Australia during the 2006-2008 period.

[91] Given the admission that Apotex likely would have used one of its "own sites", it is more likely than not that Apotex would have done, in the hypothetical world, exactly what it did in the real world by sending technology transfers to APIPL and ARPL as opposed to Signa, IPCA and/or Intas. All that this implies is that Apotex would have entered the UK and Australian markets at a later date than in the real world. It would have entered those markets after the infringing period, thus not legally competing with Servier in the hypothetical world.

IV. Conclusion

[92] For the above reasons, although I conclude that Signa, IPCA and/or Intas could have and would have manufactured perindopril for sales in the UK and Australia during the infringing period, it is more likely than not that Apotex would not have used one or more of those third-party suppliers to produce non-infringing perindopril and would rather have pursued its technology transfers in favour of APIPL and ARPL and entered those markets at a later date. It follows that paragraphs 3 and 4 of this Court's judgment dated June 18, 2015 are reaffirmed.

[93] Costs on this redetermination are granted in favour of Servier following the principles set out in this Court's Order dated November 6, 2015.

JUDGMENT in T-1548-06

THIS COURT'S JUDGMENT is that:

1. The defendant Apotex Inc. is ordered to pay to the plaintiffs, within 60 days from this judgment, its profits attributable to the infringement of ADIR's Canadian Letters No 1,341,196 in the amount of $56,000,000, plus any further amounts of return on profits compounded from December 1, 2014 to the date of this judgment, at a rate of prime;

2. The defendant Apotex Pharmachem Inc. is ordered to pay to the plaintiffs, within 60 days from this judgment, its profits attributable to the infringement of ADIR's Canadian Letters No 1,341,196 in the amount of $5,172,000, plus any further amounts of return on profits compounded from December 1, 2014 to the date of this judgment, at a rate of prime plus 1%;

3. Costs on this redetermination are granted in favour of the plaintiffs following the principles set out in this Court's Order dated November 6, 2015.

"Jocelyne Gagné"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1548-06
STYLE OF CAUSE:	ADIR ET AL v APOTEX INC. ET AL
PLACE OF HEARING:	MONTRÉAL, QUEBEC
DATE OF HEARING:	NOVEMBER 21, 2017
JUDGMENT AND REASONS:	GAGNÉ J.
DATED:	MARCH 28, 2018

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