

Federal Court



Cour fédérale

**Date: 20150618**

**Docket: T-1548-06**

**Citation: 2015 FC 721**

**Ottawa, Ontario, June 18, 2015**

**PRESENT: The Honourable Madam Justice Gagné**

**BETWEEN:**

**ADIR  
and  
SERVIER CANADA INC.**

**Plaintiffs**

**and**

**APOTEX INC.  
and  
APOTEX PHARMACHEM INC.**

**Defendants**

**PUBLIC JUDGMENT AND REASONS**  
**(Confidential Judgment and Reasons issued June 8, 2015)**

I. Overview

[1] On July 2, 2008, as the liability phase of the trial before this Court came to a close, my colleague Snider J granted the plaintiffs' claim against the defendants; she found that the defendants had infringed claims 1, 2, 3 and 5 of ADIR's Canadian Letters Patent No 1,341,196

[196 Patent] by manufacturing, selling, offering for sale and otherwise dealing in perindopril containing products in Canada. She further found that the plaintiffs were entitled to elect between an accounting of the defendants' profits and their damages sustained by reason of the infringing activities (*Laboratoires Servier v Apotex Inc*, 2008 FC 825 [*Liability judgment*]). The *Liability judgment* was upheld by the Federal Court of Appeal (aff'd 2009 FCA 222) and leave to appeal to the Supreme Court of Canada was denied.

[2] The plaintiffs elected an accounting of the defendants' profits; as a result, an additional 17 day hearing was held before me, during which I heard 16 regular witnesses and 6 expert witnesses. These reasons for judgment address the evidence adduced and the parties' arguments that pertain to the remedy phase of the trial.

[3] In searching for the portion of the infringers' profit which is causally attributable to the invention (*Monsanto Canada Inc v Schmeiser*, 2004 SCC 34 [*Schmeiser*], at para 101), the plaintiffs bear the burden of establishing the defendants' revenues attributable to the sale of the infringing products, while the defendants are required to establish the costs incurred to produce and sell the infringing products and any apportionment necessary under the circumstances. The profits to be disgorged will consist of the difference between the defendants' gross revenues and its current and capital expenses directly attributable to the infringement (*Monsanto Canada Inc v Rivett*, 2009 FC 317 [*Rivett FC*], aff'd 2010 FCA 207 [*Rivett FCA*]).

[4] These reasons will discuss in detail the notion of causation since it underscores two of the arguments advanced by the defendants. They argue that: i) a portion of their revenues should be

disaggregated as part of the sale price was paid on account of non-infringing indemnity and legal services offered to affiliates in the United Kingdom [UK] and Australia ; and that ii) there were non-infringing alternatives [NIA or NIAs] available to them, thereby warranting the “differential profit” approach found to be the preferred mean of accounting profits by the Supreme Court in *Schmeiser*—as a result, the defendants are of the view that the profits to be disgorged are substantially reduced, even to zero.

[5] As the parties disagree as to the reading and application of *Schmeiser* in this case, a review of the pre and post-*Schmeiser* case law is called for.

## II. Facts and proceedings

### *General remarks*

[6] For a presentation of the parties and a complete factual background to angiotensin-converting enzyme (ACE), ACE Inhibitors in general and perindopril in particular, I refer the reader to section III of Snider J’s *Liability judgment*.

[7] It has also been found in the *Liability judgment* and discussed at length before me that Apotex Pharmachem Inc. [Pharmachem] manufactured a large quantity of bulk perindopril active pharmaceutical ingredient [API] that it sold to Apotex Inc. [Apotex] as early as April 2004 and to Apotex Netherland B.V. around June 27, 2008. As a formulator, Apotex used the perindopril API to manufacture and sell 8 mg strength perindopril erbumine tablets for the Canadian market and, for export sales to its affiliates in the UK, Australia and the Netherlands, it manufactured

2mg, 4mg and 8mg strength perindopril erbumine tablets as well as tablets containing a combination of perindopril erbumine and indapamide [Combination product].

[8] Apotex and Pharmachem are privately owned companies and members of the Apotex group of companies. They are held by Apotex Pharmachem Holdings Inc. [APHI], which is held by Apotex Holdings Inc. [AHI]. AHI also holds Apotex International Inc.—the parent company of the foreign selling entities in the group. Srinu Pharmaceuticals Ltd [Srinu], Apotex Pharmachem India Pvt. Ltd. [APIPL] and Apotex Research Pvt Ltd (India) [ARPL], which are manufacturing entities, are held, in whole or in part, by APHI. AHI is in turn held by Sherfam Inc., which also holds Signa S.A. de C.V. [Signa]. [Redacted]. Except for Srinu, in which APHI only has a [redacted] interest, Dr. Sherman controls, directly or indirectly, all entities of the group.

*Apotex group of companies*

[9] The Apotex group of companies has experienced substantial growth starting in the early 2000s. Here is a list of the additions relevant to these reasons:

- In 2002, APHI entered into a joint-venture ([redacted] with Dr. T.C. Reddy) which holds Srinu, an Indian company mainly involved in the production, quality control, packaging and distribution of API and intermediate molecules (exhibit P-24);
- ARPL and APIPL were incorporated by APHI in June 2003. They are both Indian companies. ARPL mainly formulates, distributes and sells finished drug products. Its facilities were built in 2004 and were operational in December 2004. APIPL

manufactures and sells API for export markets. Its facilities were built from 2003 to 2005, and were operational in March 2005;

- In 2004, Apotex International Inc. acquired Katwijk Farma B.V., a Netherlands based company engaged in the formulation, distribution and sale of finished drug products in Europe. It changed its name to Apotex Nederland B.V. [Katwijk] in 2008;
- Also in 2004, Apotex International Inc. acquired GenRx Pty Ltd., an Australian company engaged in the distribution and sale of drug products on the Australian market. It subsequently changed its name to Apotex Pty. Ltd. [GenRx];
- In 2006, Apotex International Inc. incorporated Apotex U.K. Ltd. [Apotex UK] for the distribution and sale of drug products on the UK market;
- Apotex Europe B.V. is also indirectly held by Apotex International Inc. and it acts as a regulatory center for the activities of the Apotex group of companies in Europe. It holds European marketing approvals for the marketing and distribution of Apotex's products in the European Union;
- Finally, in September 2011, APhi acquired Signa, a Mexican company which since 1965, has engaged in the production, quality control, packaging and distribution of API and intermediate molecules.

*Apotex and Pharmachem's production and sale of perindopril*

[10] Dr. Sherman testified that his business development strategy is based on the identification of new products that have a high potential of profitability and on being the first generic manufacturer on the market for these products. He identified perindopril as a profitable target in

the late 1990s, and from 1999 to December 2003, chemists at Pharmachem underwent a complete R&D and synthesis of perindopril API. Pharmachem's first commercial batch of perindopril was ready in March 2004; it was sold to Apotex in April 2004 and delivered in June 2004.

[11] From 2004 to 2008, Pharmachem produced 16.9 kilograms of perindopril arginine, which was sold in August 2009 to ARPL. Also in the period of 2004 to 2008, Pharmachem produced 1,877.1 kilograms of perindopril erbumine API, of which:

- (a) 1,007.4 kilograms were sold and shipped to Apotex;
- (b) 869.4 kilograms were sold to Katwijk and shipped to the Netherlands on June 27, 2008 and July 7, 2008;
- (c) 0.1 kilogram was sold to third parties;

[12] With the perindopril API purchased from Pharmachem, Apotex first conducted its trials and studies and manufactured its submission batch of perindopril finished dosage or tablets (later known as Apo-perindopril), for regulatory purposes, during the month of June 2004. It started its stability studies on June 18, 2004 and conducted bioequivalence studies for the UK market from July to November 2004, and for the Australian market from April to July 2005.

[13] On February 1, 2007, Apotex obtained a Notice of Compliance from Health Canada for its 8 mg perindopril tablets and started selling them on the Canadian market on March 6, 2007.

Before Snider J issued her permanent injunction as part of the *Liability judgment* in July 2008, Apotex had sold 10.1 million perindopril tablets in Canada.

[14] In addition, Apotex made the following export sales:

- (a) From July 2006 to July 2007, 125.5 million of 2, 4 and 8 mg strength perindopril tablets were sold to Apotex UK (as discussed below, an injunction issued by the UK High Court of Justice was in force from August 2006 to July 2007, prohibiting the sales of perindopril on the UK market, by Apotex and Apotex UK);
- (b) From March 2007 to July 2008, 40.7 million tablets of 2, 4 and 8 mg strength perindopril and Combination Product were sold to GenRx;
- (c) From February 26, 2008 to July 2008, 19.7 million perindopril tablets were sold to Katwijk;
- (d) Small quantities of perindopril tablets were sold to Apotex's affiliate in the Czech Republic and to a third party in Denmark known as Orifarm Supply A/S.

### III. Issues

[15] The parties have made several admissions and have provided the Court with tables of stipulated amounts, respectively for Apotex's domestic and export sales [Table 3] and for Pharmachem's domestic and export sales [Table 4]. Taking those stipulations into consideration, the following issues/sub-issues are raised:

- (a) *What are the Defendants' revenues from the sales of perindopril products?*
  - *Can the Defendants segregate their revenues?*
  - *If so, have they adduced sufficient evidence of the quantum of revenues that should be so segregated?*

- (b) *What are the costs that can be deducted from the Defendants' revenues? (full absorption approach vs incremental costs approach)*
  
- (c) *What are the Defendants' profits from the sales of perindopril products?*
  - *Is the Differential Profit approach applicable in this case?*
  - *Were NIAs available to the Defendants?*
  
- (d) *What are the Defendants' returns on profits?*

#### IV. Discussion

##### *The Defendants' revenues from the sales of perindopril products*

[16] The parties have stipulated that Apotex's revenues for domestic sales were [redacted] and its revenues from its export sales were [redacted], for a total of **\$68,375,000**. They agree that [redacted] must be deducted from Apotex's domestic sales to account for rebates and discounts and that [redacted] must be deducted from its export sales to account for transfer price adjustment from its sales to Apotex UK and GenRx (as per the transfer price agreements that will be discussed below). However, from the agreed amount of **\$43,326,000** (\$59,714,000 minus \$16,388,000) in total export sales, the plaintiffs dispute the defendants' right to segregate and deduct a further amount of **\$22,024,374** which was allegedly paid by Apotex UK (\$19,916,211) and GenRx (\$2,108,163) for non-patent infringing indemnity and litigation services provided for in their respective transfer price agreement with Apotex (Exhibit D-50, Figure 1 of Addendum to the Expert Report of Howard N. Rosen dated September 12, 2014).



[17] Therefore, the plaintiffs contend that Apotex's total net revenues from the sale of Apo-perindopril amount to **\$51,379,000**, whereas the defendants contend that the total is **\$29,354,626**.

[18] No such dispute arises with respect to Pharmachem's revenues as its export sales were not governed by any transfer price agreement. Pharmachem's revenues from domestic sales amounted to [redacted] while its export sales amounted to [redacted], for a total of **\$13,080,000**.

(1) Segregation of Apotex's revenues

[19] This first point of dispute between the parties arose when the defendants presented a motion to file two addenda to Mr. Howard N. Rosen's expert report delivered in-chief, which I granted less than a month prior to the opening of the hearing.

[20] Mr. Rosen was heard at trial as an expert witness. He is a chartered accountant, with particular expertise in, but not limited to, the valuation of intellectual property and quantification of loss and accounting of profits in intellectual property and commercial litigation disputes.

[21] In his report filed in-chief, Mr. Rosen, after having acknowledged the fundamental principle that only profits that can be shown to have been causally derived from the infringement must be disgorged, computes said profits from Apotex's revenues from the sales of perindopril by "reviewing and summarizing a detailed report of Apotex's billing documents obtained from the company's SAP system". He therefore assesses Apotex's gross revenues from the sale of perindopril as totalling \$68,375,205 (hence the stipulated amount of \$68,375,000), from which he only deducts the transfer price adjustment and rebates and discounts to arrive at net sales

revenues of \$51,379,000 (exhibit D-49, Expert report of Howard N. Rosen-Perindopril, dated May 30, 2014, sections 4.2 and 4.18 and Schedule 4; exhibit P-4, Perindopril Sales Summary and pages 635 and 636 of the transcript of hearing).

[22] In a first addendum dated September 12, 2014 (exhibit D-50), Mr. Rosen explains that upon reviewing Mr. Ross Hamilton's report dated August 15, 2014 (exhibit P-110), he came across some clauses of Apotex's transfer price agreements with Apotex UK and GenRx, which distinguish between the price of a "Patent Challenge Product" and the price of a "Non-Patent Challenge Product". Since his interpretation of these clauses has a significant impact on his computation of Apotex's gross revenues used in the calculation of its profits, and as he felt that part of the gross revenues assessed in his May 30, 2014 report were on account of something other than the infringing product itself, he felt that it was his duty to so advise counsel for the defendants and to file this first addendum.

[23] His second addendum dated September 23, 2014 (exhibit D-51) also apportions this part of Apotex's gross revenues which he attributes to non-infringing services, but in the context of the different NIA scenarios that will be discussed below. It will therefore not be specifically addressed in this section.

[24] In summary, Mr. Rosen suggests that a further \$22,024,374 be deducted from Apotex's gross revenues from its export sales to Apotex UK (\$19,916,211) and GenRx (\$2,108,163), as this amount was paid on account of an indemnity offered by Apotex to its affiliates, and of its

undertaking to pay for and conduct the defence or claim, in the case of a patent challenge, engaged by Apotex or against its affiliates, in the affiliates' respective jurisdictions.

[25] In response, the plaintiffs filed the report of Mr. Ross Hamilton, dated November 11, 2014 (exhibit P-112), which, in particular, bears on the segregation or apportionment suggested by Mr. Rosen. Mr. Hamilton is also a qualified chartered accountant with expertise in quantification of loss and accounting of profits in intellectual property and commercial litigation disputes, including specifically in the pharmaceutical marketplace.

[26] The defendants argue that it is a trite proposition of law that an accounting of profits from the infringement of a patent is limited in scope to those revenues generated by the sale of the infringing good. As such, they argue that a proper interpretation of the transfer price agreements should lead the Court to conclude that a substantial part of the price paid by Apotex UK and GenRx was not paid on account of the infringing perindopril. Rather, it was paid on account of the increased risk of litigation in the UK and Australia which accompanies the sale of the product. Thus, these agreements, in the defendants' submissions, delineate the relationship between the parties with respect to more than the mere sale of perindopril. The agreements show increased consideration payable in certain circumstances to Apotex, on account of the significant risk Apotex would be called on to pay out its indemnity, and that these payouts would be significant where Apotex would be obliged to provide litigation services.

[27] Apotex believed that there was a risk the plaintiffs' parent companies in the UK and Australia would bring an infringement suit; Apotex asked for a higher price for the sale of

perindopril in these countries in exchange for agreeing to indemnify its own affiliates from the suits in addition to controlling and paying for all litigation related thereto.

[28] The plaintiffs argue that apportionment is not applicable in this instance as the whole of the perindopril sold by Apotex infringes the 196 Patent; Apotex would have received no revenue but for the infringement of the 196 Patent. Citing the following cases of this Court in *Beloit Canada Ltd v Valmet Oy*, [1994] FCJ 733 at para 77 [*Beloit FC*], rev'd on other grounds; [1995] FCJ, 733 [*Beloit FCA*]; *Lubrizol Corp v Imperial Oil Ltd*, [1994] FCJ 1441 [*Lubrizol, FC*]; [1996] 3 FC 40 [*Lubrizol, FCA*] at paras 9, 10 and 15 and *Varco Canada Limited v Pason Systems Corp*, 2013 FC 750 [*Varco*] at para 422, the plaintiffs contend that apportionment should only be ordered where a portion of the profits is attributable to non-infringing features of the product sold by the infringer.

[29] As will be discussed in detail in the section below dealing with the defendants' alleged NIAs, the need to apportion the infringer's revenues or profits or to apply the "differential profit" approach depends on the specific facts of each case and requires an analysis of all the evidence. The notion of apportionment is, in my view, little more than a restatement of the principle that only those profits that are causally attributable to the invention should be disgorged. As this is a question of fact, one can imagine situations where a portion of the profits is not necessarily attributable to non-infringing features of the product sold, but to non-infringing services sold with the product or rendered on the occasion of the sale of the product.

[30] In the case at bar, I agree with the defendants, as a matter of 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. Therefore, I am of the view that if part of the price paid by Apotex UK and GenRx is proven to have been paid on account of those services, then the revenues should be apportioned or segregated accordingly, in order to respect the simple “common sense view of causation” or “differential profit” (in this case gross revenues) approach (*Schmeiser*, at paras 101 and 102). The question is therefore, whether or not the defendants have provided sufficient evidence proving that part of the price paid was indeed on account of non-infringing services and indemnity.

(2) The evidence adduced by the Defendants

[31] In order to answer that question, the transfer price agreements entered into between Apotex and both Apotex UK and GenRx respectively, need to be interpreted. Although both experts have offered their own interpretation of these agreements, this task rather belongs to the Court. Therefore, both expert reports and testimonies on this issue have been considered only to the extent that they pertain to their field of expertise.

[32] A summary of the transfer price agreements was filed as exhibit D-1. In addition, the Court heard the testimony of Mr. Jeffrey Adams, Apotex’s Director of International Finance and Corporate Development at the time the agreements were drafted. He is also signatory to the transfer price agreements with the affiliates.

[33] Mr. Adam testified that, as those export sales were made to related entities, the transfer price agreements were entered into in order to comply with the requirements of the Canadian and foreign tax authorities, with the requirements of the parties' auditors and with those of the Organisation for Economic Co-operation and Development [OECD]'s transfer pricing guidelines. In order to satisfy the OECD guidelines, the transactions must meet an arm's length standard.

[34] In the Brief of Transfer Price Agreements, we find the following documents:

- (a) *Tab A : An Agreement entered into between Apotex Inc. and Apotex UK Limited, dated May 1, 2006 [UK TPA-perindopril];*
- (b) *Tab B : An Agreement entered into between Apotex Inc. and GenRx Pty. Limited, dated May 1, 2006 [GenRx TPA-perindopril];*
- (c) *Tab C : An Agreement entered into between Apotex Inc and GenRx Pty Limited, dated January 1, 2007 [GenRx TPA-combination product];*
- (d) *Tab D : An Agreement entered into between Apotex Inc and GenRx Pty Ltd., dated July 10, 2007 [GenRx TPA-general]; and*
- (e) *Tab E : An Agreement entered into between Apotex Inc. and Katwijk Pharma B.V., dated August 22, 2007 [Katwijk TPA-general]*

[35] Mr. Adams acknowledged that although some of these agreements bear earlier dates, they were all signed during the month of July 2007.

[36] The **UK TPA-perindopril** (exhibit D-1, Tab A) is a product specific transfer price agreement. In a recital, the parties acknowledge that perindopril is a generic version of a product

developed by the plaintiffs and that, as such, it is contemplated that the plaintiffs may challenge their right to manufacture, market or sell perindopril in the UK.

[37] **Section 1** of the UK TPA-perindopril is entitled *Indemnity* and it provides that Apotex will indemnify and hold Apotex UK harmless from and against all claims that the plaintiffs or any third party may bring, to the extent that such claim is based on the alleged infringement of the plaintiffs' or any other third party's patent. **Section 2** is entitled *Alleged Infringement* and provides that Apotex and Apotex UK must promptly give each other notice of any claim commenced or threatened against it. It specifies that Apotex will pay all legal expenses and control the defence to be brought against the suit and it also provides for a split 90% Apotex - 10% Apotex UK of any settlement amount or award of damages in their favour, irrespective of which of them is designated to receive such payment. **Section 3** is entitled *Patent Challenge* and adds that Apotex has the exclusive right to bring a patent challenge in the territory and again, if successful, any award would be split 90% Apotex-10% Apotex UK. **Section 4** is entitled *Procedure* and clarifies that if need be, Apotex UK may be permitted to comment on the proceedings, however Apotex controls the litigation and may compromise or settle without Apotex UK's consent.

[38] **Section 5** of the UK TPA-perindopril is entitled *Transfer Pricing*. Sub-section 5.1 enumerates several definitions to be applied to this section 5, the most relevant ones being:

(c) "**Patent Challenge Product**" means a generic pharmaceutical product manufactured by Apotex and supplied to Apotex UK for distribution and sale in the 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.

...

(e) “**Transfer Price**” in relation to the Product means the price to be paid by Apotex UK to Apotex for the supply of the Product.

[39] Sub-sections 5.2 and 5.3 are also worth reproducing at length:

**5.2 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.

**5.3 Transfer Price—Not-Patent Challenge Product.** During any period that the Product is not 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 on terms equivalent to third party norms and standards.

[40] Finally, also significant is **Section 8** which contains a standard *Severability* clause that provides that if any provision is found to be invalid or unenforceable, it is severable from the other provisions of the agreement that will remain in full force and effect.

[41] The **GenRx TPA-perindopril** (exhibit D-1, Tab B) is also a product specific agreement and is very similar to the UK TPA-perindopril. The only differences are found in its **Sections 2** and **3** (the award split is [redacted] instead of 90%-10%) and in **Section 5**. Sub-section 5.1



contains the definition on *Management Price* which is not found in the UK TPA-perindopril and which should be understood as the manufacturing cost plus the actual cost to Apotex to ship the product. It, therefore, has an impact on the determination of the profit generated by the sales. Another difference is found in the definition of the Patent Challenge Product which reads as follows:

(d) “**Patent Challenge Product**” means a generic pharmaceutical product manufactured by Apotex and supplied to GenRx for distribution and sale in the Territory during the same time that:

(i) a competitor markets and sales 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 (excluding authorized generics and swap generics that originate from Apotex/GenRx) of the same pharmaceutical product marketed and sold in the Territory;

(my emphasis)

[42] Finally, sub-section 5.3 does not provide for a specific Transfer Price- Non-Patent Challenge Product but rather cross-references, for that purpose, the GenRx TPA-general, the content of which will be discussed below.

[43] The **GenRx TPA-Combination Product** (exhibit D-1, Tab C) is modeled after the GenRx TPA-perindopril but specifically applies to the Combination Product.

[44] The **GenRx TPA-general** (exhibit D-1, Tab D) is not a product-specific agreement. For the Transfer Price-Patent Challenge Product, it refers to the Indemnity Transfer Price Agreement which, for the purpose of this case, has been proven to be either the GenRx TPA- perindopril or

the GenRx TPA- Combination Product. However, it provides for a definition of the Patent Challenge Product that does not exclude “authorized generics and swap generics that originate from Apotex/GenRx”, as do the GenRx TPA- perindopril and the GenRx TPA- Combination Product. In addition, it establishes the following formula for computing the Transfer Price-Non-Patent Challenge Product:

During any period that a Product is not a Patent Challenge Product, *GenRx* shall pay to Apotex a Transfer Price for each Shipment of the Product manufactured and supplied by Apotex to *GenRx* for commercial sale in the Territory at the lesser of

Management Price + [redacted] or

Management Price + [redacted] of the Consolidated Product Profit

Further evaluation of alternative pricing strategies such as marginal costing are in effect with appropriate approvals in the instance that above (a) or (b) are not viable due to competitive local market pricing.

[45] The **Katwijk TPA-general** (exhibit D-1, Tab E) is modeled after the GenRx TPA-general but instead of referring to the Indemnity Transfer Price Agreement in order to identify the Transfer Price-Patent Challenge Product, it refers to the Reserved Transfer Price Agreement, which was proven not to exist.

[46] It was said during the trial that one can use interchangeably the following expressions: Patent Challenge Product, Indemnity Product or Reserved Product.

[47] Throughout the discovery process, counsel for the plaintiffs requested several times that they be provided with any documents that would allow them to understand the price paid by Katwijk for Apo-perindopril, to no avail. It was only as a result of the cross-examination of Mr.

Gordon Fahner during trial that counsel for the defendants communicated a further agreement between Apotex and Katwijk, dated November 28, 2007 (D-86, Tab-5) [Katwijk-indemnity agreement] which, but for Section 5 (Transfer Price), is identical to both the GenRx TPA-perindopril and GenRx TPA-Combination Product. It is therefore solely an indemnity agreement that provides for a split [redacted] of any award or settlement payment, but does not deal with transfer price.

[48] Mr. Adams testified at trial that although it was not provided for in any written agreement, sales of Apo-perindopril to Katwijk were made by consignment. A commercial invoice at a price of cost plus [redacted] accompanied the product through customs and once the product was sold by Katwijk to an arms length customer, an accounting invoice was issued at the price of cost plus a [redacted] profit share.

[49] The defendants contend that the existence of two transfer prices for a single product requires the Court to answer the question as to what the higher price represents. They argue that the agreements should be interpreted in the context in which they were concluded; the entirety of the agreements and the true intent of the parties must be taken into account. On that basis, they submit that the difference between what is said to be the higher price and what is said to be the lower price relates to the indemnity and relevant litigation services.

[50] The plaintiffs argue that the agreements do not explicitly stipulate that the price is paid on account of products and services (as opined by Mr. Rosen) but rather explicitly provide for a definition of the "Transfer Price" as being the price to be paid for the supply of the Product.

[51] I agree with the defendants that the answer to this issue is not found in the single definition given to Transfer Price, 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. However, I do not agree that the proper interpretation of these agreements supports Mr. Rosen's theory that the difference between the higher price and the lower price, in the context of the export sales of Apo-perindopril to Apotex UK and GenRx, was paid solely on account of the indemnity provision and related litigation services, and not on account of the sale of the product. In addition, I am of the opinion that segregating or apportioning those revenues would not be equitable in this case.

[52] First, 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 hardly 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. In addition, the indemnity and related services are offered even if there is no litigation or risk of litigation or, at least in the case of the UK TPA-perindopril, even if the lower price is applicable. There is only one agreement between Apotex and Apotex UK which covers both situations. If the product is non-patent challenged, the price, as per the UK TPA-perindopril, would be that of third party norms and standard, but the indemnity would remain available. It could also be argued that with respect to Australia, the GenRx TPA-perindopril and the GenRx TPA-Combination product, which are product-specific, would remain in force if the product becomes a non-patent challenged one, but that the price would be set by the GenRx TPA-general, which price provisions are incorporated

by reference in the two previous agreements. Again, the indemnity provisions would remain binding on the parties.

[53] As indicated above, the Katwijk-indemnity agreement is, but for the Transfer Price provisions, modeled after all three product specific transfer price agreements. It could certainly not be said that sale price, be it high or low, is, in full or in part, a consideration for the indemnity and related services offered, as the agreement does not even deal with transfer pricing. Mr. Adams testified that this was probably an oversight on his part and on the part of Mr. Ben Haneveld who signed the agreement on behalf of Katwijk. However, when confronted with a similar indemnity agreement between Apotex and GenRx, for the sale of Carvedilol in Australia (P-90), he had to admit that he could provide no explanation as to why the indemnity agreements were separate from any transfer price agreement.

[54] Second, although the defendants vigorously argue that the only factor which triggers the higher price is the increased risk of litigation, Mr. Adams acknowledged that the presence of one or more generic competitors, in a given market, has an impact on the profitability of a product. As explained by Dr. Sherman, it is after all what underlines the Apotex group of companies' business strategy: identify a profitable product and be the first generic on the market.

[55] Transfer pricing has been qualified by Mr. Hamish Salmond of Apotex UK as a "mine field". In his email dated March 15, 2007 (P-88), he says it as it is: "you can charge an affiliate what ever price you like but this may cause a tax problem". He further explains that the potential double taxation on the overcharge could be annihilated if Canada and the UK have a tax treaty or

if a dispensation based on company size applies. Although he finishes his March 15 email in saying that he needs answers on those issues, in his March 19, 2007 email (D-86, Tab-3) he simply states that the 90-10 profit split is acceptable as long as the risk is born by Apotex. Mr. Salmond did not testify at trial and thus what was considered by Apotex UK when it accepted the price will be ignored. Mr. Adams admitted that transfer pricing is a challenging endeavour and as it could be seen from the Transfer Price Policy adopted subsequently by Apotex (D-86, Tab-6), many factors need to be considered, the affiliates' profits being one of them.

[56] There is an additional difficulty with the evidence before me: I am asked to compare a cost plus based price (lower price) with a profit share based price (higher price). The first being computed only on the basis of Apotex's manufacturing cost increased by 30%, whereas the second is predicated on the sale price charged by the affiliates to third parties, thus on market conditions in the affiliate jurisdiction. One can easily understand that the more favourable the market conditions are, or the less competitive it is, the greater the difference will be between the higher price and the lower price and, according to the defendants, the more value would be attributed to the indemnity and related litigation services. The manufacturing costs would be the same irrespective of market conditions. Therefore, as the affiliate sale price increases, the affiliate's profits if calculated on a cost plus 30% transfer price, would increase exponentially. However, if they are calculated with a profit share formula, they would increase in a linear way. It is likely that the choice of a higher price in that context is, at least partially, triggered by the fact that Apotex wants to benefit from those favourable market conditions.

[57] We only know the difference in price in the specific context of the sales to Apotex UK and GenRx – therefore the value allegedly attributable to the indemnity and legal services - as they were determined by Mr. Rosen who disposed of the actual revenues from the sale of perindopril to those affiliates (made at the higher price), from which he deducted the cost plus 30% figures. The difference he arrived at is substantial. As indicated above, he deducts \$19,916,211 from total revenue of \$49,282,144 (or approximately 40%) for UK and \$2,108,163 from a \$5,977,317 (approximately 35%) for Australia. This suggests that both markets were quite favourable. As we know, they were free from competition from any generic manufacturers.

[58] I agree with the plaintiffs that the evidence presented at trial indicates that Apotex's profitability is a priority for Dr. Sherman. One example of that being the important no-interest loan between APHI and Apotex that will be discussed below in the returns on profits section of these reasons. It is only normal in that context that Apotex would want to take advantage of being the first generic on the market. As to the defendants' argument that in the case of Australia, the high price would still apply in circumstances where an authorized generic enters the market and creates competition, I note that few comments were made at trial as to what exactly is covered by that exception. It reads "excluding authorized generics and swap generics that originate from Apotex/GenRx". No one provided an explanation as to what should be understood by "originate from Apotex/GenRx", or as to the likelihood such a situation occur.

[59] In my view, the difference between the higher price and the lower price is greatly predicated on Apotex's desire to bring back home a larger part of the affiliate's profits in cases where the latter is the only generic on the market.

[60] Third, the defendants' suggested interpretation fails to consider that there is an important consideration to the indemnity and related services found in specific provisions; any settlement or award amounts are to be shared to the advantage of Apotex.

[61] I need here to discuss the parallel proceedings that took place and are still pending in the UK, between Servier Laboratories Limited [Servier], plaintiffs' affiliate, and the defendant Apotex. These proceedings are presently stayed pending the outcome of this case before the Canadian courts. The key stages of these proceedings can be summarized as follows :

- The French perindopril patent, owned by Servier had expired in 2006. However in July of 2000, it had applied for a further patent covering a particular crystalline form of perindopril erbumine, which was registered by the European Patent Office (947 Patent);
- Defendant Apotex took the view that the 947 Patent was invalid, it obtained market authorization for its product in July 2006 and, as was evidenced at trial before this Court, immediately launched its Apo-perindopril in the UK, that is, the finished product dosage manufactured in Canada;
- In August 2006, Servier issued a claim for patent infringement against defendant Apotex and Apotex UK and obtained an injunction restraining them from selling perindopril in the UK until trial. As part of the injunction relief, Servier undertook to compensate the defendants, should the 947 Patent be found invalid or should they be held not to infringe it (cross-undertaking);



- On July 11, 2007, Pumfrey J, of the High Court of Justice, found the 947 Patent to be invalid and refused to maintain the injunction pending the appeal. An appeal was filed and dismissed;
- While Norris J, of the High Court of Justice, was writing his decision on the cross-undertaking damages, Servier submitted an application to amend its pleadings and to introduce the Liability judgment that had just been rendered by Justice Snider of this Court. Servier argued that the defendants' claim should be dismissed as the perindopril Apotex UK would have sold but for the injunction, would have been manufactured in Canada and would have been an infringement of the plaintiffs' 196 Patent. They therefore pleaded the defence of *ex turpi causa*, also known as the "illegality defence";
- Norris J declined to allow the amendment and, on October 9, 2008, he granted judgment in favour of the defendants in the amount of £17,5 million ([2008] EWHC 2347 (ch));
- On February 12, 2010, the UK Court of Appeal granted Servier's appeal and allowed Servier's amendment. The case was sent back to the High Court of Justice for consideration of Servier's illegality defence ([2010] EWCA Civ 279);
- On March 29, 2011, Arnold J, of the High Court of Justice, ruled that the defendants' claim was barred by the *ex turpi causa* rule and dismissed it ([2011] All ER (D) 318 (Mar); [2011] EWHC 730 (Pat)); £17,5 million was repaid to Servier;

- The Arnold J decision was appealed from. Just before the appeal was heard, Apotex accepted in principle Servier's proposition that an amount equal to what this Court would order Apotex to pay to the plaintiffs in Canada for infringement of the 196 Patent in manufacturing and exporting products for sale in the UK market, had there been no interlocutory injunction preventing those sales, should be deducted from the damages awarded by Norris J [paragraph 26 concession];
- On May 3, 2012, the UK Court of Appeal allowed the defendants' appeal and ruled that on the specific set of facts before it, notably in the light of the paragraph 26 concession, the illegality defence did not bar the defendants' claim on the injunction cross-undertaking ([2012] EWCA Civ 593);
- On October 29, 2014, just a few weeks before the beginning of the trial before this Court, at the remedy phase of the case, the UK Supreme Court ruled that there was no good public policy reason to apply the illegality defence in the circumstances and dismissed the appeal.

[62] As things presently stand, Servier, who is not a party before this Court, has to pay to the defendant Apotex and to Apotex UK, an amount of £17,5 million, less any profits made by Apotex on its sales of Apo-perindopril to Apotex UK. As per the paragraph 26 concession, this latter amount will be assessed by the UK High Court of Justice who will apply the approach retained by this Court.

[63] As to the impact of the UK proceedings on the case before me, I only need to consider that as per the UK TAP-perindopril, 90% of the £17,5 million award is owed to Apotex. That is a significant consideration for the indemnity and legal services offered by Apotex to Apotex UK.

[64] The paragraph 26 concession is referred to in a letter from the defendants' UK counsel to Servier's UK counsel, dated March 6, 2012 (P-40), which, in part, reads as follows:

“In the meantime, on the assumption that Servier will not seek to obtain compensation in Canada in respect of the UK award to Apotex, we are instructed to confirm that Apotex accepts in principle (notwithstanding paragraphs 24 to 28 of the Re-Amended Confidential Points of Reply) that a deduction should be made to the damages awarded by Norris J in the UK proceedings, based on an assessment in the damages inquiry in the UK of what the Canadian Court would have ordered Apotex entities to pay in Canada had the sales actually been made.”

[65] That makes it clear to me why the plaintiffs did not seek to include the defendants' share of the Norris J award in the defendants' gross revenues from the sales of perindopril to Apotex UK. Absent a stipulation on Servier's part, the plaintiffs could have requested that it be added to the defendant's gross revenues for the determination of the defendants' profits to be disgorged.

[66] According to the same logic, I have to agree with the plaintiffs that instead of deducting \$22 million dollars from the top line revenues from the sales of perindopril tablets, the defendants should have asked to deduct from those revenues the costs incurred from litigating its dispute with Servier in the UK. This was not asked and no evidence of those costs was adduced, probably because they were amply covered by the award.

[67] For these reasons, I am of the view that the defendants have not adduced sufficient evidence to convince me that the difference between the cost plus price and the profit share price, in the specific context of the sales between Apotex, on one part, and Apotex UK and GenRx, on the other part, was paid on account of the indemnity and legal services provided for in the three product specific transfer price agreements.

*Costs that can be deducted from the defendants' revenues (Full absorption vs incremental costs approach)*

[68] The parties' expert, Dr. Rosen and Mr. Hamilton, agree that the following costs have to be deducted from the defendants gross revenues from the sales of perindopril:

- i) Those standard costs incurred in respect of manufacturing Apo-perindopril: raw materials, packaging materials, direct labour, set-up/clean-up, direct overhead and direct quality assurance;
- ii) Those standard costs incurred to sell Apo-perindopril: supply expenses, freight expenses, distribution expenses and commission expenses.

[69] However, they disagree as to other costs incurred by the defendants, but not directly attributable to perindopril. Those costs are: indirect overhead, indirect quality assurance, fixed overhead, depreciation, rent, freight related salary and benefits [Disputed costs].

[70] The Disputed costs are fixed in nature, in the sense that they do not vary with the level of activity or output.

[71] The defendants argue that the full absorption cost accounting, which includes a portion of the fixed costs, should be used because it properly reflects the defendants' full business venture as a whole, including their manufacturing facilities, staff and overhead, which contribute to their revenue earning operations.

[72] On the other hand, the plaintiffs contend that variable cost accounting, also known as "incremental cost" or the "differential cost" method, should be applied. This method "requires that the Court deduct from the gross revenue received by the infringer the variable or current expenses directly attributable to the infringement and any increased, fixed or capital expenses that are directly attributable to the infringement" (*Rivett FC*, at para 30).

[73] Possibly, and exceptionally, a portion of fixed costs may be deducted, for example when it can be shown that they directly contribute to the production of the infringing product, or that some specific set of facts could, one day, justify the use of the full absorption cost in an accounting of profits. However, the facts of this case do not warrant this Court to depart from its jurisprudence (*Rivett FC*, at para 30; *Teledyne Industries, Inc v Lido Industrial Products Ltd*, [1982] FCJ No 1024 [*Teledyne*] at para 23; *Apotex Inc v Lundbeck A/S*, 2013 FC 192 [*Lundbeck*], at para 300; *Varco* at para 417).

[74] Mr. Rosen candidly admitted that he was aware of the trend developed by the jurisprudence of this Court – he testified on behalf of Apotex in *Lundbeck* and failed to convince my colleague Harrington J – but he remains convinced that the full absorption cost approach is the only one that should be applied when, as is the case for the defendants, the infringer is in the

business of challenging patents. Should the defendants lose all of their cases, says Mr. Rosen, they would never be permitted to deduct their fixed costs from the gross revenues to be disgorged in favour of the patentees. I find this argument to be somewhat weak. In addition, it was shown in this case that the production of perindopril tablets only represented approximately 1% of Apotex's total production during the 2004-2008 period (D-2, Tab-7). As a consequence, the defendant had sufficient revenues from sales of other products to absorb their fixed costs and indirect overhead.

[75] The defendants did not need to expand their plants to manufacture perindopril, nor did they have to purchase new machinery, engage new employees or subcontract any portion of the production of perindopril.

[76] On November 16, 2014, the defendants provided the plaintiffs with a document disclosing overtime costs incurred by Apotex in relation to "Distribution" and "Operations". Despite the plaintiffs' objection, production of that document was permitted during Mr. Fahner's testimony the next day (D-2, Tab-6). As conceded by Mr. Fahner, those overtime amounts are already included in Apotex's standard costs for "Operations" used by both experts, such that only the "Distribution" amount of \$4 million for the entire production should be considered. As the production of perindopril represents roughly 1% of Apotex's total production, we are talking here about a deduction of approximately \$40,000. In any event, I agree with the plaintiffs that as the incremental cost of sales related to perindopril has been stipulated by the parties, the defendants are precluded from bringing some variances from that stipulation. The same could be said about utilities costs.

[77] Under those circumstances, I agree with Harrington J who held in *Lundbeck* that indirect overhead, indirect quality insurance, fixed overhead, depreciation and rent are too remote to be related to the production of perindopril (*Lundbeck*, at paras 300-301). They would have been incurred had the defendants manufactured perindopril or not.

[78] The parties have stipulated that: i) Apotex's incremental cost of sales amounts to \$12,919,000 plus \$216,000 for incremental freight expense and \$26,000 for sales commission expense for a total of **\$13,161,000**; and that ii) Pharmachem's incremental cost of sales totals \$9,322,000 plus \$7,000 in incremental freight expense, for a total of **\$9,329,000**.

*Defendants' profits from the sales of perindopril*

(3) Is the Differential Profit approach applicable in this case?

*Defendants' position*

[79] During the trial, the defendants tried to establish factually various scenarios in which they could have manufactured perindopril API and finished dosage from jurisdictions other than Canada. As the defendants assert, the production envisioned in these alternative scenarios features a variety of manufacturers, including related affiliates and third parties. The idea is that these alternative activities would not have infringed the 196 Patent.

[80] These scenarios have an impact on the accounting of profits because they concern the export sales of perindopril tablets by the defendants. Accordingly, if there were a number of viable non-infringing alternative sources of bulk API and perindopril tablets, it would have

resulted in Apotex and Pharmachem earning either less or more profits than they did as a result of manufacturing and selling those tablets from Canada. From the defendants' point of view, this submission is based on the premise that the sales would have been made to the same customers, at identical gross sale prices, in accordance with the transfer price arrangements discussed above.

[81] The defendants also base their submissions on the *Liability judgment* and Snider J's finding at paragraph 509 that "Apotex could have avoided all of the manufacturing infringement by making perindopril-containing product outside of Canada. This is not just speculation".

[82] As regards the case law, the defendants submit that the Supreme Court of Canada made it clear in *Schmeiser* that an examination of NIAs is at the heart of the accounting exercise. To the defendants, *Schmeiser* was not merely suggesting that the Court consider the profits that might have been obtained using the next best non-infringing option. This Court has a duty to consider all the reasonable possibilities of NIAs and to weigh all the evidence available including where necessary, to draw reasonable inferences.

[83] In the defendants' view, the mere fact the NIA exercise is hypothetical in nature should not deter the Court from drawing factual conclusions. To support their position, the defendants argue that the hypothetical nature of an NIA exercise is no different than the inherently hypothetical nature of any damages assessment. They argue that while assessing hypothetical constructs is an inherently difficult exercise, as in the circumstances of contract and damages in tort, difficulties should not prevent this Court from awarding a remedy. They cite passages from cases dealing with damages and tort to emphasize the role of the trial judge in dealing with



hypothetical questions. In essence, they assert there is no real dispute about what Apotex and Pharmachem did in the real world. What does matter is what arrangements Apotex and Pharmachem could have made in the hypothetical world and what non-infringing profits they could have made in that world.

[84] As regards the proper approach to be applied, the defendants submit that *Schmeiser* constituted a “watershed moment” in the case law bearing on accounting of profits because the case, by employing the “differential profit approach” replaced the formalistic “differential cost approach” favoured by earlier decisions. The approach is also to be preferred in the defendants view, citing *Schmeiser* and *Rivett*, since it “isolates and identifies the profit that was generated because of the patented invention”.

#### *Plaintiffs’ position*

[85] For their part, the plaintiffs submit that the actual profit approach should be employed for determining the defendant’s profits because the entire profits are causally connected to the manufacture and sale of the infringing perindopril. In their view, the differential approach advanced by the defendants is only applicable when a relevant non-infringing option is available, and is relevant; in the case at bar, no such option is available because there is no appropriate non-infringing comparator. The plaintiffs give a series of reasons why the differential approach should not be applied: (i) the equities and facts favour the actual profits approach; (ii) as mentioned, there is no next best non-infringing product comparator; (iii) the hypothetical alternative manufacturer scenarios contemplate the sale legally of the patented product itself; and

(iv) the aforementioned scenarios were not available to the defendants in similar conditions (this last point will be dealt within the next section).

[86] The plaintiffs submit that *Schmeiser* and the case law that has followed has not completely displaced other methods. It is open to the trial judge to use the actual profits approach based on the circumstances and equities of the case. To date, the plaintiffs argue the differential profits approach has only been applied in *Schmeiser*, *Rivett* and *Jannssens* (the soybean/canola cases) while *Lundbeck* and *Varco*, considered the approach but applied an actual profits determination because there was no relevant non-infringing option to consider.

[87] The plaintiffs assert that the differential approach is not so different from apportioning profits where the infringer alleges that only certain components were infringing and that only the profits causally related to them should be disgorged. However, the plaintiffs submit that an apportionment of profits is typically conducted as part of the actual profits approach and warranted in limited cases. They conclude that apportionment is made redundant when the court employs a differential profits approach because the use of a non-infringing product comparator already isolates the portion of the infringer's profits that is truly attributable to the infringement of the patented inventor. Thus, the question becomes not whether some portion of the infringer's product is non-infringing, but whether there is a non-infringing product comparator. If there is none, then all of the infringer's profits must be disgorged.

### *Analysis*

[88] The parties hold different views about the significance and impact of *Schmeiser* on the equitable remedy of accounting of profit and, more specifically on this case. A review of the case law is, therefore, called for.

[89] In *Reading & Bates Construction Co. v Baker Energy Resources Corp*, [1995] 1 FC 483 [*Reading & Bates*], the Appeal division of the Federal Court found the plaintiff's "pull back patent" was infringed when the defendant installed a gas pipeline under the St. Lawrence River. The "pull back patent" refers to a method of drilling and lining a hole, followed by pulling a liner back through the hole with a reamer as a production pipe is attached. In that case, the Court discussed the method for calculating the amount of profits to be disgorged as counsel argued the amount of profits is to be calculated as the difference between the actual profits earned and the profits that would have been earned through use of an alternative, non-infringing method that most likely would have been used by the infringer instead of the infringing method.

[90] The Court was not prepared to apply the hypothetical comparison, and was of the view that "one has to look at the profits that the appellant actually made through the infringing acts, not the profit that it would have made had he used a non-infringing method" (at para 21). On the facts of the case, which featured an important contract –failure to succeed in the undertaking meant no revenue at all, a "No Hole, No Pay" contract. It was the first time an installation of this nature was done over the distance stipulated. Apportionment of profits was rejected because the whole operation in the installation of the pipeline was found to infringe the patented method. It was clear that alternative methods, in comparison to the patented method, would not be reliable for the project of the kind undertaken.

[91] *Beloit* concerned infringing press sections of four paper making machines. It was argued on appeal that because the paper machines were sold as package deals, no machines could have been sold whatsoever by the defendant if the infringing press sections were not included. Upholding the trial judge, the Federal Court of Appeal ruled that the plaintiffs were entitled to the profits only realized from the sale of the press sections that infringed their patent. The judges emphasized that the question was one of fact. The evidence showed that the driving force for the purchases of the machines was not the press section but another component. The trial judge concluded that “the facts clearly show there were numerous reasons why the defendant was successful in its bid for the sale of those machines. None of them, in my view, are in any way related to the infringing press section” (at para 80). However, as there was still, to a certain extent, a connection strong enough between the profits earned and the press sections, the defendant was required to disgorge its profits realized from the sale of the press sections that infringed the plaintiff’s patent.

[92] In *Lubrizol*, the plaintiff’s patent was a type of additive or dispersant for motor oil. It was infringed by Imperial Oil’s production and sale of various brands of motor oil containing the patented additive. On appeal it was argued by Imperial Oil that it was entitled to apportion its profits on its sales as between those attributable to the infringing additive and those attributable to other factors like different additives or goodwill. The Court concluded that the motor oils may have achieved market share and profits for reasons other than the presence of the patented additive. As Lubrizol had not invented motor oil in its entirety, the Court concluded, “a finding that Imperial’s motor oils infringed the Lubrizol patent does not necessarily amount to a finding

that all the profits from the sales of such motor oils are profits arising from the infringement” (para 10).

[93] In *Wellcome Foundation Ltd v Apotex Inc*, [1998] FCJ No 1205 [*Wellcome*], the defendant Apotex manufactured and sold a combination drug with active components TMP and SMX in a ratio of 1:5. The TMP was found to contain TAA which was produced by the plaintiff's patented process. That meant TMP manufactured by using TAA as an intermediate was the infringing activity. One of the key issues in the case dealt with the extent of infringement and with the revenues earned by the defendant from its use of infringing TMP—whether some portions of Apotex's product, which contains some TAA in proportion, should be treated, in full, as containing infringing product.

[94] In the light of the specific facts of that case, both the “Differential profit” approach (which required the analysis of the best NIA) and apportionment were considered.

[95] Apotex had argued the most appropriate method was comparing actual profits with those that would have resulted from Apotex utilizing a non-infringing product available to it; non-infringing TMP, as available at the time, at the same cost as incurred in the use of the infringing TMP acquired by Apotex. Mackay J rejected the argument which he described as the “comparative approach”. It could not be established that Apotex knew or even that it could have known that some foreign suppliers may have used the patented process of the plaintiff (that is, TAA as an intermediate) to produce TMP and that others did not. There was no evidence Apotex knew at the time some TMP was produced without infringing the patent, nor that it had detailed

knowledge of the methods of production of foreign manufacturers or its foreign suppliers from which it purchased the TMP.

[96] Apotex also argued that at the time it acquired the TMP, it might have applied for and obtained a compulsory licence as others did, paying a fee to the plaintiffs, for production of TMP. Mackay J was of the view that the proposition was no more than a hypothetical assessment (at para 35):

“In my view, none of the possible licence fee arrangements was intended to or did equate to profits. Moreover, those possible courses of action were not pursued at the time by Apotex. In my opinion the royalty Apotex might have paid to plaintiffs under a licensing arrangement is not a measure of the profits derived from infringement.”

[97] However, returning to the alternative scenarios more generally argued by Apotex, Mackay J said that all the possible bases for comparison were: “speculative, based on hypothetical courses of action that, even if they might have been followed by Apotex, were not followed. All ignore the issues of actual profits earned by Apotex which the remedy to account for profits is intended to capture, to compensate the plaintiffs for the unwarranted and unlawful infringements of their patent interests” (at para 37). Mackay J also held, citing *Reading & Bates*, that the acceptance of those arguments would undermine the *Patent Act*, RSC, 1985, c P-4.

[98] As regards apportionment, Mackay J states, at paragraph 57: “No case was referred to me concerning an accounting of profits from use of an infringing active ingredient used with another in a combination pharmaceutical product.” However, he was of the view that apportionment was appropriate and proceeded to apportion along lines of a ratio of 60% to 40%, as TMP was the

more significant active ingredient of the combination drug and that profit from SMX also resulted from the defendant's successful efforts to develop the generic combination product on the market.

[99] In *Bayer Aktiengesellschaft and Miles Canada Inc v Apotex Inc*, [2001] OSJ 4 [*Bayer*], the plaintiff was a German company which had a patent for a capsule formulation of a compound known as Nifedipine. As stated by the Ontario Court of Appeal at the liability stage, "The patent is directed to a new dosage unit form for the coronary dilator, Nifedipine, being an instant oral-release compound and a method of its production." (at para 5)

[100] Apotex was granted a licence to import, make and sell Nifedipine and its capsule in return for a royalty. Upon disagreement between the parties, the licence was terminated. The Court was of the view that Apotex infringed after the termination of the licence.

[101] At the remedy stage, Apotex argued that in the context of the accounting of profits, the sales of its capsule had nothing to do with the utility of the patented invention, namely the instant oral release function because when it obtained its regulatory approval, it was only for its administration of Nifedipine, "swallowed whole". Apotex argued that only a small proportion of its profits was derived as a result of infringing the patent since only a small number of the Apo-Nifed capsules sold were actually used in a manner which took advantage of the patent. In the circumstances, Apotex urged the Court to apply the principle of apportionment.

[102] Upon review of the case law on apportionment and causation, (*Beloit, Lubrizol, Wellcome, Teledyne Industries, Reading & Bates*), the Court concluded that the defendant must identify non-infringing elements that had an impact on the marketability of the product. What actually did seem important appears in the reasons at paragraph 25 [emphasis added]:

If the patent is with respect to the entire combination, the ability of the defendant's capsule to be bitten may have been relevant to the issue of infringement, but it is not relevant to the issue of apportionment. It having been determined that the defendant's product infringes the plaintiffs' patent, it is not open to the defendant to argue that a single aspect of the infringing product was not a factor in the marketability of that product. It may be that the defendant could have successfully marketed a product with features different from the plaintiffs'. The fact is that it did not. Since the plaintiffs' patent pertains to the whole of the plaintiffs' product, so too does the defendant's infringement. Any profits earned by the defendant on the sale of its infringing product are therefore properly viewed as the property of the plaintiffs. This is consistent with case law suggesting that the appropriation and sale of the plaintiffs' entire product does not lend itself to apportionment of profits: *Teledyne Industries Inc. v. Lido Industrial Products Ltd., supra*; *Westinghouse Electric Manufacturing Co. v. Wagner Electric Manufacturing Co., supra*.

[103] In *Schmeiser*, the Supreme Court of Canada found that the “preferred means” of calculating an accounting of profits is a “differential approach”. The following two paragraphs state the relevant principles [emphasis added]:

101 It is settled law that the inventor is only entitled to that portion of the infringer's profit which is causally attributable to the invention: *Lubrizol Corp. v. Imperial Oil Ltd.*, [1997] 2 F.C. 3 (C.A.); *Celanese International Corp. v. BP Chemicals Ltd.*, [1999] R.P.C. 203 (Pat. Ct.), at para. 37. This is consistent with the general law on awarding non-punitive remedies: “[I]t is essential that the losses made good are only those which, on a common sense view of causation, were caused by the breach” (*Canson Enterprises Ltd. v. Boughton & Co.*, [1991] 3 S.C.R. 534, at p. 556, *per* McLachlin J. (as she then was), quoted with approval by Binnie J. for the Court in *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142, at para. 93).



102 The preferred means of calculating an accounting of profits is what has been termed the value-based or “differential profit” approach, where profits are allocated according to the value contributed to the defendant’s wares by the patent: N. Siebrasse, “A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms” (2004), 20 *C.I.P.R.* 79. A comparison is to be made between the defendant’s profit attributable to the invention and his profit had he used the best non-infringing option: *Collette v. Lasnier* (1886), 13 S.C.R. 563, at p. 576, also referred to with approval in *Colonial Fastener Co. v. Lightning Fastener Co.*, [1937] S.C.R. 36.

[104] In that case, the defendant was found to have infringed Monsanto’s patented genes and cells. Canola cultivated from a seed containing Monsanto’s gene and cells survives if sprayed with Roundup. The idea is that Roundup could be sprayed after the canola plants have emerged, killing all weeds except the canola—avoiding the need to delay seeding to accommodate early weed spraying and use of other types of herbicides.

[105] At trial, it was found that Mr. Schmeiser saved, planted, harvested and sold the crop from plants containing the gene and plant cell patented by Monsanto. The Court concluded that on the facts before it, no causation could be found between the profits gained by Mr. Schmeiser and the cultivated Roundup-ready canola because no finding was made at trial that he sprayed Roundup herbicide to reduce the weeds. Therefore, Mr. Schmeiser made no profits as a result of the invention.

[106] In *Rivett*, just as in *Schmeiser*, the defendants were found to have infringed Monsanto’s “Glyphosate-Resistant Plants” patent. Mr. Rivett grew, harvested and sold soybeans which he knew contained genes and cells claimed by the patent. While the decision of Zinn J was

overturned on a different issue, the Federal Court of Appeal was of the view that he had not erred in choosing the differential approach.

[107] Several important remarks are called for. The Federal Court of Appeal was of the view that pre-*Schmeiser* case law (*Teledyne, Reading & Bates, Wellcome* and *Bayer*) was unnecessary in determining the issue. In its view, an exercise in apportionment was not necessary nor possible because “there were no profits from infringement to oppose to those that were not caused by the infringement” (at para 36). As Monsanto did not invent soybeans, a differential profit approach had to properly account for this fact, affording Monsanto the portion of the profits which equals the “profit differential expected” of soybeans containing the patented gene when compared to conventional soybeans. The Federal Court of Appeal, at paragraph 37, endorsed Zinn J’s reasons [emphasis added]:

“[t]he differential profit approach ... isolates and identifies the profit that was generated because of the patented invention. In short, it looks to those profits that result from the invention that is protected and eliminates those profits that may be earned but that have no causal link to the invention. Profits that are made that are not attributable to the invention may be retained by the wrongdoer.”

[108] At paragraphs 39-41, the Federal Court of Appeal added that it did not read *Schmeiser* as closing the door “definitely” on other valuation methods better suited to a different set of facts for the trial judge. And, at paragraph 31, it implicitly suggested that unless a case is put before the court, showing a factual matrix materially different from the case at hand, the trial judge is not bound by any particular approach.

[109] In *Lundbeck*, the patent at issue was known as the (+)-Citalopram compound, which is used for treating clinical depression. The patent claims the compound itself, as well as methods to make it and its non-toxic salts. Harrington J found the patent valid, and Apotex admitted that in the event the patent was found to be valid, in all respects it had been infringed. Harrington J granted Lundbeck's election of an accounting of Apotex's profits and addressed the remedy in the same reasons. The decision does not reproduce *verbatim* the submissions of the parties; yet, in the light of the methodology adopted by Harrington J in his reasons, including his discussion of expert testimonies and the case law, it can be said that the arguments raised in the present case echo those raised in *Lundbeck*.

[110] As regards the application of the "Differential profit" approach, Harrington J discussed the impact of the Supreme Court's *Schmeiser* decision, particularly on the case before him, with only but a few sentences found in three paragraphs:

[281] In *Monsanto Canada v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902, [2004] SCJ No 29 (QL), Chief Justice McLachlin and Mr. Justice Fish, speaking for the majority, stated at paragraphs 100 and following that the accounting of profit remedy was based on "differential profits" and referred to an article by Professor Norman Siebrasse entitled "A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms" (2004), 20 C.I.P.R. 79. Professor Siebrasse was of the view that Canadian jurisprudence was somewhat inconsistent. He opined that the "differential profit" approach was clearly stated by the United States Supreme Court in *Mowry v Whitney*, 81 U.S. 620 (1871) at page 651:

The question to be determined in this case is, what advantage did the defendant derive from using the complainant's invention over what he had in using other processes then opened to the public and adequate to enable him to obtain an equally beneficial result.

[282] In *Monsanto*, the Court held that having elected for an accounting of profits, the plaintiff could not claim damages. Schmeiser had made no profit in the use of a patent relating to Canola in that he could have reached the same result without recourse to it.

[283] This case is quite different. The only active ingredient in the Apotex product was (+)-Citalopram and so it must turn over all profit less legitimate expenses incurred.

[111] In *Merck & Co., Inc v Apotex Inc*, 2013 FC 751 [*Merck*], a case with respect to damages for patent infringement, the defendants had constructed some version of an NIA defence. Snider J found the availability of the defence in a damages case to be the determinative question. She discusses the concept and general principles, not only those related to damages, but also to accounting of profits.

[112] The patent at issue involved a product-by-process patent of lovastatin, an anti-cholesterol drug. The patent covers the drug particularly when made with a micro-organism known as *Aspergillus terreus* [AFI-1 process]. During the liability phase of the trial, Snider J found that some, but not all of the lovastatin API manufactured by the defendants, were by way of the AFI-1 process and therefore infringing.

[113] During the second phase of the case, the defendants asserted they had the capability to manufacture lovastatin API by using a non-infringing process; that is, by using an alternative micro-organism known as *Coniothyrium fuckelii* [AFI-4 process].

[114] Relevant for our purposes is the plaintiff's claim for lost profits of every tablet it would have sold domestically to replace each and every infringing tablet sold by the defendants in the

relevant period. The defendants in response asserted that the plaintiffs were only entitled to a reasonable royalty for several infringing batches on the basis that Apotex had available to it a non-infringing alternative. Apotex tried to prove that after a given period, it could have used the AFI-4 process to manufacture sufficient quantities of the drug by way of this process to supply the domestic market.

[115] The evidence showed that Apotex had used the AFI-4 process for about 40% of its sales domestically during the period of infringement. At trial however, Apotex tried to show that as of the date it received its Notice of compliance [NOC], the company had the regulatory approval, the capacity and physical capability to produce all of the tablets that it sold domestically by the non-infringing AFI-4. The argument goes on to say that the plaintiff was only allowed a royalty assessed in the equal sharing of the difference in the cost of producing tablets with the infringing AFI-1 process and the non-infringing AFI-4 process.

[116] Besides the fact that she viewed the Differential Profit approach not to apply in a damage case, Snider J found herself compelled by policy reasons to reject Apotex's NIA defence. She found it "would result in an inadequate compensation for injured plaintiffs and the infringer escaping responsibility for its infringement." To her the submission advanced was quite simply, that "I would have harmed you just as much even if I had not infringed!" (at para 113). First, she did not find it punitive to compensate the plaintiff for lost profits where the defendants used the non-infringing alternative. Second, she agreed with the plaintiffs that, if adopted, the NIA defence would be inconsistent with the intent of the *Patent Act*, and would create an incentive to infringe;

if the defence is accepted, a competitor will always choose to infringe rather than use the more expensive and less efficient non-infringing alternative.

[117] Finally, in *Varco*, the patent at issue covered the braking function in automatic drilling systems. The defendants had developed an AutoDriller adopting the same pressure parameters. They admitted that without these features of its AutoDriller, they would not have had the sales they did. Phelan J adopted in full the same principles and approach enunciated by Zinn J in *Rivett*. In my view, whatever causal issue which could have been foreseen to exist, was largely resolved by the admission made by the defendants that had they not infringed, it was most likely that they would not have sold any AutoDriller. The Court had found that there was no non-infringing option to use as a comparison.

\* \* \*

[118] With respect, I am of the view that the Supreme Court did not make new law in *Schmeiser*, nor did it suggest that in an accounting of profits, courts are bound to always consider NIA products, options or scenarios, as fanciful as they may be. In my view, 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” (*Schmeiser*, at para 101). In other words, the “Preferential profit” approach is preferred over the actual profit approach when the latter would lead courts to order the infringer to disgorge its profits from its sales, whether or not the invention was only a portion or component of the good sold or used and whether or not the infringer’s profits were only partly attributable to the infringement.

[119] In that search for causation, courts have developed a variety of different formulas or used different terminologies, depending of the facts of each case, to simply decipher the use of the invention by the infringer and the extent in which this use contributed to the infringer's gross revenues or profits. "Segregation" (as it was employed by the defendants in this case to discuss the indemnity and legal services provided for in the transfer price agreements), "Apportionment" and the "Differential profit approach" are all reformulations of that same notion and they are concepts that attempt to capture causation. 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.

[120] I agree with Zinn J's remarks, in *Rivett FC*, about the *Wellcome* case on the concept of an NIA [emphasis added]:

[55] The decision in *Wellcome Foundation* provides some insight into the limits on a non-infringing alternative. The defendant Apotex argued that it could have obtained a compulsory licence to use the patent from the plaintiff and thus the difference in profits it did earn and those it would have earned if it had such a licence was merely the cost of the licence fee. It was proposing that the best non-infringing alternative was the product it sold, but sold legally under a license. Professor Siebrasse questions whether this was a valid alternative ...

[56] I take a somewhat different view of this decision. In my view, that the case involved the compulsory license comparison is irrelevant. Rather, if the position urged upon the Court by Apotex had been adopted, then the "Catch me if you can" scenario discussed previously would have resulted. If the proper measure of profits to be disgorged involves a comparison to the same product, but manufactured and sold legally, i.e. with a license, then neither of the purposes of an accounting of profits would have been achieved. In my view, what this and other decisions show is

that the next best non-infringing alternative that is to be considered when using the differential profits approach cannot be what one would have done had one complied with the law, i.e. obtained a license to use the patent. Whether the license is available through a compulsory scheme or on the open market, is irrelevant. The comparison is to the profit that would have been earned from using the next best product that is not the patented product itself, with the latter acting as a baseline from which to calculate added value. That results in a true reflection of the profits made from the invention – the necessary causal link.

[121] The defendants have asked me to deduct from their profits to be disgorged the profits that they would have made had they manufactured all of the perindopril API and finished tablet dosage that they export during the relevant period from abroad. To accept the defendants' position would be to provide them a perfect shelter against the consequences of any future patent infringement in Canada. Now that the Apotex group of companies own important manufacturing facilities in India and in the Netherlands, along with a [redacted] interest in manufacturing facilities in Mexico, they would never have to disgorge any profits from infringing a Canadian patent, as they would only have to prove that their affiliates had the capacity to manufacture abroad and that they would have been willing to do so in an effort to advance a NIA defence. We know that manufacturing costs are lower in India, Mexico and surprisingly in the Netherlands (according to Mr. Ben Haneveld). Therefore, profits from manufacturing abroad would most likely exceed profits from manufacturing in Canada in any given scenario. These scenarios are exactly the "catch me if you can" situation contemplated by Zinn J in *Rivett FC*.

[122] The defendants' NIA defence in this case is akin to the position they had tried to put forward in *Wellcome*: that they could have obtained a compulsory licence from the patentee and legally manufacture the product. Neither position finds any support in the case law.



[123] Finally, the defendants cite Snider J's finding at paragraph 509 of the *Liability judgment* that "Apotex could have avoided all of the manufacturing infringement by making perindopril-containing product outside of Canada, this is not just speculation".

[124] First, the Federal Court of Appeal made clear in *Lubrizol* that the issue of causation is a question of fact that is not predetermined at the liability stage.

[125] Second, Snider J's observation does not support the defendant's NIA defence. She was merely blaming the defendants - at the liability stage and for that purpose only - for the choice they made when they decided to manufacture and sell perindopril from Canada, knowing that the plaintiffs had an unexpired Canadian patent. In the light of her understanding of the Differential profit approach, as expressed in *Merck* above, one cannot imagine that Snider J meant, in paragraph 509 of her reasons, that the defendants thus had a valid NIA defence in the present case.

[126] Therefore, in my respectful view, the defendants are distorting the doctrine of the Supreme Court of Canada in *Schmeiser* and "the common sense view of causation". Their NIA defence will be rejected.

(4) Were NIAs available to the defendants?

[127] Considering my previous conclusion, there is no need for me to assess whether or not one or more of the defendants' affiliates or third party manufacturers would have had the capacity and would have been willing to manufacture abroad the same quantities of perindopril API and

finished dosage tablets as the defendants did in the relevant period, and the price for which they would have done so.

[128] However, as more than half of the time spent at trial was devoted to the evidence pertaining to that question, I will provide a few comments.

[129] The following expert witnesses were heard by the Court, specifically on the availability of foreign manufacturers, on their capacity to obtain all required regulatory approvals for export sales in the UK and Australia and on the price which would have been charged to the defendants (all of these witnesses were called by the defendants, except when stipulated otherwise):

- Ben Haneveld, the Managing Director of Katwijk;
- Oscar Vivanco, Signa's General Manager;
- Suresh Babu, leader of production at APIPL;
- Rajesha B Chowdegowda, Deputy General Manager at ARPL;
- Rajesha Goel, corporate finance controller at APIPL and ARPL;
- T.C. Reddy, Managing Director of Srimi;
- Murali Sarma, President of Generics at Ipca Laboratories Ltd.[Ipca];
- Marc Comas, Executive vice-president of Global licensing and third party sales at Intas Pharmaceuticals Ltd. [Intas];
- Darren Hall, Vice-President Global Supply Operation at Pharmachem;
- Chetan Doshi, Director of Formulation Development, Solid Dosage at Apotex;
- Renka Panchal, Director International Regulatory Affairs at Apotex;
- Philip Altman, expert in Australian pharmaceutical regulatory affairs;

- Penelope Field, expert in Australian pharmaceutical regulatory affairs (called by the plaintiffs);
- Angus Cameron, expert in European human pharmaceutical and regulatory affairs;
- Graham C. Higson, expert in European human pharmaceutical regulatory affairs (called by the plaintiffs).

[130] In addition, part of the testimonies of Dr. Sherman, Dr. Rosen (defendants' expert accountant) and Messrs Hamilton (plaintiffs' expert accountant), Fahner (Apotex's Senior Vice President Operations and Finance) and Berhalter (Pharmachem's Vice-President of Global Finance) also addressed the NIA issue.

[131] The main task of those witnesses was to persuade this Court that the defendants could have manufactured abroad the same quantity of perindopril API and finished dosage tablets as they had sold to their foreign clients during the relevant period. Some would have supplied the API (APIPL, Srini and Signa) and some would have supplied the finished dosage tablets (ARPL, Katwijk, Intas and Ipca). All of them provided the price at which they would have sold their product to the defendants, thus allowing Mr. Rosen to compute the profits which the defendants would have earned in each scenario. Those scenarios were compared with the actual profits earned from the infringement.

[132] As regards perindopril API, two out of five scenarios put forward would have generated Pharmachem more profits, namely the hypothetical supply of API by Srini (B-1) or Signa (B-2). For the finished dosage tablets, four out of eight scenarios would have generated Apotex more

profits than it actually earned, that is if the tablets would have been supplied by either Intas using Srini's API (T-3), Intas using Signa's API (T-4), Intas using full volume of APIPL's API (T-5) and Intas using APIPL's limited API volume and Srini supplying the rest of the volume (T-7) (Expert report of Howard N. Rosen, dated May 30, 2014, exhibit D-49 , pages 54 and 89). Under those scenarios, the defendants would have zero profit to disgorge in favour of the plaintiffs. All other scenarios would have substantially reduced the amount of profits to be disgorged.

[133] There are a few elements in the evidence which are, in my view, key to this issue.

[134] First, I agree with Strayer J in *Reading & Bates*, at paragraph 11, that "the measurement of profits should be as between the infringing method actually used and any other method which would most probably have been used. When the test is put this way it subsumes other possible tests such as that based on the most profitable non-infringing method that might have been used. In my view, the Court should look at all the circumstances and try to determine which alternative would, all things considered, most likely have been used."

[135] The defendants spared no efforts to convince me that perindopril was, at the relevant time, readily available on the international market. In addition to Srini and Signa (APIPL was not yet ready to manufacture at a commercial scale at the time), the defendants filed an extract from the 2006 Directory of World Chemical Producers (P-91) and Dr. Sherman explained that Calyx, Cipla, Glenmark, Hetero, Varda and Hritik were all Indian manufacturers listed under "perindopril erbumine" API (transcript, pages 1893-1904). In addition, Katwijk, Intas and Ipca

(ARPL was not yet ready to manufacture at a commercial scale at the time) could have formulated the perindopril tablets.

[136] One wonders why then the defendants chose to manufacture in Canada where the plaintiffs had an unexpired patent. It could be because, as transpired from Dr. Sherman's testimony, when the defendants have a choice, they prefer to manufacture themselves. At the relevant time, aside from the important manufacturing facilities they had in Canada, the defendants had a [redacted] interest in Srimi (2002) and they had purchased Katwijk (2004). Incidentally, a technology transfer for perindopril was initiated in 2004, between the defendants and Signa (a third party). However, Signa received instruction in July 2004 to stop the project. No explanation was provided as to the reasons why this technology transfer was not completed and as to why Signa did not manufacture perindopril API for the defendants.

[137] As for Srimi, Dr. Reddy had to make several concessions during his cross-examination:

- Most of the figures found in the letter he countersigned on May 6, 2014 (D-75, Tab-3) contained current information and did not reflect Srimi's situation as of 2004-2005;
- Srimi's R&D block was built in 2007, before they had an old small one;
- Srimi's sales in 2005-2008 were significantly higher for intermediates than for API;
- Srimi had never manufactured perindopril before; the only ACE inhibitor it had manufactured was ramipril;

- Srimi did not have Good Manufacturing Practices [GMP] compliance in the UK and it only received GMP approval for Australia in November of 2008;
- When confronted with Mr. Rajesh Goel of APIPL's email string, he conceded that the price provided in the letter (D-75, Tab-3) was given to him by Mr. Goel and is based on actual costs incurred by APIPL and not on Srimi's manufacturing costs;

[138] The defendants have failed to convince me that Srimi could have completed the technology transfer for perindopril, obtained both GMP approvals and manufactured the required quantity of perindopril API at the relevant time, or at the price indicated in the May 6, 2014 letter.

[139] Mr. Haneveld testified on behalf of Katwijk and instructed the Court of the following:

- Katwijk has never manufactured perindopril;
- It has never received the marketing approval to make perindopril tablets at its facilities;
- Katwijk received from the defendants 866,65 kg bulk perindopril API on June 28, 2008 and July 7, 2008; it stored it for 9 months before shipping it to APIPL and did not formulate perindopril tablets with it (Mr. Haneveld's testimony contradicted that of Suresh Babu as to the reason for waiting 9 months before shipping the bulk API);
- Katwijk did not have perindopril tablets available to support the regulatory submission for the UK, which was filed on January 31, 2005, and for Australia, which was filed on July 30, 2005.

[140] Again, the defendants have failed to convince me that Katwijk could have completed the technology transfer for perindopril, obtained all marketing approvals and manufactured the required quantity of perindopril tablets at the relevant time.

[141] Finally, even if the defendants' affiliates had demonstrated that they could have manufactured the required quantity of perindopril API and tablets, the defendants have not convinced me that this would have resulted in any profits for them. The evidence is clear and uncontradicted: neither Katwijk nor APIPL/ARPL, who started manufacturing perindopril API and tablets after Snider J issued her permanent injunction against the defendants, remitted their profits to the defendants. In other words, if those profits had made their way to Canada, it would most probably have been through dividends paid to Katwijk, APIPL and ARPL's mother companies, Apotex International Inc. and APHI, not to the defendants.

[142] On the whole, the defendants have not convinced me that any of the scenarios put forward would most probably have been used, nor have they convinced me that if either one had been used, it would have resulted in profits actually remitted to the defendants.

*Return on profits*

[143] The objective of an accounting of profits is to restore the wrongdoer in the position it would have been in, had there been no infringement. Therefore, an accounting of profits must include the indirect profits or return made by the infringer on the profits earned from the sale of the infringing product. This is to prevent the unjust enrichment of the infringer who "retains and

thus is deemed to benefit from, the profits gained from his misappropriation” (*Teledyne*, above at p. 226). The quantification of that return on profits is the last issue in dispute between the parties.

[144] In the determination of that return on profits, a plaintiff is “only entitled to the profits actually made, not those which might have been made had the infringer [...] pursued a different line of business policy” (*Beloit, FC*, above, at para 34).

[145] The Court heard the testimony of Dr. Sherman and Mr. Fahner and of both accounting experts on the issue. There is no dispute that, in this case, the defendants cannot trace what they did with the profits earned from the sales of perindopril because all of their profits are mingled together and used in the business’ day-to-day operations.

[146] In similar circumstances, courts have considered that the infringer is deemed to have reinvested those profits: “Interest at the current rate is then charged on the amount of profit retained” (*Teledyne*, above at para 22). As the objective is one of fairness and equity, it had been held that “the awarding of compound prejudgment interest as deemed earnings on the profits is the rule” (*Reading & Bates*, above at para 42) and that “it would, in such a case, be a fair presumption that an ordinary business [person] would be expected to realize as a net profit, calculated on a differential or direct cost account method, something above the prime bank lending rate existing at the time.” (*Teledyne*, above at para 22). Presumably, the infringer would have made the most beneficial use of the profits from infringement (*Reading & Bates*, above at para 48).



[147] To date, Canadian courts have used the prime lending rate plus 1 or 2 % as proxy for a return on profits (*Teledyne*, at para 22; *Ductmate Industries v Exanno Products Ltd* (1987), 12 FTR 42; *Diversified Products Corp v Tye-Sil Corp.* (1990), 30CPR (3d) 324 at 353 (FCTD) aff'd CPR (3d) 385; *Reading & Bates*, at para 48; *Wellcome*, at paras 61-62; and *Lundbeck*, at para 308).

(5) Apotex

[148] At all relevant time, Apotex benefited from an intercompany loan from APHI. There was a daily conciliation and when Apotex's revenues exceeded its operating expenses, the intercompany loan account was credited. Up until March 2007, the interest rate on that loan was prime less 0.25% on any amount owed that exceeded \$446 million (no interest was paid on the first \$446 million). As of April 2007, Apotex paid no interest on its loan with APHI (D-2, Tabs 9 and 10).

[149] The defendants argue that the proceeds from the sales of perindopril were not used to grow the business but rather only served to reduce their intercompany account with APHI; as Apotex always had sufficient funds available from the intercompany account, the revenues from the sale of perindopril merely reduced the amount that had to be drawn from that account.

[150] As a result, the defendants argue that Apotex's return on profits should be limited to prime minus 0.25% until the end of March 2007 and that it should be nil after that date. In the alternative, the actual rate should be used until the end of March (prime minus 0.25%), as it was

a suitable benchmark, and an assumed rate of prime should be used as of April 2007, where no other benchmark existed.

[151] It seems to me that the defendants' main proposition does not take into account the multitude of choices offered to companies that are of the same size of the defendants in conducting their business and the fact that amongst all of those choices, paying back a low bearing interest loan or a loan bearing no interest might not be a number one priority. Mr. Fahner acknowledged that the revenues from the sales of perindopril were used by the defendants for their day-to-day operations and various capital requirements. All depended on their needs: like any other business, they paid dividends, invested in R&D and used the funds for growth and expansion.

[152] Considering the defendants are operating in a highly profitable environment, I view a benchmark of prime, as suggested by the plaintiffs, as being fair and equitable. In light of this fair benchmark and the circumstances of this case, I see no reason why there should be a different treatment between the period when the intercompany loan bore interests at prime minus 0.25% (again, only on the excess of \$446 million) and the period when it bore no interests.

(6) Pharmachem

[153] During the same period, Pharmachem also benefited from an intercompany loan from APhi. That loan however bore interests at prime plus 0.5% (D-20, Tabs 13 and 14). It also had two loans from the Bank of Nova Scotia [BNS]: for the period in dispute between the parties, the

operating loan bore interests at prime plus 0.5% and the non-revolving loan bore interests at prime plus 1% (D-20, Tabs-15-16).

[154] The defendants submit that the prime plus 0.5% interest should be applied throughout, whereas the plaintiffs submits that as of November 2011, the rate of prime plus 1% should prevail as it is likely that the defendants would have chose to pay back the higher interest loan first. The defendants blame Mr. Hamilton for not having verified if the non-revolving loan could be paid back before term. However, in all fairness, on cross-examination, Mr. Hamilton attempted to verify in his record but was told not to worry about it. In addition, while the defendants could have adduced such evidence themselves, they have not done so.

[155] Therefore, I agree with the plaintiffs that it is likely that, as of November 2011, the defendants would have preferred to pay back the higher interest loan. In my view, it is fair and equitable to apply, before November 2011, the prime plus 0.5% interest rate, and to apply the prime plus 1% interest thereafter.

#### V. Conclusion

[156] Based on the foregoing, the issues that arise from this accounting of profits must be answered as follows: (i) the defendants are not allowed to deduct from their revenues from the sale of perindopril those amounts computed by Mr. Rosen and stated to have been paid on account of the indemnity provided to their affiliates; although I agree with the defendants that apportionment would have been appropriate in those circumstances, I am of the view that the evidence adduced does not support the defendants' position; (ii) the defendants are only allowed

to deduct from their revenues their stipulated incremental costs; (iii) the defendants' NIA defence is rejected; and (iv) as regards returns on profits, Apotex should apply a prime rate and Pharmachem should apply a prime plus 0.5% interest rate to return on profits earned before November 2011, and a prime plus 1% interest rate thereafter.

VI. Defendants' stay motion

[157] At the end of the trial before me, defendants' counsel advised the Court that they would bring a motion for an order staying the operation and effect of this judgment until the latest of:

- (a) *All appeals from this judgment, including any applications for leave to appeal to the Supreme Court of Canada and any resulting appeal to that Court are exhausted; and*
- (b) *The final determination and quantification, including any and all appeals, by the UK Courts, of:*
  - i. The "cost of manufacture point" identified in the order of Lewison J., dated September 21, 2010 in the UK High Court of Justice, Chancery Division, Case No. 0603050; and
  - ii. The "paragraph 26 concession" identified in the judgment of UK High Court of Justice Court of Appeal (Civil Division), case No. A3/2011/1158 dated May 3, 2012.

[158] The stay motion was filed on March 9, 2015 and presented before me on May 11, 2015.

[159] The defendants argue that it would be unfair for this accounting of profits judgment to have immediate effect while the UK proceedings are stayed. They say no funds should exchange hands until the amounts owing are determined with finality.

[160] The defendants' position fails to account for the fact that the plaintiffs are not parties to the UK proceedings and that Servier Laboratories Limited, who benefited from the injunction in that jurisdiction, is not a party before this Court (plaintiffs' affiliates were struck out as plaintiffs by an order of Snider J). It also fails to consider that the proceedings are presently stayed in the UK as a result of the paragraph 26 concession which was made by Apotex as a means to oppose the illegality defence raised by Servier in the UK. It finally fails to consider that part of the profits to be disgorged by defendants in favour of plaintiffs, in Canada, has nothing to do with sales made in the UK market but is rather attributable to sales made in Canada, in Australia and in the Netherlands.

[161] As a result of the paragraph 26 concession, the UK High Court of Justice needs to consider this Court's accounting of profits judgment in order to quantify Apotex and Apotex UK's damages sustained as a result of the injunction granted in the UK. No similar constraint is imposed on this Court who has heard all the evidence required to quantify the defendants' profits which are causally attributable to their infringing activities in Canada.

[162] For the same reason, there is a flaw in the analogy which the defendants draw to Rule 219 of the Federal Courts Rules, SOR/98-106 [Rules], which allows this Court to stay an order it makes under the Rules for summary trial and judgment, equally so for the analogy they make to the defence of equitable set-off.

[163] However, what is determinative of the defendants' motion is their failure to meet the test for stay pursuant to Rule 398. As to that kind of motion, a defendant must convince the Court

that there is a serious issue to be tried, that he would suffer irreparable harm if a stay is not granted and that the balance of convenience favours the granting of a stay (*RJR-MacDonald Inc v Canada (Attorney general)*, [1994] 1 SCR 311).

[164] Even if I were to accept the defendants' submission that the three "factors relate to each other, and strength on one part of the test ought to be permitted to compensate for weakness on another" (*Hudson Bay Mining & Smelting Co., Limited v Dumas et al*, 2014 MBCA 6, at para 82; *Turbo Resources Ltd v Petro Canada Inc.*, [1989] 2 FC 451 (FCA), at para 29 and *Bell Canada v Rogers Communications Inc.*, [2009] OJ No 3161, at para 39), it remains that all three questions have to be answered in the affirmative (*Janssen Inc v Abbvie Corporation*, 2014 FCA 112 at paras 12-14).

[165] Yet, the defendants failed to bring clear and convincing evidence that enforcement of this judgment would cause them irreparable harm. That failure is determinative of their motion.

[166] Aside from the fact that no affidavit was filed in support of the defendants' motion, they assert that irreparable harm lies in a loss of incentive, on their part, to move quickly in seeking a final determination and calculation of their damages in the UK. Conversely, absent a stay of operation and effect of this judgment, the plaintiffs will have the benefit of having enforced this judgment and of the stay of the UK damages judgment.

[167] Again, the defendants confuse the plaintiffs with their UK affiliates. In addition, their argument is at best speculative, just as it would be speculative to assert that a stay of this

judgment, which grants the plaintiffs a greater amount than that granted to Apotex in the UK, would give Apotex an incentive not to proceed expeditiously in any appeals in Canada and in the UK.

[168] It is for the UK High Court of Justice to case manage the UK proceedings, not for this Court.

[169] For these reasons, the defendants' motion for an order staying the operation and effect of this judgment will be dismissed.

## VII. Addendum

[170] Following the release of the Confidential Judgment and Reasons to the parties, the defendants proposed significant redactions be made relating to information about Apotex which is non-public: i) its ownership and organizational structure; ii) some financial information; and iii) intercompany agreements between Apotex and its various parent companies and affiliates.

[171] In a direction issued on June 8, 2015, which accompanied the Confidential Judgment and Reasons, this Court had asked explicitly: “[r]easons for each such proposed redaction should be provided.”

[172] The defendants only provided global, rather than specific reasons, justifying the proposed redactions. They state in their letter dated June 15, 2015 that “Apotex maintains the

confidentiality of this information at all times, and produced it in the within litigation in accordance with the Protective Order governing the proceeding.”

[173] The plaintiffs take no position with respect to the information which relates to the defendants’ ownership and organizational structure. However, they take issue with the other two categories of proposed redactions.

[174] First, the Protective Order issued at the beginning of the proceedings, which governs over the parties during and after the proceedings, does not bind the Court while disposing of the case on the merits. At this stage, the Court has to weigh the interests at stake and assess whether to displace the general rule for openness and publicity of Court proceedings and judgments.

[175] Second, the test which must be applied by the Court, in deciding whether to exercise its discretion to issue a confidentiality order under Rule 151 of the Rules, has been set by the Supreme Court of Canada in *Sierra Club of Canada v Canada (Minister of finance)*, 2002 SCC 41, where Iacobucci J, on behalf of the Court, states:

[53] ... A confidentiality order under Rule 151 should only be granted when:

- (a) such an order is necessary in order to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonably alternative measures will not prevent the risk; and
- (b) the salutary effects of the confidentiality order, including the effects on the right of civil litigants to a fair trial, outweigh its deleterious effects, including the effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings.



[54] As in *Mentuck*, I would add that three important elements are subsumed under the first branch of this test. First, the risk in question must be real and substantial, in that the risk is well grounded in the evidence, and poses a serious threat to the commercial interest in question.

[176] Finally, the burden falls on the party making the application to displace the general rule that proceedings and judgments of the courts are public (*Canada Broadcasting Corp. v New Brunswick (Attorney General)*, [1996] 3 SCR 480, at para 71).

[177] In the present case, the defendants do not identify an important commercial interest at stake, nor do they identify the serious risk which must be prevented in relation to that commercial interest, should the information they wish to redact be made public. Therefore, there is nothing for me to weigh against the deleterious effects of the confidentiality order.

[178] In addition, most of the information which the defendants wish to redact from the judgment is necessary in order to fully understand the reasons. This is an accounting of profits case and one would have difficulty accounting profits without assessing revenues and expenses. Therefore, as the defendants have not proven risk or prejudice, only the information that is inessential to the full understanding of the reasons of the Court has been redacted.

**JUDGMENT**

**THIS COURT'S JUDGMENT is that:**

***On the stay motion***

1. The defendants' motion for an order staying the operation and effect of this judgment is dismissed;
2. Costs on the motion are granted in favour of the plaintiffs.

***On the quantum of the defendants' profits and return on profits***

3. The defendant Apotex Inc. is ordered to pay to the plaintiffs, within 60 days from this judgment, its profits attributable to the infringement of the 196 Patent 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;
4. 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 the 196 Patent 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%;
5. The parties will have 14 days from the date of the public version of these reasons to simultaneously provide their submissions as to costs on the action, and an additional 7 days to reply to the other party's submissions.

"Jocelyne Gagné"

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Judge

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-1548-06

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**PLACE OF HEARING:** TORONTO, ONTARIO

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**JUDGMENT AND REASONS:** GAGNÉ J.

**CONFIDENTIAL JUDGMENT  
AND REASONS DATED:** JUNE 8, 2015

**PUBLIC JUDGMENT AND  
REASONS DATED:** JUNE 18, 2015

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