Federal Court

Cour fédérale

Date: 20110524
(Amended on May 30, 2011)

Docket: T-1668-10

Citation: 2011 FC 505

BETWEEN:

ASTRAZENECA CANADA INC. AND ASTRAZENECA AKTIEBOLAG

Plaintiffs (Defendants by Counterclaim)

and

APOTEX INC.

Defendant (Plaintiff by Counterclaim)

PUBLIC FURTHER AMENDED REASONS FOR ORDER
(Confidential Reasons for Order issued April 29, 2011)

CRAMPTON, J.

[1] This motion was brought by the Plaintiffs for, among other things, an interlocutory injunction to restrain the Defendant and certain associated individuals from making, constructing, importing, exporting, using, offering to sell or selling to others to be used, Apo-Esomeprazole and/or esomeprazole magnesium pending the trial of this action, which is scheduled to begin in September, 2013.

[2] For the reasons that follow, I find that the Plaintiffs have not demonstrated, on a balance of probabilities, that they are likely to suffer irreparable harm if an interlocutory injunction is not issued. I also find that the Plaintiffs have not demonstrated that the balance of convenience lies in their favour. Accordingly, this motion will be dismissed.

I. Background

A. *The Parties and the product at issue*

[3] The within action concerns five patents that are owned by the Plaintiffs, AstraZeneca Aktiebolag ("AstraZeneca") and AstraZeneca Canada Inc. ("AstraZeneca Canada"). Those patents contain claims that cover certain forms of the drug "esomeprazole", which is sold by the Plaintiffs under the brand name NEXIUM, as well as certain processes used to produce that drug.

[4] Specifically, Canadian Patent No. 2, 139, 653 (the '653 Patent), which was issued to AstraZeneca on July 10, 2001 and expires on May 27, 2014, contains claims that cover optically pure esomeprazole magnesium.

[5] Canadian Patent No. 2, 290, 963 (the '963 Patent), which was issued to AstraZeneca on March 28, 2006 and expires on May 25, 2018, contains claims that cover esomeprazole magnesium trihydrate.

[6] Canadian Patent No. 2, 193, 994 (the '994 Patent), which was issued to AstraZeneca on May 3, 2005 and expires on July 3, 2015, contains claims directed to the process of making optically pure esomeprazole.

[7] Canadian Patent No. 2, 226, 184 (the ‘184 Patent), which was issued to AstraZeneca on August 5, 2008 and expires on June 26, 2016, contains claims related to a certain process used to make esomeprazole.

[8] Canadian Patent No. 2, 274, 076 (the ‘076 Patent), which was issued to AstraZeneca on September 30, 2008 and expires on December 16, 2017, also contains claims related to a process used to make esomeprazole.

[9] AstraZeneca and its affiliates (sometimes collectively referred to in these Reasons as “AstraZeneca”) develop and commercialize prescription medicines around the world. Through its subsidiary, AstraZeneca Canada Inc., it is the second largest innovative pharmaceutical company in Canada in terms of dollar sales. As of March 1, 2011, AstraZeneca employed about 987 people across Canada.

[10] AstraZeneca Canada has sold NEXIUM brand tablets containing esomeprazole magnesium trihydrate, in 20 milligram and 40 milligram strengths, since 2001. It purchases those tablets from AstraZeneca.

[11] Esomeprazole belongs to the class of medications known as “proton-pump inhibitors” (“PPIs”), which are used to treat gastric-acid related conditions. The Canadian PPI market is continuing to grow significantly from its current size of approximately 23 million prescriptions. That market also is highly competitive, with approximately seven alternative PPI drugs available, including a new entrant which entered the market in September 2010.

[12] Since its launch in September 2001, annual dollar sales of NEXIUM have risen from approximately $6 million in 2001 to over $281 million in 2010. According to AstraZeneca, NEXIUM was the best-selling PPI in Canada in 2010 and ranked among the top 5 prescription products in Canada by sales. In addition, NEXIUM is the number one "switched to PPI," is recommended by 61% of physicians, is the highest ranking PPI in unaided awareness by patients, is the most self-reported prescribed PPI, and is the number one PPI doctors would select for themselves.

[13] There is currently no generic version of NEXIUM available in Canada.

[14] The Defendant, Apotex Inc., is a privately-owned Ontario company that carries on business as a manufacturer and distributor of a broad range of "generic" pharmaceutical products. Together with its affiliates (collectively, "Apotex"), it has over 5,000 employees in Canada.

B. *Steps taken by Apotex to launch a generic version of esomeprazole*

[15] The within action was launched by the Plaintiffs on October 15, 2010, following seven proceedings that the initiated in late 2007 under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended by SOR/98-166 (the "PMNOC Regulations"), to prohibit the issuance of a Notice of Compliance ("NOC") to Apotex for its proposed esomeprazole magnesium tablets. Those proceedings were initiated after Apotex filed seven Notices of Allegation ("NOAs") under the PMNOC Regulations earlier that year.

[16] In addition, on June 8, 2007, Apotex filed a patent application in Canada entitled "Process for the Preparation of Esomeprazole and Salts Thereof." That application refers to a United States Patent that AstraZeneca alleges corresponds to the '994 patent.

[17] After Apotex withdrew a number of its NOAs, AstraZeneca pursued only two of the aforementioned NOC proceedings.

[18] The first of those proceedings (Court File No. T-372-08) involved the '963 Patent. That proceeding was dismissed on consent on May 25, 2010, after AstraZeneca advised the Court that it was no longer asserting that Apotex's allegation of non-infringement of the '963 Patent was not justified, as contemplated by subsection 6(2) of the PMNOC Regulations, and after Apotex agreed that the Court need not make any determinations in respect of its allegations of invalidity of the '963 Patent.

[19] The second NOC proceeding (Court File No. T-371-08) was dismissed by Justice Hughes on June 16, 2010, on the basis that Apotex's allegation of invalidity of the '653 Patent was justified, within the meaning of section 6(2).

[20] The following day, June 17, 2010, Apotex received an NOC for its esomeprazole magnesium tablets. As of that date, Apotex was legally entitled to begin selling its generic esomeprazole tablets ("Apo-Esomeprazole") in Canada.

[21] On July 13, 2010, at AstraZeneca's request, Apotex provided an "on the record" confirmation of its intention to launch its Apo-Esomeprazole product. Then, on July 26, 2010,

Apotex again confirmed to AstraZeneca that it was proceeding with the production of launch quantities of Apo-Esomeprazole.

[22] On February 1, 2011, Apo-Esomeprazole was listed as esomeprazole magnesium trihydrate by the drug formulary in Quebec, where sales of NEXIUM are particularly strong, accounting for approximately 42% of AstraZeneca Canada's total Canadian NEXIUM sales. In addition, on November 25, 2010, Nova Scotia Pharmacare listed Apo-Esomeprazole as a non-insured interchangeable benefit. On February 9, 2011, the New Brunswick Drug Plan also posted a non-benefit interchangeable listing for Apo-Esomeprazole.

[23] On March 7, 2011, Apotex launched Apo-Esomeprazole and announced that it had commercial inventories of that product available in Quebec, New Brunswick and Nova Scotia, where it is listed at 89% of the price of NEXIUM.

II. Preliminary Motions

A. *AstraZeneca's motion to strike*

[24] On April 1, 2011 Apotex filed an affidavit sworn by Dr. Stephen Horne, the Vice President, Research and Development, at Apotex Pharmachem Inc. ("API"). According to Dr. Horne's affidavit (the "Horne Affidavit"), API currently makes esomeprazole magnesium for supply to Apotex Inc., using a process developed in-house (the "API Process").

[25] On April 13, 2011, AstraZeneca filed a motion for an Order to strike the Horne Affidavit in its entirety, or, in the alternative, to strike out paragraphs 17 to 29 of that affidavit. The grounds for that motion were stated to be that the Horne Affidavit: (i) contains evidence which is procedurally

prejudicial to AstraZeneca and/or is clearly irrelevant; and, in the alternative, (ii) does not meet the criteria for evidence adduced by an expert witness, as set forth in Rule 52.2 of the *Federal Courts Rules*, SOR/98-106 (the "Rules"). AstraZeneca's Notice of Motion also relied upon Rule 3, which provides that the Rules "shall be interpreted and applied so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits."

[26] In its written submissions, AstraZeneca stated that it would suffer prejudice if the Horne Affidavit were not completely or partially struck from the Court Record, because AstraZeneca did not have an opportunity to contemplate and respond to the information in that affidavit before the evidence on this motion was due. In addition, it stated that the information in the Horne Affidavit was clearly irrelevant because it could not assist the Court to properly construe the claims of the patent, as that is the subject matter for expert opinion. It also submitted that, to the extent that paragraphs 17 to 29 are alleged to be expert opinion, they should be struck for failing to comply with the Code of Conduct for Expert Witnesses, including the requirements that an expert witness: (i) be impartial, independent and objective; and (ii) sign the statutory declaration contemplated by the Code.

[27] I disagree with AstraZeneca's submissions.

[28] With respect to the issue of prejudice, AstraZeneca's Motion for an interlocutory injunction was brought without prior notice on March 11, 2011. The schedule that was subsequently established on consent for the hearing of that Motion required Apotex's evidence to be served by April 1, 2011, the same date upon which the Horne Affidavit was filed. Cross-examinations did not need to be concluded until April 8, 2011, and AstraZeneca had the right to file, on or before April

12, 2011, a Supplemental Motion Record and a Supplemental Memorandum of Fact and Law to address Apotex's evidence and matters which may have arisen on cross-examination.

[29] However, on April 4, 2011, AstraZeneca advised Apotex of its decision not to cross-examine Dr. Horne on his affidavit. It then advised the Court, in a teleconference call on April 15, 2011, that it would not require a postponement of the hearing on its Motion for an interlocutory injunction, to permit it to have additional time to: (i) conduct cross-examinations on either the Horne Affidavit or the supplementary affidavit of Andrew Harrington, discussed below; or (ii) file any additional materials in respect of the Horne Affidavit. In contrast to Apotex, which sought leave to file a supplementary affidavit from one of its experts after receiving new information from AstraZeneca, AstraZeneca sought no such leave to file any response whatsoever to the Horne Affidavit.

[30] Given the foregoing, I am satisfied that it would not be appropriate to grant the Motion to strike on the ground of any prejudice that otherwise might result to AstraZeneca. This is not the type of exceptional situation contemplated by the jurisprudence applicable to motions to strike (see, for example, *Belgravia Investments Ltd. v. Canada*, [2000] F.C.J. No. 1246 (QL), at para. 10; *Temple Marble & Granite Ltd. v. "Mecklenburg I" (The)*, 2002 FCT 1190, at para. 2; and *GlaxoSmithKline Inc. v. Apotex Inc.*, 2003 FC 920, at para. 4). It could not have been a surprise to AstraZeneca that Apotex would adduce evidence regarding the API Process.

[31] As a practical matter, for the reasons explained below, no prejudice will flow to AstraZeneca because the Horne Affidavit has been adduced in support of Apotex's submission that

there is no serious issue to be tried, and I have determined in Part III.C of these Reasons below that there is such a serious issue to be tried.

[32] I am also unable to accept AstraZeneca's claims that the information in the Horne Affidavit is irrelevant and of no assistance to the Court. To the contrary, I found that information to be quite relevant and helpful in better understanding Apotex's position on the issue of whether there is a serious issue to be tried in the within action.

[33] This brings me to the assertion that the Horne Affidavit contains impermissible expert evidence. This assertion is largely based on Dr. Horne's statements, at paragraph 4 of his affidavit, that he was asked to address whether: (i) the API Process uses the same process as claimed in the '994 Patent; (ii) neutral esomeprazole in a solid, crystalline form, as claimed in the '076 Patent, is used or produced in API's Process; and (iii) the optical purity of esomeprazole is increased at any stage during API's process by selectively removing racemic omeprazole, as claimed in the '184 Patent. AstraZeneca attempted to support its position on this issue by noting that the Horne Affidavit states that Dr. Horne is "able to describe API's Processes and to respond to [the above-listed] questions because of [his] education and industrial experience as a medicinal and process chemist … and by reason of [his] role at API and [his] involvement in the research and development of API's Process."

[34] I am satisfied that: (i) the Horne Affidavit does not attempt to provide an expert construction of any of the claims in the patents mentioned in the immediately preceding paragraph above; and (ii) Dr. Horne was not being put forth as an expert. In my view, Dr. Horne simply provided factual information in his affidavit, primarily based on his knowledge of API's processes. To provide that

factual information, he necessarily had to describe his understanding of the patents in question (*R. v. Graat*, [1982] S.C.J. No. 102 (QL), at para. 305, [1982] 2 S.C.R. 819, 144 D.L.R. (3d) 267; D. M. Paciocco and L. Stuesser, *The Law of Evidence* (5th ed. 2008), at pp. 26-31; and Alan W. Bryant, Sydney N. Lederman and Michelle K. Fuerst, Sopinka, Lederman & Bryant: *The Law of Evidence in Canada*, 3rd edition (Toronto: LexisNexis Canada Inc., 2009, at 774-777). In describing his understanding of those patents, he simply and very briefly: (i) quoted the plain language in those patents; and (ii) stated his understanding of what each of those patents claimed. He spent a total of four sentences describing his understanding of the '994 Patent, five sentences describing his understanding of the '076 Patent, and seven short sentences describing his understanding of the '184 Patent. By contrast, he spent nine full paragraphs describing API's Process, which was the clear focus of his affidavit.

[35] As the Vice President of Research and Development at API, Dr. Horne was as well placed as anyone to provide the factual information regarding the API Process that was set forth in his affidavit. The fact that he happened to be an organic chemist by education and to have more than 18 years of experience as a medicinal and process chemist in the pharmaceutical industry did not: (i) disqualify him from being a fact witness; (ii) transform his fact evidence into expert evidence; or (iii) require him to adduce his evidence pursuant to Rule 52.2 of the Rules.

[36] Accordingly, for the reasons set forth above, I dismissed AstraZeneca's Motion to strike the Horne Affidavit at the end of the hearing of that Motion.

B. *Apotex's Motion to file a supplementary affidavit*

[37] On April 15, 2011, Apotex filed a Notice of Motion to seek an Order granting leave to deliver a supplemental affidavit of Mr. Andrew Harrington. Mr. Harrington was one of three experts who swore an affidavit in support of Apotex's response to AstraZeneca's Motion for an interlocutory injunction.

[38] Mr. Harrington is a chartered accountant, a chartered financial analyst and a chartered business valuator. He is currently a Managing Director in the Toronto office of Duff & Phelps Canada Limited ("D&P") and is a member of that firm's Dispute and Legal Management Consulting Practice. D&P is the successor firm to Cole Valuation Partners Limited. According to his initial affidavit, Mr. Harrington has more than ten years of experience in business and intellectual property valuation and has served as an expert witness in the quantification of damages relating to intellectual property and various commercial litigation matters.

[39] The principal focus of Mr. Harrington's initial affidavit was upon claims made in an affidavit sworn on March 11, 2011 by AstraZeneca Canada's President and Chief Executive Officer, Marion McCourt. Ms. McCourt was cross-examined on that affidavit on April 5, 2011. During that cross-examination, she was asked about the business transformation plan that is discussed in her affidavit. Ms. McCourt revealed that a written presentation describing that plan had been prepared and she undertook to provide a copy of that document (the "Transformation Plan") to Apotex. That document ultimately was produced to Apotex on April 10, 2011, after the completion of cross-examinations on all of the affidavits on the Plaintiffs' Motion for an interlocutory injunction. However, it was not until April 12, 2011 that AstraZeneca agreed, after a case conference with my colleague Justice Campbell, to permit Apotex to share a copy of the document

with its experts. Two days later, on April 14, 2011, Mr. Harrington swore the supplemental affidavit that was the subject of Apotex's Motion to file.

[40] In his supplemental affidavit, Mr. Harrington stated, among other things, the following:

> The Transformation Plan also provides previously unavailable information that allows me to calculate the level of profits generated on sales by AstraZeneca Canada even if it loses its Nexium exclusivity. With this new information, I am able to determine that, even without Nexium exclusivity, the profits generated on sales by AstraZeneca Canada will be almost $[*] billion in the period 2011 to 2014.

[41] The reason that the Transformation Plan enabled Mr. Harrington to calculate AstraZeneca Canada's profits was that it provided previously unavailable information with respect to AstraZeneca Canada's costs. With that information, Mr. Harrington was able to provide more robust estimates for AstraZeneca Canada's revenues between 2011 and 2014, and to also provide estimates of AstraZeneca's profits for those years, which he was unable to do on the basis of previously available information.

[42] Based upon the information contained in the Transformation Plan, Mr. Harrington estimated that AstraZeneca Canada's revenues in the period 2011 to 2014 will be approximately $[*] billion, and that, even if AstraZeneca were to lose 80% of its NEXIUM sales over the period May 1, 2011 to May 27, 2014, its total revenues would be approximately $[*] billion.

[43] He further estimated that the contribution margin from AstraZeneca Canada's total sales over that period, assuming a loss of 80% of its NEXIUM sales, would be approximately $[*] billion. After drawing on other information contained in the Transformation Plan to estimate

AstraZeneca Canada's fixed costs for that same period to be approximately $[*] million, he then estimated that AstraZeneca Canada's profits for that period would be approximately $[*] billion. Once again, that estimate was based on the assumption, which Mr. Harrington described as being conservative, that AstraZeneca Canada would permanently lose 80% of its sales of NEXIUM on May 1, 2011. As Mr. Harrington noted, his estimates of AstraZeneca Canada's revenues and profits would obviously be greater if it is able to hold onto more than 20% of the sales of NEXIUM.

[44] AstraZeneca opposed Apotex's Motion for leave to file Mr. Harrington's supplemental affidavit on five grounds.

[45] First, it claimed that the evidence provided in the affidavit was outside the area of Mr. Harrington's expertise. I disagree. A review of Mr. Harrington's *curriculum vitae* demonstrates that he "specializes in the quantification of loss and accounting of profits in intellectual property dispute matters and damages in commercial litigation matters," and that he "has been involved in over 500 valuation, damage quantification, consulting and other advisory engagements in numerous industries."

[46] Second, AstraZeneca claimed that Apotex did not previously consider information pertaining to AstraZeneca Canada's profits to be sufficiently important to request such information prior to, or during, the cross-examination of Ms. McCourt. Accordingly, AstraZeneca asserted that Apotex ought not to be permitted to split its case with evidence based on information that it already had or did not need.

[47] In my view, neither of these objections provides a basis for preventing Apotex from responding to information that previously had not been disclosed. On the particular facts of this case, it would make little sense to permit Apotex to request a document that it learned about during cross-examination, only to then prevent it from responding to relevant new information contained within that document. That information was relevant because it enabled Apotex to better respond to some of the claims made by Ms. McCourt, Dr. Gulati and Dr. Biloski, regarding irreparable harm that the Plaintiffs claim they will suffer if the interlocutory injunction that they have requested is not granted.

[48] Third, AstraZeneca submitted that the information in the supplemental affidavit was unnecessary, redundant or marginally relevant, and of no assistance to the Court. For the reason explained immediately above, I do not accept this submission. On the contrary, I found the information contained in Mr. Harrington's supplementary affidavit to be very relevant and material to my determination of AstraZeneca's motion for an interlocutory injunction.

[49] Fourth, AstraZeneca submitted that the information contained in the supplementary affidavit will cause material prejudice to AstraZeneca Canada.

[50] I agree that AstraZeneca would be prejudiced if leave were granted to Apotex to file the supplementary affidavit. However, that prejudice will be suffered primarily because the evidence in that affidavit, which is based on previously unavailable information contained in the Transformation Plan, undermines claims made by Ms. McCourt, Dr. Gulati and Dr. Biloski. Among other things, those claims include assertions that "the introduction of generic esomeprazole magnesium in Canada … will have an immediate, catastrophic and irreversible impact on AstraZeneca Canada"

and will "imperil the [current] transformation [of AstraZeneca Canada and its] future performance". This context in which the Plaintiffs will suffer prejudice weighs against them in the consideration of their fifth submission, to which I will now turn.

[51] Finally AstraZeneca submitted that it would not be in the interests of justice to permit Apotex to file Mr. Harrington's supplementary affidavit.

[52] Given my assessment of the first four submissions made by the Plaintiffs, I conclude that it would not be in the interests of justice to refuse Apotex leave to file Mr. Harrington's supplementary affidavit, particularly given that: (i) Mr. Harrington was made available to be cross-examined on that affidavit; and (ii) Apotex was unable to cross-examine Ms. McCourt on the Transformation Plan document after its production, because she was allegedly out of the country or otherwise unavailable during the short period of time between the time when Apotex obtained the Transformation Plan and the date of the hearing on AstraZeneca's Motion for an interlocutory injunction. AstraZeneca refused to avail itself of the opportunity to cross-examine Mr. Harrington on his supplementary affidavit and must now face the consequences.

[53] AstraZeneca submitted in the alternative that certain paragraphs in Mr. Harrington's supplementary affidavit be struck. However, during the hearing of this preliminary motion, and after I agreed to strike the last sentence in paragraph 5 of that affidavit, counsel to AstraZeneca abandoned this submission.

III. Analysis

A. *The general legal principles applicable to this Motion*

[54] An applicant for an interlocutory injunction must satisfy the following well-known tri-partite test:

i. There is a serious issue to be tried;

ii. The applicant is likely to suffer irreparable harm if the injunction is not granted; and

iii. The balance of convenience favours the granting of the injunction (*RJR-MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311 at 334 and 342, 111 D.L.R (4th) 385 [*RJR-MacDonald*]).

[55] As to the first prong of the test, an applicant's burden is fairly low. The Court simply has to be satisfied that the applicant has raised at least one issue that is serious, in the sense of being "neither vexatious, nor frivolous" (*RJR-MacDonald*, above, at 335 and 337) nor "destined to fail" (*Laperrière v. D.&A. MacLeod Company Ltd.*, 2010 FCA 84, 66 C.B.R. (5th) 96, at para. 11).

[56] The second prong of the test, concerning irreparable harm "refers to the nature of the harm suffered rather than its magnitude. It is harm which either cannot be quantified in monetary terms or which cannot be cured, usually because one party cannot collect damages from the other" (*RJR-MacDonald*, above, at 341). At this stage of the analysis, the harm in question is harm that will be suffered by the applicant. Any harm that will be suffered by the respondent is considered in assessing the balance of convenience (*RJR-MacDonald*, above, at 341). In addition, the harm

claimed by the parties must be demonstrated to be clear and not speculative (*Bayer HealthCare AG v. Sandoz Canada Inc*., 2007 FC 352, [2007] F.C.J. No. 585 (QL) [*Bayer Healthcare*], at para. 35; *Aventis Pharma S.A. v. Novopharm Ltd.*, 2005 FC 815, 40 C.P.R. (4th) 210 [*Aventis Pharma*], at para. 59; *Abbott Laboratories Ltd. v. Apotex Inc.*, [1998] O.J. No. 2159 (QL) (Ont. Gen. Div.) [*Abbott Laboratories*], at para. 18).

[57] The third prong of the test is "which of the two parties will suffer the greater harm from the granting or refusal of … [the] injunction" (*RJR-MacDonald*, above, at 342). In addition, other factors may be taken into consideration in determining where the balance lies (*RJR-MacDonald*, above, at 342). In this regard, "either the applicant or the respondent may tip the scales of convenience in its favour by demonstrating to the court a compelling public interest in the granting or refusal of the relief sought" (*RJR-MacDonald*, above, at 344 and 348).

A. *General observations*

[58] In the case at bar, each of the parties made certain sweeping statements that I feel compelled to address, in the interest of discouraging similar statements and certain related hyperbole in the future.

[59] With respect to the first prong of the test, the serious issue to be tried, Apotex asserted that because this Court determined Apotex's allegations of invalidity with respect to the '653 Patent to be justified in the NOC proceedings last year, "there is no reasonable basis to continue to presume that the patent is valid". This position ignores the settled law that: (i) determinations in NOC proceedings "do not operate as res judicata" in a subsequent action in which infringement of the same patent that was the subject of the NOC proceedings is alleged; and (ii) "NOC proceedings are

quite different from subsequent infringement or impeachment actions" (*Apotex v. Pfizer Ireland Pharmaceuticals*, 2011 FCA 77, at paras. 23-24; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, at para. 42, 52 C.P.R. (4th) 145; *Novartis A.G. v. Apotex Inc.*, 2002 FCA 440, at para. 9; *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234, at para. 116). In short, the presumption of the validity of a patent that is established by virtue of subsection 43(2) of the *Patent Act*, R.S.C. 1985, c. P-4 [the *Patent Act*] remains, notwithstanding any findings that may have been made in respect of the patent in proceedings under the NOC Regulations.

[60] With respect to the second prong of the tri-partite test, irreparable harm, Apotex suggested that AstraZeneca would not suffer irreparable harm because, "even if no interlocutory injunction is granted, and even if Apotex takes even more of the market for esomeprazole than is estimated by Astra's CEO, Astra will still enjoy almost $[*] billion of profits between now and the end of 2014." To the extent that this statement may be interpreted as advancing the position that an applicant who is making profits, even significant profits, cannot ever be found to suffer irreparable harm, it must be rejected. As counsel to Apotex appropriately conceded during oral argument, the law does not require applicants for interlocutory relief to establish that they are likely to become unprofitable if the injunction they seek is not granted.

[61] Apotex also submitted that "[t]he relief sought by Astra is unprecedented and, if granted, would signal a fundamental change to the regime within which the generic pharmaceutical industry operates." In this regard, it observed "[t]his Court has never granted an interlocutory injunction to restrain a party from selling its product after that party has already suffered under a statutory injunction imposed by the [PMNOC] Regulations." AstraZeneca did not dispute this observation.

[62] To the extent that this submission stands for the proposition that the balance of convenience generally should be found to lie in favour of a respondent generic drug manufacturer in circumstances where it has been prevented from launching its product, for up to 24 months, as a result of a prohibition order preventing the Minister of Health from issuing an NOC to a generic, as contemplated by the PMNOC Regulations, it must be rejected.

[63] The same is true of Apotex's suggestion that the granting of an interlocutory injunction in cases such as the case at bar would somehow be inconsistent with the underlying spirit of the PMNOC Regulations, because such an injunction would prove devastating to "the very business model within which Apotex operates." In cross-examination on his affidavit dated April 1, 2011, Apotex's Chief Executive Officer, Mr. Bernard Sherman, extended this claim by stating, at p. 42 of the Transcript, that if an interlocutory injunction were granted to AstraZeneca in the case at bar, "it would destroy the business model for us in the whole generic industry and render useless the regulations, the whole regulatory regime." In oral argument, counsel to Apotex appropriately acknowledged that the fact that a generic drug manufacturer has acted in accordance with the PMNOC Regulations does not preclude the possibility that a patentee who may have been unsuccessful in proceedings under those Regulations may obtain an interlocutory injunction, if it can satisfy the applicable tri-partite test.

[64] It is settled law that the balance of convenience must be assessed on a case by case basis (*RJR-MacDonald*, above, at 342-343; *American Cyanamid Co. v. Ethicon Ltd.*, [1975] 1 All E.R. 504 (H.L.); *Canadian Javelin Ltd. v. Sparling* (1978), 4 B.L.R. 153, 59 C.P.R. (2d) 146 (F.C.T.D.); affirmed on other grounds (1978), 22 N.R. 465 (F.C.A.)). In this regard, the weight that may be

attributed to any particular consideration also must be assessed on a case by case basis. (*RJR-MacDonald*, above). In case at bar, it is not necessary to devote time to discussing this consideration, as I have found, for the reasons discussed in Part III.E of these Reasons below, that AstraZeneca has not otherwise demonstrated that the balance of convenience lies in its favour. The issue as to whether it would be inconsistent with the underlying spirit of the PMNOC Regulations to enjoin a generic drug manufacturer from launching its product after that manufacturer has already been delayed from launching its products by a statutory injunction under those regulations is best left for another day, when the issue has been more fully argued. The same is true of the issue of how any such inconsistency that may be found to exist may factor into the balance of convenience of analysis.

[65] Finally, in oral argument, AstraZeneca suggested that my assessment of the balance of convenience should also take into account the public interest in patent rights and the promotion of innovation and drug discovery. I agree that this may well be a legitimate consideration to be considered in assessing the overall balance of convenience in appropriate cases. However, it is difficult for the Court to accord material weight to this consideration in the absence of evidentiary support. Where such support is not forthcoming, it cannot be expected that this consideration will be a determinative factor in the assessment of the balance of convenience. Therefore, counsel would be well advised to provide evidentiary support for this type of submission in future cases.

[66] This is particularly so where, as in the case at bar, there is uncontested evidence of a likely and substantial adverse impact on the public interest, in the form of delaying a significant reduction in drug prices, if the requested injunction is granted.

C. *Serious issue to be tried*

[67] Based on the record before me, I am satisfied that there is a serious issue to be tried.

[68] In the within action, AstraZeneca has alleged infringement of claims in five patents, namely, the '653 Patent, the '963 Patent, the '184 Patent, the '076 Patent and the '994 Patent. Until such time as the presumption of validity set forth in subsection 43(2) of the *Patent Act*, above, is displaced by "evidence to the contrary," that presumption stands.

[69] Apotex attempted to make much of the fact that the '653 Patent and the '963 Patent were the subject of prior NOC proceedings that were resolved in its favour. However, as discussed at paragraph 18 above, the proceeding resolving the latter patent was resolved on consent, after AstraZeneca advised that it was no longer asserting that the allegation of non-infringement of the '963 Patent was not justified in that application. It is noteworthy that AstraZeneca and Apotex agreed, as part of their resolution in that proceeding, that "the Court need not make any determination on the invalidity allegations" that had been made by Apotex in that proceeding.

[70] With respect to the NOC proceedings concerning the '653 Patent, Justice Hughes dismissed AstraZeneca's application for an order prohibiting the Minister of Health from issuing an NOC to Apotex for esomeprazole magnesium tablets, after he reviewed an extensive evidentiary record, totalling more than 9,000 pages of evidence and argument, much of which was not placed before the Court on this Motion. By the time that proceeding was heard by Justice Hughes, the "overriding issue [was] whether the allegations made by Apotex in its Notice of Allegation that Claim 8 of the '653 patent is invalid, are justified within the meaning of section 6(2) of the NOC Regulations"

(*AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714 at para. 32, 88 C.P.R. (4th) 28 [*AstraZeneca* 2010]). Ultimately, Justice Hughes determined that Apotex's allegation that Claim 8 of the "'653 Patent is invalid for lack of sound prediction and to utility as for obviousness, is justified" (*AstraZeneca* 2010, above, at para. 138).

[71] Having regard to the foregoing, to the jurisprudence discussed at paragraph 59 above, and to the fact that three of AstraZeneca's patents were not the subject of any NOC proceedings, I am not prepared to accord much significance to the above-mentioned NOC proceedings for the purposes of this Motion.

[72] I am satisfied that the issues that have been raised in the within action are not frivolous, vexatious or destined to fail. In my view, those issues are complex and will require a substantial evidentiary record before they can be determined by this Court, particularly having regard to the fact that Apotex conceded in its written submissions that "the esomeprazole magnesium used in Apo-Esomeprazole is made by a process that was designed to avoid" infringing AstraZeneca's patents.

[73] I am also satisfied that Dr. Horne's explanations as to why, in his view, the claims made in the '994 Patent, the '076 Patent and the '184 Patent are not infringed by API's Process and the products produced in that process, are not sufficient to demonstrate that there is no serious issue to be tried in respect of those matters, particularly given that Apotex has not disputed in this Motion that its esomeprazole magnesium tablets are a generic form of NEXIUM, as referenced in its NOC submissions to Health Canada.

[74] As my colleague Justice Snider has observed: "It is clear from the jurisprudence that the hearing of an interlocutory injunction is not the time to finally determine the merits of a claim … Only after a much deeper consideration of all of the evidence that will come forward in the context of a trial should such a determination be made" (*Laboratoires Servier v. Apotex Inc*., 2006 FC 1493 [*Servier*], at para. 25; *Turbo Resources Ltd. v. Petro Canada Inc.* (1989), 24 C.P.R. (3d) 1 at 16, [1989] 2 F.C. 451 (C.A.)). Of course, prior to the fixing of the time and place for the trial in an action, a defendant such as Apotex is free to bring a motion for summary judgment pursuant to Rule 213 of the Rules. However, Apotex did not do so, perhaps because it was aware of the view that the "inherently complex, and technical" nature of patent infringement actions is a factor that would weigh against granting summary judgment (see, for example, *Wenzel Downhole Tools Ltd. and William Wenzell v. National-Oilwell Canada Ltd. et al.*, 2010 FC 966, at para. 38).

[75] The same logic applies to the consideration of the first prong of the tri-partite test in motions for interlocutory relief in drug patent infringement actions. It is this complex and technical nature of such actions that distinguishes them from the other types of actions that were at issue in many of the authorities relied on by Apotex in support of its position that there is no serious issue to be tried in the within action.

D. *Irreparable harm*

[76] AstraZeneca has claimed that "[t]he early introduction of generic esomeprazole magnesium in Canada – more than three years before the '653 Patent expiry [sic] and during a critical period for the business – will have an immediate, catastrophic and irreversible impact on AstraZeneca Canada".

[77] To provide a sense of the importance of NEXIUM in its product portfolio, AstraZeneca adduced evidence of its forecasts that, in the absence of the entry and rapid expansion of a generic rival to NEXIUM, sales of NEXIUM will grow from approximately $281 million in 2010 to $[*] million in 2011, $[*] million in 2012, $[*] million in 2013 and $[*] million to May 2014, when the '653 Patent will expire. AstraZeneca did not explain why it did not provide the Court with forecasts for the balance of 2014 and for the period 2015 to 2018, when the '184, '076, '994, '963 Patents will all expire. According to Apotex, and as conceded by counsel for AstraZeneca at the hearing, if AstraZeneca prevails with all of its claims in the within action, Apotex will be subject to a permanent injunction until 2018.

[78] AstraZeneca Canada has also forecasted that the importance of NEXIUM in its product portfolio will increase substantially, from accounting for approximately [*]% of its total sales in 2011 to [*]% in 2012 and [*]% [over 40%] in 2013. This significant increase in the importance of NEXIUM to AstraZeneca Canada is in part attributable to the fact that the patent protection for its leading drug product, CRESTOR (rosuvastatin calcium), will expire in 2012. CRESTOR has apparently accounted for approximately 30-40% of AstraZeneca Canada's total sales since 2008.

[79] In addition to the substantial monetary losses that it claimed it will suffer if the injunction is not granted, AstraZeneca submitted that it will suffer various intangible types of harms that cannot reasonably be quantified, namely, "the immediate loss of employee engagement, customer relationships, talent, innovation and creativity, and reputation." It further claimed that the harm that it will suffer will extend beyond its NEXIUM business, to include adverse impacts on "all of its products in both the current product portfolio (i.e., products existing in the marketplace) and future

product portfolio (i.e., products yet to enter the market), from the company's pipeline and from externalization."

[80] Virtually all of these types of claims have been consistently considered and rejected in other cases considered by this Court. AstraZeneca has not provided any persuasive evidence or submissions to persuade me to treat its claims any differently. In short, as discussed below, its claims are unsubstantiated and are little more than bald assertions. I therefore find that AstraZeneca has failed to establish that it is likely to suffer any cognizable type of irreparable harm.

(i) *Permanent loss of NEXIUM "market"*

[81] AstraZeneca claimed that if Apotex is not enjoined from continuing to roll-out its generic esomeprazole magnesium in Canada, it will suffer "permanent damage to the NEXIUM market." In this regard, AstraZeneca Canada estimated that it would lose "about [*]% of its NEXIUM sales within three months of genericization and about [*]% within ten months as a result of Apotex's esomeprazole market entry at this time."

[82] AstraZeneca also asserted that "AstraZeneca Canada will cease promotion of NEXIUM if the product is genericized". This is allegedly because "[i]t would be pointless to spend money, time, energy and efforts [*sic*], only to grow sales of generic esomeprazole (since the generic would be the principal beneficiary of such growth)." In response to Apotex's position that protecting the market position of NEXIUM would make sense because AstraZeneca would receive greater damages if it prevails in the within action, AstraZeneca responded that "litigation is inherently unpredictable" and that "[i]t is not reasonable for AstraZeneca Canada to assume that it will succeed in the infringement action and to operate its business on that basis."

[83] AstraZeneca added that an important consequence of ceasing to promote NEXIUM would be that the overall market for the drug will shrink, "resulting in a permanent decrease in the NEXIUM market" by the time the within action is decided, which it forecasted will be almost three years from now.

[84] In support of its claims, AstraZeneca submitted affidavit evidence from Ms. McCourt as well as from two experts, Dr. Ranjay Gulati and Dr. Alan Biloski.

[85] In her affidavit, Ms. McCourt repeated the claims made in AstraZeneca's written submissions and stated that generic products typically are listed on provincial and private formularies at a fraction of the drug innovator's prices. As a result, "once a generic enters the market it is expected that a substantial portion of the innovator's market for that drug will be lost within months." For this reason, "as soon as a generic version of an AstraZeneca product enters the market, AstraZeneca Canada considers that market lost, and the business is restructured accordingly."

[86] Based on her experience with launches of other generic products, Ms. McCourt stated that she expects that "Apotex will quickly flood the market with lower priced generic esomeprazole." She also asserted that "AstraZeneca Canada will cease promotion of NEXIUM if the product is genericized." She added that "the loss of NEXIUM at this time will destabilize and imperil the transformation [of its organization that was recently implemented] and imperil its future performance." This is based on her forecast that, in the absence of Apotex's continued roll-out of

Apo-Esomeprazole, NEXIUM will generate approximately $[*] billion in sales between now and May 2014. This represents "about [*] of the total [forecasted lifetime] sales of NEXIUM."

[87] Dr. Biloski and Dr. Gulati supported Ms. McCourt's position that it would not make economic sense to continue promoting NEXIUM once that product has become genericized. In short, they agreed that such action would simply serve to increase sales of the generic product more than to increase sales of NEXIUM. They added that such promotion would utilize resources that could be better spent on more fruitful endeavours. Indeed, Dr. Gulati asserted that "continued promotion of NEXIUM would require significant financial capital which would no longer be available due to the rapid erosion of the revenue stream following NEXIUM genericization." Dr. Biloski and Dr. Gulati both opined that the harm to AstraZeneca that would likely flow from generic erosion of NEXIUM's sales would not be reasonably quantifiable. Dr. Gulati explained that this was "because of the multiplicity of exogenous and endogenous factors which necessarily impact a business' outcomes in its market and sphere of operation." Likewise, Dr. Biloski supported his conclusion on the basis of "the wide variability in the future commercial outcomes of AstraZeneca Canada's business if [NEXIUM] were to retain market exclusivity until May 27, 2014 …".

[88] I do not agree with either: (i) the position that it would not make sense to continue to promote NEXIUM once that product has become genericized; or (ii) the position that the various harms that AstraZeneca has asserted under this heading would not be reasonably quantifiable.

[89] With respect to the promotion of NEXIUM, I find the evidence of Apotex's experts to be more analytically robust and persuasive.

[90] Dr. Bower appropriately noted that AstraZeneca has not provided any information with respect to the fixed costs involved in promoting NEXIUM. Therefore, he questioned the basis for Dr. Gulati's assertions that such promotion would require "significant financial capital" and that such capital "would no longer be available." In addition, given that AstraZeneca has not provided any information with respect to the profits earned by AstraZeneca Canada, he appropriately questioned how Dr. Gulati could conclude that AstraZeneca Canada would not be able to access the capital in question, whether from its parent company or otherwise. Dr. Bower also properly noted that there is no evidence in the Motion Record to support Dr. Gulati's conclusion that any growth from continued promotion would "taper off quickly."

[91] Dr. Hollis provided various calculations that served to confirm the common sense view that, "the firm that benefits from the promotional efforts will be the firm that is successful in the patent infringement action." Thus, even in the absence of an interlocutory injunction, AstraZeneca would be the only beneficiary of the promotional efforts, assuming that it prevails in the within action, and assuming that it can reasonably quantify and prove its damages. Given that AstraZeneca launched the within action fairly recently, and is continuing to pursue it, it is reasonable to assume that AstraZeneca believes that it will prevail.

[92] I agree with Dr. Hollis' observation that it is not reasonable for a firm that speculatively invests hundreds of millions of dollars in "finding and developing new drugs that may or may not be approved by regulatory authorities", to claim that it would not make good business sense to continue to promote NEXIUM, a proven blockbuster drug, until trial. Based on figures derived from AstraZeneca's own evidence, and assuming a 50% chance of prevailing in the within action, Dr.

Hollis estimated that AstraZeneca's expected revenues over the next three years would be approximately $[*] million if the requested injunction is granted, and $[*] million, which is only 5% less, if the requested injunction is not granted. If AstraZeneca believes that it has a greater chance of prevailing, the difference in the expected values of its revenues, with and without an injunction, would be even less. For example, Dr. Hollis calculated that this difference would be only approximately 1.6%, if the probability of AstraZeneca prevailing in the within action is 80%.

[93] Andrew Harrington agreed with Dr. Hollis' view that, if AstraZeneca Canada does in fact anticipate that it will succeed in the within litigation, "it would be prudent action to continue the full sales and marketing initiative and thereby preserve Nexium's share in the PPI market pending the outcome of the trial in this matter." In his view, this would be "sensible given that, if successful in the litigation, AstraZeneca Canada will have a damages award against Apotex equal to the amount of its lost sales to Apotex." Mr. Harrington acknowledged that there is no certainty that AstraZeneca Canada will in fact prevail in the within action. However, he estimated that, "depending upon which patent or patents AstraZeneca Canada succeeds upon, the benefit to AstraZeneca of maintaining the Nexium® market will be between $[*] billion and over $[*] billion." Although he did not refer to the marketing costs that would be required to continue to promote NEXIUM, his conclusion that "the prospective revenue opportunity benefit to AstraZeneca Canada of continuing to promote Nexium® is very substantial at a relatively low cost" strikes me as being much closer to the mark than the unsubstantiated assertions of Dr. Gulati and Dr. Biloski.

[94] Mr. Harrington also astutely questioned "why any reasonable business person would accept the risk" of Apotex successfully arguing, in the within action, that "the entirety of AstraZeneca Canada's losses were attributable to AstraZeneca Canada's irrational decision to allow the Nexium®

market to collapse." This observation would apply with equal force even if Apotex only succeeded in ultimately establishing that a portion of AstraZeneca Canada's damages were attributable to its decision to stop promoting NEXIUM.

[95] I do not accept AstraZeneca's suggestion that the analyses provided by Dr. Hollis and Mr. Harrington were outside their respective areas of expertise. In my view, Dr. Hollis' analysis was well within the domain of his extensive background and expertise in economics and competition between branded and generic drugs. Similarly, Mr. Harrington's analysis was well within the field of his extensive background and expertise in dispute consulting, business and intellectual property valuation, and the quantification of loss and accounting of profits in intellectual property dispute matters and damages in commercial litigation matters.

[96] Considering the foregoing, and in the absence of additional financial and other evidentiary support from AstraZeneca or its experts, I do not accept that it would make good business sense for AstraZeneca Canada to discontinue promoting NEXIUM if this Motion for an interlocutory injunction is not granted. This is particularly so given that: (i) AstraZeneca's patent protection is likely to last for approximately three more years, if not until 2018, when the last of the patents in the within action expires (*Servier*, above, at para. 71); and (ii) AstraZeneca Canada has not provided any evidence to indicate that the costs associated with continuing to promote NEXIUM would likely exceed the profits that could reasonably be expected to be derived from those promotional efforts.

[97] In my view, if AstraZeneca Canada does cease or reduce its promotional activities in respect of NEXIUM, any harm that it may suffer will flow from its own actions, not the continued roll-out

of Apotex's generic product. Moreover, such harm is likely to be quantifiable and, thus, not irreparable (*Servier*, above, at paras. 48 and 71; *Merck & Co. v. Nu-Pharm Inc*. (2000), 4 C.P.R. (4th) 464, [2000] F.C.J. No 116 (QL) (T.D.) [*Merck & Co*], at paras. 36 to 38; *Bristol-Myers Squibb Co. v. Apotex Inc*., 2001 FCT 1086, 15 C.P.R. (4th) 190 (F.C.T.D.) [*Bristol-Myers*], at para. 29; *Bayer Healthcare*, above, at para. 85; see also, *Aventis Pharma*, above, at paras. 43, 74-77 and 113).

[98] Turning to AstraZeneca's claim that the various other harms asserted under this heading would not be reasonably quantifiable, I acknowledge that, at this point in time, it may be difficult to accurately forecast the harm that AstraZeneca is likely to suffer, at least on a temporary basis, if this Motion is not granted. However, that difficulty is likely to be reduced by the time it is necessary to calculate damages in the within action (*Servier*, above, at para. 52).

[99] In any event, "[t]he jurisprudence is clear that difficulty in precisely calculating damages does not constitute irreparable harm, provided there is some reasonable methodology that could, at the time damages would be assessed, measure those damages" (*Servier*, above, at para. 51; *Aventis Pharma*, above, at para. 61; *Abbott Laboratories*, above, at para. 17).

[100] Moreover, I am satisfied that any such damages are likely to be quantifiable and recoverable (*Servier*, above, at para. 73; *Bayer Healthcare*, above, at para. 64; *Merck & Co*, above, at para. 41; *Abbott Laboratories*, above, at para. 24; *Fournier Pharma Inc. v. Apotex Inc.* (1999), 2 C.P.R. (4th) 351, [1999] F.C.J. No. 1689 (QL) (T.D.) [*Fournier Pharma* 1] at para. 66; *Bristol-Myers*, above, at paras. 21-22; *Pfizer Ireland Pharmaceuticals v. Lilly Icos LLC*, 2003 FC 1278, 29 C.P.R. (4th) 466 at paras. 27-29; *Pfizer Ireland Pharmaceuticals v. Lilly Icos LLC*, 2004 FC 223, 30 C.P.R. (4th) 317, at para. 39; *Aventis Pharma*, above, at paras. 79, 84 and 88).

(ii) *Negative impact on other existing products, customer relationships and employees*

[101] AstraZeneca claimed that, due to the fact that Apotex is launching Apo-Esomeprazole "at a time when major structural changes to the business have just been made, [this will lead to a] downward spiral of intangible harms which could negatively impact on sales of all of AstraZeneca Canada's products in the immediate and longer term." These structural changes were part of the recent implementation of a major business transformation which included the elimination, in December 2010, of [*]% of the total employees of AstraZeneca Canada. This business transformation was effected, at least in part, in anticipation of the loss of patent protection on CRESTOR, in 2012. However, that transformation allegedly did not take into account the possible genericization of NEXIUM. In addition, the employee reductions did not include any sales staff.

[102] AstraZeneca stated that "it is not aware of any major pharmaceutical company that has survived the loss of their top two selling products (which account for 50% or more of their revenue) in such a narrow time frame as faced in the present situation."

[103] In this context, AstraZeneca claimed that "the loss of NEXIUM at this time will destabilize and imperil the transformation of AstraZeneca's future performance." In part, this is allegedly attributable to the fact that additional employee reductions will have to occur, and this will "necessarily have to include the sales force." AstraZeneca claimed that this would "be particularly devastating" and of long duration, "because relationships with and knowledge of customers are built over years" and because most employees have responsibilities that cover more than one product or support the entire organization.

[104] AstraZeneca further claimed that "[t]here is undoubtedly little or no interest on the part of the global business to rescue a poorly performing arm, especially one in a small market such as Canada when there are potentially larger emerging markets that are competing for AstraZeneca's investment." In this regard, Ms. McCourt stated in her affidavit that [*].

[105] Ms. McCourt also stated in her affidavit that the continued roll-out of Apo-Esomeprazole will result, in the near and longer term, in "a real and substantial negative impact to the current portfolio of products in the market today as AstraZeneca Canada will have lost the resources, both financial and human, and competitiveness it presently enjoys."

[106] Dr. Gulati added, in his affidavit, that "[r]esearch has also shown that as businesses downsize and reduce their key customer support personnel, their ability to deliver ancillary value-added service decline [*sic*], which in turn reduces customer satisfaction, loyalty, and repurchase intentions."

[107] With respect to its employees, AstraZeneca claimed that its "recent layoffs and restructuring have likely shaken many employees". However, it anticipates that, "absent further bad news, employees will be able to focus and gain renewed confidence in AstraZeneca's future". That said, the news that Apotex has been permitted to continue to roll-out Apo-Esomeprazole would "create stress perceived by job insecurity" as well as a "loss of employee morale, focus, commitment and energy." If it is not able to "maintain a high level of employee engagement," AstraZeneca claimed that "[k]ey priorities in 2011 and beyond, including product launches, will be derailed if employees are distracted and demoralized, and suffer stress and loss of pride and confidence in the company." In turn, AstraZeneca asserted that "a number of high performing employees, who would not be part

of the downsizing, would leave, preferring not to work in a company that has suffered such a setback," thereby compromising AstraZeneca Canada's competitiveness in the immediate and longer term. AstraZeneca added that if it prevails in the within action, "all of this lost talent would not simply be available to be re-hired and it will not be possible to quickly replace and rebuild the employee base."

[108] In her affidavit, Ms. McCourt reiterated the various claims set forth above and stated that the Transformation Plan that AstraZeneca Canada implemented in the first quarter of this year "assumes and depends on exclusivity for NEXIUM until patent expiry." In other words, that plan did not take account of Apotex's launch of Apo-Esomeprazole, which Apotex had previously confirmed was being pursued. In this latter regard, Ms. McCourt stated that it would be "illogical to conduct business assuming a possible blow at an unknown future time, including directing employees to prepare for such an eventuality. Certainty is needed."

[109] Accordingly, Ms. McCourt claimed that "[t]he significant and rapid loss of NEXIUM revenue means that a significant further reduction of the size and structure of the business will be required over a short period of time. Further reductions will be in the range of [*]%." She added: "I believe that the company will not be able to absorb the further changes at this time without significant harm," particularly given that the company has just implemented an approximately [*]% reduction of the employee base.

[110] Based on his understanding of Ms. McCourt's affidavit, Dr. Gulati stated in his affidavit that "it is entirely reasonable and most likely necessary to expect a further significant downsizing of the company if there is early genericization of NEXIUM." He added that this would be

compounded by additional voluntary departures, especially by persons within the company's sales force, "who will view AstraZeneca Canada – having lost its top two selling drugs in such a short period of time, as a defeated company with no opportunity for growth." In his view, these further employee reductions, over and above those recently implemented, "would be dramatic and catastrophic to AstraZeneca Canada." In short, he stated that these reductions:

> … would likely create a destructive chain reaction within the organization, resulting in loss of employee engagement, commitment and motivation, physical and psychological strain on employees, loss of institutional memory, disruption of relationships between sales representatives and physicians, negative impacts on the climate for creativity, and negative impacts on reputation harming both the survivors and the organization itself, creating an environment of uncertainty for all persons within the company.

[111] After elaborating on the foregoing and drawing upon the findings in a number of recent articles that discuss research into corporate downsizing, Dr. Gulati opined that the alleged harms to AstraZeneca are not reasonably quantifiable in monetary terms, that is to say, quantifiable within a reasonable degree of accuracy.

[112] Dr. Biloski stated in his affidavit that, "further significant cuts will almost certainly be the inevitable result of a commercialization of generic NEXIUM in 2011 and the consequential loss of a significant NEXIUM revenue stream." In addition, he stated that he is "not aware of any major pharmaceutical companies that have been able to survive the loss of their top two selling products (which account for 50% or more of their revenue) in such a narrow time frame – and AstraZeneca Canada will likely be no different."

[113] Furthermore, he opined that, having regard to AstraZeneca's fiduciary obligation towards its shareholders and the likelihood of finding better returns from investments in countries such as China, it is "entirely reasonable that [AstraZeneca] would choose to forego providing a lifeline of financial and other support and allow AstraZeneca Canada to experience a sudden and pronounced decline."

[114] Consistent with Dr. Gulati's view, Dr. Biloski also opined that the impact of the above-described harms on AstraZeneca Canada "[are] not reasonably quantifiable given the wide variability in the future commercial outcomes of AstraZeneca Canada's business if [NEXIUM] were to retain market exclusivity until May 27, 2014 …" .

[115] I have great difficulty believing that AstraZeneca Canada did not account for the likelihood of a loss of significant sales of NEXIUM, when it recently implemented a reduction of approximately [*]% of its workforce, particularly given the facts discussed in the paragraphs immediately below. In any event, I find that AstraZeneca's claimed harms are exaggerated, speculative and unsubstantiated. To the extent that any such harms do materialize between now and the time at which damages are calculated in the within action, I find that they are likely to be reasonably quantifiable and compensable.

[116] As with the claims discussed in Part III.D (i) above, I find the evidence of Apotex's experts to be more analytically robust and persuasive than the evidence of Ms. McCourt, Dr. Biloski and Dr. Gulati. In this context, where I must determine which conflicting evidence to accept for the purposes of assessing whether alleged irreparable harm has been clearly demonstrated, the Business

Judgment Rule, as summarized in *BCE Inc. v. 1976 Debentureholders*, 2008 SCC 69 at para. 40, has no application

[117] In his affidavit, Dr. Bower notes that AstraZeneca Canada: (i) has known since late 2007 that Apotex was seeking to obtain an NOC to market its generic esomeprazole product; (ii) is aware that Apotex obtained that NOC in June 2010; and (iii) thought that the risk of Apotex launching its product was so high that it commenced the within action. In these circumstances, he stated: "I find it hard to believe that Astra Canada would undertake a business transformation, commencing in late 2010, the success of which depended upon this launch not occurring."

[118] Similarly, Dr. Hollis stated in his affidavit that he found it surprising that AstraZeneca would have to reduce its workforce by a further [*]% because, in anticipation of the genericization of CRESTOR, a drug which historically delivered over twice as much revenue as NEXIUM, the company recently cut approximately [*] employees. In this regard, Dr. Hollis pointed out that NEXIUM "is chiefly insured under private insurance plans, which have historically not been as aggressive in moving patients from brand name to lower priced generic drugs." He also noted that the Province of Quebec "has a policy of allowing innovative medicines to be fully reimbursed for 15 years following their introduction," such that "for the public plan in Quebec, Astra is likely to retain a healthy share of the market." In addition, he suggested that Apotex's proposed selling price of Apo-Esomeprazole, at 89% of NEXIUM's price, will likely deter some people who might otherwise choose the generic product. In the absence of more specific information about AstraZeneca Canada's financial situation, Dr. Hollis concluded: "It appears that Astra would not be financially constrained and thus would be able to maintain the staff required to continue to promote Nexium to physicians."

[119] Dr. Hollis also responded to Dr. Gulati's suggestion that AstraZeneca Canada would not likely survive the genericization of its top two selling drugs by noting that Pfizer Canada lost its exclusivity on Norvasc and Lipitor in the space of one year. In this regard, Dr. Hollis noted that those two drugs accounted for approximately 63% of Pfizer Canada's revenues in 2008, and that, "despite these losses, [Pfizer Canada] continues to operate."

[120] Dr. Hollis also responded to Dr. Biloski's view that it would be entirely reasonable for AstraZeneca to withhold funding from AstraZeneca Canada if NEXIUM is genericized, as more attractive investment opportunities are available elsewhere in the world. In short, Dr. Hollis stated that this view "seems poorly founded," because if Canadian opportunities are not more attractive than opportunities elsewhere, "they should not be funded in any case, regardless of the potential cash flow from sales of Nexium."

[121] With respect to AstraZeneca Canada's financial resources, as discussed at paragraph 40 above, Mr. Harrington estimated that, even with the genericization of NEXIUM, AstraZeneca Canada's profits would be almost $[*] billion in the period 2011 to 2014. Mr. Harrington also estimated the cost of maintaining [*]% of AstraZeneca Canada's existing workforce to be [*] [less than $50] million, after tax.

[122] On a related point, Dr. Bower also noted, in his affidavit, that Ms. McCourt provided no explanation as to how AstraZeneca Canada concluded that the genericization of NEXIUM would necessitate a further [*]% reduction of its workforce. He also noted that Ms. McCourt did not

provide any information as to the annual cost savings that AstraZeneca Canada would expect to achieve by such a reduction.

[123] Given Ms. McCourt's statement, in her affidavit, that the recent implementation of the Transformation Plan has strengthened AstraZeneca Canada, and has resulted in a "new, more efficient and responsive operating model," Dr. Bower stated that he found "Ms. McCourt's statements as to how she intends to respond to Apotex's market entry for esomeprazole to be all the more perplexing." I endorse Dr. Bower's view.

[124] With respect to Ms. McCourt's statement that reducing AstraZeneca Canada's workforce by a further [*]% would have a devastating and long term impact on the company, and would prevent the company from successfully implementing the ongoing Transformation Plan, Dr. Bower opined that, "[i]t is illogical in the extreme to damage the very asset that would enable Astra Canada to survive and, indeed, thrive in the years to come." With this in mind, Dr. Bower opined that these statements, and the similar statements made in the affidavits of Dr. Biloski and Dr. Gulati, "vastly exaggerate the likely effects of the job cuts."

[125] After reviewing some of the relevant literature on corporate downsizing, Dr. Bower observed: "Thus, the literature states that whether or not the downsizing causes serious long-term harm to the company is largely within the control of its management." He also noted that some of the literature cited by Dr. Gulati reports that the adverse effects of corporate downsizing are "relatively short-lived." In addition, he referred to substantial and successful downsizings that have occurred at Xerox Corporation, Ford Motor Company and IBM.

[126] Dr. Bower then referred to an article, entitled "Death of a Salesman: AstraZeneca Replaced Entire Nexium Salesforce with Telemarketers," which reported upon a recent corporate downsizing that was implemented by AstraZeneca Canada's U.S. affiliate ("AstraZeneca U.S."). That article reported that, in 2009, AstraZeneca U.S. "reduced its salesforce headcount by 430 full-timers, a 50 percent cut," and replaced them with a 300 person call centre and an Internet site. As a result of this initiative, "essentially all detailing of Nexium was eliminated," even though NEXIUM's patent protection in the U.S. apparently will not expire until 2014. Notwithstanding this substantial reduction in its salesforce, the sales and market share of NEXIUM reportedly did not decline in 2009.

[127] Dr. Bower also referred to other articles reporting on other workforce cuts within AstraZeneca's global enterprise. Based on those articles, he concluded that "it would appear that, since 2007, the AstraZeneca group of companies has announced cuts to its workforce totalling 23,550 jobs, which cuts are to be completed by 2013." Based on another source that reported a total pre-downsizing workforce of 65,000, Dr. Bower estimated that the total reported cuts constituted approximately 36% of AstraZeneca's [total worldwide] workforce.

[128] With respect to the recent cuts implemented by AstraZeneca Canada, Mr. Harrington noted that, on page 11 of the Transformation Plan, it is indicated that a key objective was to eliminate "unnecessary layers of management and small spans of control," and to "streamline cross-functional processes."

[129] Having regard to the foregoing, I find it implausible that AstraZeneca did not take Apotex's announced entry into the esomeprazole business into account when it planned and recently implemented a [*]% reduction of its workforce. This is particularly so given that: (i) on July 13, 2010, at AstraZeneca's request, Apotex provided an "on the record" confirmation of its intention to launch Apo-Esomeprazole; (ii) on July 26, 2010, it again confirmed to AstraZeneca that it was proceeding with the production of launch quantities of Apo-Esomeprazole; (iii) AstraZeneca filed the within action on the same day that Ms. McCourt presented the Transformation Plan to Mr. Fante for approval; and (iv) Ms. McCourt acknowledged during the cross-examination on her affidavit that "[a] competent CEO will most deliberately plan for events that are deemed likely to occur."

[130] In any event, given the evidence of Mr. Harrington and Dr. Hollis, I find it implausible that AstraZeneca will not have, or have access to, sufficient resources to maintain its workforce at a level which would avoid the devastating and catastrophic harms that it has claimed will result if Apotex is not enjoined from continuing to roll-out Apo-Esomeprazole.

[131] In addition, I find it implausible that AstraZeneca Canada's employees would react in the manner claimed by Ms. McCourt, particularly given that they have known for approximately 10 months now that Apotex obtained an NOC in respect of Apo-Esomeprazole, a fact that Ms. McCourt acknowledged when she admitted, during cross-examination on her affidavit, that she had sent a press release to AstraZeneca's employees regarding that NOC, soon after its issuance last June.

[132] Moreover, I find it implausible that any of the claimed harms will materialize if Apotex continues its roll-out of Apo-Esomeprazole. Having regard to Mr. Harrington's evidence that if any

of these claimed harms do materialize, they will be "measurable in a reliable and traditional manner," I also find that such harms would be reasonably quantifiable and compensable if they do materialize. I note that these findings are consistent with the jurisprudence with respect to these types of claimed harms (*Fournier Pharma Inc. v. Apotex Inc.* (1999), 1 C.P.R. (4th) 344, [1999] F.C.J. No. 504 (QL) (T.D.) [*Fournier Pharma 2*], at para. 9; *Fournier Pharma 1*, above, at paras. 55 and 75; *Aventis Pharma*, above, at paras. 94-97; *Bayer HealthCare*, above, at paras. 58 and 70-73; *Servier*, above, at paras. 37, 45 and 48; *Wellcome Foundation Ltd. v. Interpharm Inc.* (1992), 41 C.P.R. (3d) 215, [1992] F.C.J. No. 123 (QL) (T.D.)).

(iii) *Negative impact on pipeline products*

[133] AstraZeneca submitted that it "expects [*] new products to be launched in 2011 and 2012, and several more beyond that." As a result of the other harms that it has alleged, it claimed that it would "be going into these (and 2012) product launches wounded and severely disadvantaged." As a result, the "uptake and success" of some of its future products "will therefore be critically diminished." This is alleged to be an "unquantifiable impact which the business will never get back in the product's life cycle." In the case of at least one pipeline product, VIMOVO, which is a combination of NEXIUM and naproxen, the Plaintiffs claimed that the list price of the product "will likely be based on the price of the component drugs, if it is listed at all." As a result, AstraZeneca asserted that "[i]t will be impossible for AstraZeneca Canada to obtain the price, and therefore the revenues, it would have if esomeprazole was not genericized early."

[134] In her affidavit, Ms. McCourt reiterated the foregoing claims and added that, as part of the ongoing business transformation plan, more resources are being shifted to effective launch strategies in relation to the company's pipeline products.

[135] Dr. Biloski supported the above described claims by stating that: (i) losing key provider relationships will make it difficult to change prescribing behaviour of physicians; (ii) losing the most creative employees will deny a company the ability to optimize its promotional programs; and (iii) "the unexpected erosion of a flagship product such as NEXIUM can have a terminal impact on AstraZeneca Canada by foreclosing its ability to revitalize its product line."

[136] As with the claims discussed Part III.D. (i) and (ii) above, I find the claims that have been made in respect of AstraZeneca's pipeline products to be entirely speculative and unsubstantiated. Indeed, I agree with Dr. Bower's view that these claims "vastly exaggerate the likely effects of the job cuts" that Ms. McCourt claimed will have to be made if the requested injunction is not granted. I also agree with Dr. Hollis' opinion that "if pricing of Vimovo on any formulary is compromised by the generic esomeprazole, that would be a relatively easy harm to calculate."

[137] In short, I find that AstraZeneca has not clearly established that it will suffer any irreparable harm in connection with its pipeline products.

(iv) *Negative impact on reputation and future business development opportunities*

[138] AstraZeneca claimed that the "early genericization of NEXIUM, and the consequential harms described above," would result in "a negative reputational impact" in the eyes of "potential business development partners, who would consider AstraZeneca Canada, along with other innovators in Canada, for the development of their products." An example of such a partnership is its marketing alliance with Bristol-Myers Squibb Canada in relation to the sale of ONGLYZA, a diabetes drug.

[139] AstraZeneca claimed that "roughly [*]%" of its future sales will "derive from outside AstraZeneca's laboratories" and that AstraZeneca Canada develops and self funds some of those partnerships with third parties. It asserted that a "[l]oss in revenue will mean that acquisitions and in-licensing will no longer be possible or compromised" and that the likely perception of AstraZeneca Canada as a substantially weakened competitor would adversely impact upon its ability to partner with other companies, who would be "attracted to more financially robust companies." Moreover, it claimed that [*].

[140] In her affidavit, Ms. McCourt essentially repeated these claims.

[141] Dr. Biloski supported these claims by, among other things, opining that "Canadian subsidiaries of multinational pharmaceutical companies such as AstraZeneca Canada have a critical need to supplement the parent company product pipeline with locally sourced license and partnership deals."

[142] Dr. Gulati opined that it would not be possible to quantify the harm to AstraZeneca from this adverse impact on its reputation, because the extent of that impact "will not be known."

[143] I find the claims that have been made by AstraZeneca in respect of the impact of the early genericization of NEXIUM on AstraZeneca Canada's reputation and its future business development opportunities to be entirely speculative, unsubstantiated and exaggerated.

[144] Once again, I find the evidence of Apotex's experts to be more analytically robust and persuasive than that of Ms. McCourt, Dr. Biloski and Dr. Gulati.

[145] I agree with Mr. Harrington that, as a company that will continue to have several hundred million dollars in sales, even assuming a 100% loss of NEXIUM sales, "there is no reason to believe that there would be any significant, if any, losses in business development opportunities." This is particularly so given that, as Dr. Hollis noted: (i) "virtually every [branded drug] company has faced generic entry in spite of patents it believed were valid, and this is simply an expected part of the business;" and (ii) "[g]enerally, [prospective] partners would look to Astra for its expertise in marketing products. This is not put in doubt by the generic sales of esomeprazole." I am also inclined to accept Dr. Hollis' opinion that "it is the reputation of the parent companies that is far more important [to prospective partners] than that of the local subsidiaries."

[146] In addition, as Dr. Bower noted, it is difficult to understand (i) "how the presence of a competing product for Nexium can have any effect on the perception that Astra Canada is a 'high quality company';" and (ii) "how the loss of market exclusivity three years before that loss was expected (and after the drug had already enjoyed exclusivity for ten years) could affect that 'innovation' image."

[147] Dr. Biloski stated, in his affidavit: "In my direct experience, there is no faster way to change the perceptions of a research-based pharmaceutical company than via the unexpected generic erosion of a flagship product." Dr. Hollis characterized this as being an "extraordinary claim." He stated that in his "experience, the fastest way to change the perceptions of any pharmaceutical company is for it to be found that the drugs produced and marketed by the company are dangerous for the people…" He then noted that, "in late April 2010, the U.S. Department of Justice announced that an agreement had been reached with AstraZeneca whereby AstraZeneca had agreed

to pay $520m to resolve allegations that it had marketed the antipsychotic drug Seroquel for off-label uses". I agree with his opinion that the fact that AstraZeneca has "managed to survive, and indeed flourish, in the period after this public announcement, draws into serious question the hypothesis that Astra will not be able to address negative 'perceptions' brought on by Apotex's market entry."

[148] In addition, I find that Dr. Biloski's evidence is undermined by the fact that he acknowledged, in cross-examination on his affidavit, that he did not know whether AstraZeneca Canada would remain "a top three [pharmaceutical] company" in Canada without NEXIUM. Indeed, he conceded that he not know where AstraZeneca Canada would place relative to other pharmaceutical companies in Canada.

[149] In summary, I find that AstraZeneca has not clearly established that it will suffer any irreparable harm in connection with its reputation and future business development opportunities. I note that this finding is consistent with determinations made by this Court in cases such as *Merck & Co.*, above, at para. 34; *Fournier 1*, above, at para. 74; *Bristol-Myers Squibb*, above, at para. 30; *Pfizer Ireland 1*, above, at para. 26; *Pfizer Ireland 2*, above, at para. 41; and *Merck Frosst Canada Inc. v. Canada (Minister of Health)*, [1997] F.C.J. No. 953 (QL) (TD), at para. 12.

(v) *Innovation and creativity*

[150] In its written submissions, AstraZeneca claimed that "as a result of the negative impact on employees and climate just described, there would also be a loss of creativity and innovation." The same bald assertion is made by Ms. McCourt, in her affidavit. A similarly unsubstantiated claim was made by Dr. Biloski, who stated, in his affidavit, that AstraZeneca Canada "is more likely to be

successful with the discovery and/or in-licensing and launch of new products if it continues to enjoy the cash flow from NEXIUM throughout its expected patent life to May 27, 2014."

[151] In my view, Ms. McCourt's claim is somewhat undermined by her inability to identify, during cross examination on her affidavit, the last drug product sold by AstraZeneca in Canada that was actually innovated by AstraZeneca Canada.

[152] In any event, in the absence of any substantiation whatsoever for the claims that have been made under this heading, they are purely speculative and have not been clearly demonstrated to constitute irreparable harm (*Servier*, above, at paras. 37 and 71; *Merck & Co.*, above, at paras. 35-36).

(vi) *General conclusion with respect to irreparable harm*

[153] Given the conclusions I have reached with respect to each of the categories of irreparable harm that AstraZeneca has claimed it is likely to suffer if the injunction that it has requested is not granted, I find that AstraZeneca has not clearly established that it is likely to suffer any such irreparable harm whatsoever.

E. *Balance of convenience*

[154] Given my conclusion immediately above, it is not necessary for me to address the third prong of the tri-partite test for the granting of an interlocutory injunction. Nevertheless, I will do so, in the event that I may have erred in my analysis of one or more of the irreparable harms that AstraZeneca has claimed.

[155] In its oral submissions, AstraZeneca suggested that my assessment of the balance of convenience should take into account the harm to the public interest in patent rights and the promotion of innovation and drug discovery, which would result from a decision not to grant the interlocutory injunction that AstraZeneca has requested in this Motion.

[156] As briefly discussed in Part III.B above, I agree that this may well be a legitimate consideration to be considered in assessing the overall balance of convenience, in appropriate cases. However, in this particular case, this claim is nothing more than a bald assertion. AstraZeneca has provided no evidence whatsoever of any adverse impact that would result from a decision not to grant the requested injunction.

[157] When pressed on this point during the hearing of this Motion, counsel to AstraZeneca was unable to provide any evidence to support the assertion that a refusal to grant this Motion might adversely impact upon innovative activity, whether in Canada or elsewhere. In the particular circumstances of this case, this is not surprising, particularly given that (i) much of the innovative activity in the drug industry is conducted outside Canada, and largely directed towards markets outside Canada; (ii) interlocutory injunctions are permitted in other jurisdictions that are as likely as Canada to be in the minds of drug innovators located abroad; and (iii) AstraZeneca has already had the benefit of approximately 10 years of full patent protection in respect of its production and sale of esomeprazole in Canada.

[158] In its written submissions regarding the balance of convenience prong of the tri-partite test for injunctions, AstraZeneca submitted that the potential loss of jobs is a significant matter of public

interest that should be dealt with in my analysis. In this regard, AstraZeneca baldly asserted that "[t]here will be an obvious negative impact on the approximately [*] workers who will lose their full time employment and benefits if Apotex is not restrained" from continuing to roll-out its Apo-Esomeprazole product. AstraZeneca also submitted that "there will be a significant impact on AstraZeneca's ongoing and future performance," as described in the section of its submissions dealing with the irreparable harm prong of the tri-partite test.

[159] Given my findings that AstraZeneca has not demonstrated that these unsubstantiated harms are likely to materialize, they do not merit material weight in the balancing of convenience assessment in this case.

[160] On the other side of the ledger, Apotex has identified certain harms that I am prepared, on the particular facts of this case, to accept are likely to result if the requested injunction is granted and if Apotex prevails in the within action.

[161] Specifically, if Apotex 's roll-out of Apo-Esomeprazole is suspended until a judgment is rendered in its favour, it claimed that it would either (a) lose the benefit of having launched the first generic competitor to NEXIUM (if its generic rivals, including three of whom are in the process of attempting to obtain their own NOCs, are able to launch their products before that time), or (b) merely be one of a number of generic entrants at that time, (if those rivals are enjoined from launching until that time). In either case, it would lose the ability to command the high price that it would have charged, but for the granting of the injunction.

[162] I am satisfied that it is likely to be particularly difficult to quantify the extent of such losses. In contrast to the situation that AstraZeneca faces, where any sale lost to Apotex will be known and quantifiable, it will be more difficult to ascertain what Apotex's total sales of Apo-Esomeprazole would have been, but for the injunction.

[163] In addition, AstraZeneca has known since Apotex received an NOC in respect of Apo-Esomeprazole, almost ten months ago, that Apotex was legally in a position to launch that product. A few weeks later, at AstraZeneca's request, Apotex provided an "on the record" confirmation of its intention to launch Apo-Esomeprazole. Two weeks after that, on July 26, 2010, Apotex again confirmed to AstraZeneca that it was proceeding with the production of launch quantities of Apo-Esomeprazole. On October 15, 2010, AstraZeneca considered the threat of Apotex's entry to be sufficiently serious that it launched the within action. However, it still did not file this Motion for an interlocutory injunction.

[164] It was not until after Apo-Esomeprazole was listed by Nova Scotia Pharmacare in November 2010, and then in Quebec and New Brunswick in February of this year, that AstraZeneca finally retained Dr. Gulati and Dr. Biloski and then filed this Motion.

[165] In my view, given the foregoing, the significant time, effort and monetary resources that Apotex expended between the time it received an NOC on June 17, 2010 and the time that this Motion was launched on March 11, 2011 are factors to be considered on Apotex's side of the ledger in the balancing of convenience analysis.

[166] Another factor to be considered on Apotex's side of the ledger is the fact that there is uncontested evidence of a likely and substantial adverse impact on the public interest that would result from enjoining Apotex from continuing its roll-out of Apo-Esomeprazole. This adverse impact is the delay of a significant reduction in the price of esomeprazole that would benefit the public. Unlike the harm that AstraZeneca would suffer from the loss of sales of NEXIUM (if the injunction is not granted and it prevails in the within action), and unlike the harm that Apotex would suffer from the deferral of its recoupment of the substantial investment it has made to date in preparing to launch Apo-Esomeprazole (if the injunction is granted and it prevails in the within action), the public will never be compensated for having suffered this harm.

[167] Considering all of the foregoing, I find that AstraZeneca has not demonstrated that the balance of convenience lies in its favour.

IV. Conclusion

[168] Based on my findings that AstraZeneca has not met its burden in respect of the second and third prongs of the tri-partite test applicable to interlocutory injunctions, this Motion will be dismissed.

[169] Given my finding with respect to the tri-partite test, it is not necessary to address the distinct issue that Apotex has raised with respect to delay and *Laches*.

V. Confidentiality

[170] AstraZeneca requested extensive redactions from the public version of these reasons. In addition to confidential financial information, it requested the redaction of (i) various assertions made by Ms. McCourt regarding claimed negative impacts of the early genericization of NEXIUM on AstraZeneca Canada's transformation and future; (ii) certain related information with respect to further downsizing and restructuring that it claimed would be necessary if the requested injunction were not granted, (iii) certain information pertaining to claimed adverse impacts on other products in its portfolio, its ability to retain key employees, its reputation, its ability to attract third parties to enter into potential business development opportunities, and its ability to launch new products; (iv) claims made regarding AstraZeneca Canada's future ability to access funds from its parent company; and (v) claims made regarding the possible list price of VIMOVO.

[171] This Court takes the protection of confidential information very seriously. However, parties cannot expect that requests to maintain the confidentiality of bald, unsubstantiated assertions or speculative will necessarily be granted. Such requests will be considered on a case-by-case basis.

[172] Pursuant to Rule 151 of the Rules, the Court must be satisfied that information in respect of which a request for confidentiality has been made should be kept confidential, notwithstanding the public interest in open and accessible court proceedings.

[173] In *Sierra Club of Canada v. Canada (Minister of Finance)*, 2002 SCC 41, [2002] 2 S.C.R. 522, at para. 53, the Supreme Court of Canada stated:

> 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.

[174] With respect to the first branch of the aforementioned test, the Supreme Court identified, at paras. 54 to 57 of its decision, the following three elements:

i. 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;

ii. in order to qualify as an "important commercial interest", the interest in question cannot merely be specific to the party requesting the confidentiality order, the interest must be one which can be expressed in terms of a public interest in maintaining confidentiality; and

iii. the Court must consider not only whether reasonable alternatives to a confidentiality order are available, but must also restrict the order as much as is reasonably possible, while preserving the commercial interest in question.

[175] It follows from the foregoing that the less well grounded are the assertions in the evidence, the less likely it is that the Court will agree to maintain them in confidence. Moreover, even where the Court agrees that information contained in an assertion or claim ought to be maintained in confidence, it is required restrict the scope of redactions from its reasons as much as is reasonably possible, while preserving the commercial interest in question,

[176] With the foregoing principles in mind, I have rejected most of AstraZeneca's extensive requests for redactions, on the basis that they are not "well grounded in the evidence" (*Sierra Club*, above; *Abbott Laboratories Limited v. Canada (Minister of Health)*, 2005 FC 989, at paras. 100 and 102; *Pfizer Canada Inc. v. Novopharm Limited*, 2010 FC 668, at para. 37). This includes AstraZeneca's bald, largely unsubstantiated or speculative assertions with respect to the various adverse impacts that will be associated with the "early genericization" of NEXIUM, including:

i. the "immediate, catastrophic and irreversible impact" that this will have on AstraZeneca Canada, including the other current and pipeline products in its portfolio;

ii. the "destabilization and imperilling" of AstraZeneca Canada's ongoing transformation;

iii. the fact that AstraZeneca's transformation did not take into account the possible genericization of NEXIUM;

iv. additional employee reductions and voluntary departures;

v. its reputation and ability to attract third parties to enter into potential business development opportunities;

vi. the unlikelihood of AstraZeneca accessing funds or other assets from its parent company; and

vii. the possibility that the list price of VIMOVO will be be lower, because it "will likely be based on the price of the component drugs, if it is listed at all".

[177] The unsubstantiated and unpersuasive nature the claims in respect of which AstraZeneca has sought confidentiality protection is such that I am satisfied that any salutary effects that might be associated with maintaining the confidentiality of the claims and related evidence would not outweigh the deleterious effects that would be associated with such action. These deleterious effects include the significant difficulty that the public would have to discern the nature of those claims, why they were rejected and what might be required to establish similar claims in the future. If I were to accept the extensive confidentiality requests that AstraZeneca has made, important parts of these Reasons for Judgment would be difficult, if not impossible, for the public to follow. This includes persons who may consider making such claims in the future.

[178] Notwithstanding the foregoing, I am satisfied that the confidentiality of certain information set forth in the confidential version of these Reasons for Judgment ought to be maintained. This includes (i) specific financial and sales figures; (ii) specific figures with respect to the further reduction in its workforce that AstraZeneca’s has asserted is likely to occur if the requested

injunction is not granted; (iii) advice that Ms. McCourt attested to having received from someone in AstraZeneca; (iii) the number of new products that AstraZeneca Canada expects to launch in 2011 and 2012; and (iv) a particular claim that was made regarding AstraZeneca Canada's ability to enter into potential business development opportunities.

"Paul S. Crampton"

_____

Judge

Ottawa, Ontario
May 24, 2011
(Amended on May 30, 2011)

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1668-10
STYLE OF CAUSE:	Astrazeneca Canada Inc. et al v. Apotex Inc.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	April 19, 2011
REASONS FOR ORDER:	CRAMPTON J.
DATED:	Confidential Reasons for Order – April 29, 2011 Public Further Amended Reasons for Order – May 24, 2011 (Amended on May 30, 2011)

APPEARANCES:

Gunars Gaikis Yoon Kang	FOR THE PLAINTIFFS (DEFENDANTS BY COUNTERCLAIM)
Andrew Brodkin Julie Rosenthal	FOR THE DEFENDANT (PLAINTIFF BY COUNTERCLAIM)

SOLICITORS OF RECORD:

SMART & BIGGAR Barristers and Solicitors Toronto, Ontario	FOR THE PLAINTIFFS (DEFENDANTS BY COUNTERCLAIM)
GOODMANS LLP Barristers and Solicitors Toronto, Ontario	FOR THE DEFENDANT (PLAINTIFF BY COUNTERCLAIM)