Date: 20080213

Docket: T-1747-00
T-1878-02

Citation: 2008 FC 184

Toronto, Ontario, February 13, 2008

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

AB HASSLE, ASTRAZENECA AB and ASTRAZENECA CANADA INC.

Applicants

and

APOTEX INC. and THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] The Respondent Apotex Inc. has made a motion in each of these two proceedings to set aside a final Order made by this Court and affirmed by the Federal Court of Appeal in each proceeding on the grounds that a subsequent Order of this Court, also affirmed on appeal, in yet another proceeding, requires the setting aside the two earlier Orders. For the reasons that follow, I find that the motions are dismissed with costs.

[2] All the proceedings that are under a consideration have been brought under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (NOC Regulations) and concern a drug containing a medicine known as omeprazole.

[3] A brief explanation of the technology is needed. This explanation is not intended to serve as a detailed analysis or construction of the patents. Omeprazole is a medicine said to be useful in treating certain conditions relating to the stomach. When swallowed, however, the stomach acid affects the medicine detrimentally. As a result, forms of this medicine such as a capsule or tablet containing granules which comprise a core of a blend of omeprazole and other materials include a coating over those cores with a substance that protects the core from the acidic environment of the stomach and which dissolves once the granules reach the alkaline environment of the gut. This coating is called an enteric coat. It was determined, however, that the enteric coat itself would attack the omeprazole and compromise its effectiveness. Thus an intermediate coat, called a subcoat, was placed between the omeprazole-containing core and the enteric coat. This is the subject of certain patents owned or controlled by the Applicants and asserted in the two earlier NOC proceedings at issue in these motions. It was also determined that, in some situations, a coating would form by itself between the omeprazole-containing core and the enteric coat. This is referred to as an *in situ* coating or subcoating. This is the subject another patent owned or controlled by the Applicants and asserted in a third NOC proceeding.

[4] Apotex wanted to market a generic version of omeprazole and asserted, in general (because the specifics were disputed in some of the proceedings) that it simply applied an enteric coating

directly to the core. Thus the NOC Regulations were engaged in three proceedings that are of interest here.

[5] The first is an application brought by AstraZeneca *et al.*, T-1747-00 which resulted in one of the Orders now sought to be set aside. This proceeding was heard by Justice Kelen of this Court who, in his decision released September 4, 2002 (neutral citation 2002 FCT 931) allowed the application by AstraZeneca making the following disposition at paragraph 67 of his Reasons:

> ***67*** *For the foregoing reasons, this application is allowed for a declaration that the Apotex letter dated August 1, 2000 does not comply with the Regulations, and therefore does not constitute a Notice of Allegation under the Regulations. Accordingly, the Minister of Health is prohibited from issuing a Notice of Compliance with respect to this purported Notice of Allegation.*

[6] The substantive issue that Kelen J. had to determine related to Canadian Patent 1,292,693 (the ’693 patent) which he said was typical of the three patents at issue, the other two being Canadian Patent 1,302,891 and Canadian Patent 2,166,483. In particular, the issue which he considered was whether Apotex’s Notice of Allegation as to non-infringement was sufficient. No technical information or samples of the product were provided by Apotex. Kelen J. said at paragraph 56:

> ***56*** *In the case at bar, the detailed statement is not sufficiently complete for the patentee to respond to the allegation. The expert witnesses called by both sides were expected to "shadow-box". They had no tablets to analyze. They had insufficient information to know whether the generic omeprazole tablets have a subcoating. The experts agreed that there may be a type of subcoating, but they could only speculate. The reason for the speculation is not because the patentee had not proven, on the balance of probabilities, that the subcoating exists, but because the patentee cannot, on the basis of the information provided by the generic manufacturer, respond*

> *to the allegation of non-infringement. The statement of facts in the NOA is not sufficiently detailed or complete. For this reason, I find that the NOA is deficient under the Regulations.*

[7] The question that was debated between the experts for the parties was whether the Apotex product, by any reaction between the core and enteric coating, spontaneously created something between them and whether that could constitute a "subcoat". At paragraph 58, Kelen J. said:

> ***58*** *In the case at bar, the NOA similarly is based on a pure assertion of fact, namely that the Apotex drug did not contain a "subcoating". In Rhoxalpharma, supra, the Court found that the generic omeprazole tablets did contain a spontaneously generated subcoating which infringed patent claim no. 1 in patent '693. In this case, the Court cannot ignore this finding that a spontaneously generated subcoating is considered a "subcoating" within the meaning of patent '693, particularly since this construction of the patent claim was upheld by the Federal Court of Appeal.*

[8] Kelen J. determined that Apotex's Notice of Allegation and refusal to supply samples resulted in a fatal deficiency as to its allegation of non-infringement. Thus he allowed AstraZeneca's application. At paragraph 64 to 66 he said:

> ***64*** *Were the results of the direct application of the enteric coat to the core to truly not infringe the patents, it seems reasonable that Apotex would have conducted a chemical analysis and submitted the results. In Rhoxalpharma, supra, the Court had the benefit of a scientific analysis of the omeprazol tablets in question. This is the best evidence. Apotex could have submitted this evidence to prove non-infringement in this case, but declined at its own risk and peril. Justice in this case required this evidence.*
>
> ***65*** *The refusal by Apotex to provide samples and the resultant speculative and inconclusive expert evidence, underlines the applicants' first submission that the Notice of Allegation is deficient in providing the detailed factual and legal information required under the Regulations. The Court agrees that the NOA is deficient in this respect because without the information, the*

> *experts' evidence about infringement is inconclusive and speculative.*
>
> ***66*** *To summarize, the NOA is deficient in that the required detailed statement of the legal and factual basis for the allegation of non-infringement does not:*
>
> > *1. provide the facts about the formulation of the new drug and/or samples of the new drug so that the applicants could determine whether the generic omeprazole tablets have an "inert subcoating"; and,*
> >
> > *2. provide the legal basis, which Apotex argued at the hearing, that patent '693 claim no. 1 has an implied "process limitation", i.e. that the "inert subcoating" in patent claim no. 1 is restricted to a subcoating applied by a process described in the patent specifications, but not referred to in patent claim no. 1.*

[9] It is to be noted that Kelen J. did not attempt to make a detailed analysis of the patent or any construction of the claims.

[10] The Federal Court of Appeal heard an appeal from Kelen J.'s decision and in its decision released November 23, 2003 (neutral citation 2003 FCA 409), dismissed the appeal. It its unanimous decision delivered by Rothstein J.A. (as he was then) the Court placed a construction upon claim 1 of the '693 patent. Rothstein J.A. concluded at paragraph 24:

> ***24*** *I conclude that patent claim 1 describes a pharmaceutical preparation which, in its finished product form, contains a subcoating or separating layer between the core and enteric coating, however the subcoating or separating layer is formed.*

[11] The Court of Appeal reviewed Kelen J.'s decision and said at paragraphs 25 and 26:

> ***25*** *In finding the Notice of Allegation inadequate in this case, the motions judge relied on the decision of this Court in Genpharm Inc. v. The Minister of Health and Procter & Gamble Pharmaceuticals (Canada) Inc., 2002 FCA 290 at paragraphs 22 to 25. In Genpharm, the Notice of Allegation failed to address relevant patent claims. In this case, the Notice of Allegation does address the relevant patent claim.*
>
> ***26*** *The point to be made is that the adequacy of the Notice of Allegation must be decided on the facts of each case, and in particular, the wording of the Notice of Allegation. Although I entertain some doubt that the Notice of Allegation in this case was inadequate, it will not be necessary to decide that issue because of my determination with respect to the construction of claim 1 in the 693 Patent.*

[12] In conclusion at paragraph 27, the Court of Appeal noted Apotex's concession that, if the claim were to be construed to include a subcoat, however formed, then the appeal would fail, thus the appeal was dismissed:

> ***27*** *Apotex conceded that if claim 1 was construed, as it now has been by this Court, as disclosing a tablet which contains a subcoating or separating layer between the core and enteric coating in its finished product form, however the subcoating or separating layer is formed, its appeal must fail. Therefore, it is not necessary for me to address the issue of infringement.*
>
> ***28*** *The appeal should be dismissed with costs.*

[13] The same three patents were subsequently engaged by the same parties in the later proceedings at issue here, T-1878-02. The matter was heard by Justice Layden-Stevenson of this Court who delivered her decision on February 14, 2005 (neutral citation 2005 FC 234). She found in favour of the applicants, AstraZeneca, holding that on the basis of either, or both, issue estoppel and abuse of process, Apotex could not relitigate the matter previously determined.

[14] The arguments that Layden-Stevenson J. faced are summarized at paragraph 17 and 18 of her Reasons:

> ***17*** *AstraZeneca, in its notice of application, maintains that the NOA is not a proper NOA and detailed statement and accordingly does not comply with the Regulations. Broadly stated, the argument is that since the NOA strictly frames the issues in the proceedings and may not be expanded upon by the generic during the proceeding, Apotex' allegation of non-infringement is not justified because its evidence of non-infringement rests upon the notion that its subcoat is not continuous and is not inert. The NOA contains no such statements. Rather, the NOA rests solely on the position that the Apotex subcoating is not a subcoating that is applied to the core and is then covered with the enteric outer layer. Since the NOA makes no mention of the possibility of an in situ subcoat and makes no statement regarding non-infringement with respect to an in situ subcoat (that it is not continuous and not inert), Apotex cannot expand its grounds by either evidence or argument.*
>
> ***18*** *Apotex counters that its allegation of non-infringement is not premised entirely on a construction of the '693 patent that is limited to a formulation having a separately applied subcoating. Neither its NOA nor its evidence supports such limitation. Moreover, Apotex, for purposes of this proceeding, but without prejudice to its rights on appeal, accepts that the '693 patent extends to a subcoat created in situ, provided that such subcoat carries with it all of the characteristics of claim 1. Apotex strenuously contests that its formulation will contain such a subcoat and, on the basis of all the evidence, submits that it is clear that AstraZeneca has failed to establish that such a subcoat exists.*

and at paragraphs 24 and 25:

> ***24*** *As stated earlier, AstraZeneca's quarrel with the Apotex NOA, regarding non-infringement, is that the focus of the allegation is the subcoating and that it must be formed by a separate step in the process. Expanding on its position, AstraZeneca says that this is the entire basis for Apotex' allegation that its formulation will not contain a subcoating. Nowhere in the NOA does Apotex suggest, if its product has a subcoat between the core and the enteric coating that results from a reaction between*

> *the two, that such subcoating will not be inert or continuous. These allegations do not exist. They do not exist because the premise of the Apotex NOA is that the '693 patent cannot be interpreted to include an in situ subcoat, a matter that has been conclusively determined by the Federal Court of Appeal. AstraZeneca asserts that the issues that Apotex raises in this proceeding are simply not contained in its NOA and detailed statement. Since AstraZeneca does not allege "that the Apotex product infringes, no matter, the Gillette defence is not properly invoked with respect to infringement". AstraZeneca says that the claim requires a subcoat and if Apotex' product has a subcoat, it infringes. The circumstances under which Gillette applies are not in play.*
>
> ***25*** *Apotex argues contra. It contends that there is no issue as to the nature of the reactive material at the interface of Apotex' product and that AstraZeneca is, in essence, saying that evidence regarding the nature of that reactive material goes beyond the NOA. The record, maintains Apotex, does not support AstraZeneca's contention that Apotex did not raise the issue that if it has any material between the enteric coating and the core that the material isn't "continuous, inert, film-forming and polymeric". In support of its position, Apotex points to the notice of application, and in particular to paragraphs 29, 30 and 31. It argues that, there, AstraZeneca says that the patent includes within its scope, a subcoating, regardless of how it was applied or generated and that, in view of Mr. Justice Kelen's decision, it is uncontroverted that Apotex will have a layer of material between the enteric coating and the core in its product. Most importantly, contends Apotex, AstraZeneca requests samples, formulation particulars, and process information relating to the Apotex NDS. Therefore, AstraZeneca knew what the issue was -- does the Apotex product have reactive material that meets the confines of the patent?*

[15] Layden-Stevenson J. made a thorough analysis of the evidence and of the principles of issue estoppel and abuse of process. Her considerations are summarized at paragraphs 79 and 80:

> ***79*** *Apotex does not argue that it could not have alleged (in its previous NOA), in addition to its product not containing a subcoat, that its product would not, in any event, contain an interface or layer that was inert, continuous and polymeric. Rather, it says that*

> *its NOA in the previous proceeding raised a construction issue, that "construction" was the only issue and that it was a "bona fide issue" warranting determination. I do not disagree that the construction of claim 1 of the patent was a bona fide issue. Construction of a patent or specific claims of a patent is an issue in all cases.*
>
> ***80*** *It seems to me that Apotex' submission begs the question. It did, in the previous proceeding, allege non-infringement. Thus, it put the issue of "infringement" into play. It does not advance any explanation for its failure to put its best foot forward in the previous proceeding. To accept its submission, in my view, is tantamount to allowing it to split its case. It enables Apotex to test the waters on the construction of the patent and then, if unsuccessful (as it was), to recast its case and get a second bite at the cherry. While I would not go so far as to say (using the words of Mr. Justice Evans in P&G) that Apotex has hidden in the weeds, holding back a defence for use in subsequent litigation, it certainly put all its eggs in one basket. This omission is not of a procedural or technical nature; it is substantive. Apotex has not persuaded me that the conditions for issue estoppel have not been met regarding the issue of "infringement".*

[16] She concluded at paragraph 90 that issue estoppel applied to Apotex:

> ***90*** *I am not satisfied that this matter falls within the special circumstances exception. It boils down, in the end, to a question of whether Apotex should have more than one full opportunity to allege non-infringement and invalidity with respect to the same patent and the same formulation. I think not. The doctrine of issue estoppel applies and Apotex is estopped from alleging non-infringement and invalidity in its NOA.*

and at paragraphs 97 and 98 that abuse of process would apply as an alternative:

> ***97*** *The doctrines of issue estoppel, collateral attack and abuse of process comprehensively address the concerns that arise when finality in litigation must be balanced against fairness to a particular litigant.*
>
> ***98*** *If I am wrong in my determination that issue estoppel applies, then I conclude that Apotex' NOA constitutes an abuse of*

> *process for substantially the same reasons provided under the issue estoppel section of these reasons. I reject Apotex' suggestion that the frequency of the occasions upon which it is forced to respond to an allegation of abuse of process diminishes the merits of the submission in this matter.*

[17] The matter proceeded to the Federal Court of Appeal which, in a unanimous decision delivered by Sharlow J.A. on February 10, 2006 (neutral citation 2006 FCA 51), dismissed the appeal. On the question of infringement and sufficiency of the Notice of Allegation, Sharlow J.A. said at paragraphs 16 to 19:

> ***16*** *The notice of allegation in this case contains, in substance, the same non-infringement allegation that was the subject of AB Hassle 2003, although that allegation is described in greater detail in the notice of allegation in this case. Apotex argues that it also contains a new non-infringement allegation, which I summarize as follows: (1) If paragraph (b) of claim 1 of the '693 patent is properly construed, a product is within the scope of that claim only if it has a subcoating that is inert, continuous and comprised of polymeric film-forming compounds. (2) In the proposed Apotex product, the layer of material between the medicinal core and the outer coating lacks those characteristics. (3) Because those characteristics are not present, the Apotex product cannot be within the scope of paragraph (b) of claim 1 of the '693 patent. AstraZeneca argues that the notice of allegation and detailed statement do not raise this new non-infringement allegation, or at least do not raise it with sufficient clarity to meet the "sufficiency" test.*
>
> ***17*** *The determination of the sufficiency of an allegation is a question of mixed law and fact. The standard of appellate review is palpable and overriding error, except to the extent that a question of law can be extricated from the conclusion, on which case that question of law must be determined correctly: Housen v. Nikolaisen, [2002] 2 S.C.R. 235; see also paragraph 9 of AstraZeneca AB v. Apotex Inc. (2005) cited above.*
>
> ***18*** *The judge discussed in detail the competing arguments on the sufficiency debate (see her reasons for judgment at paragraphs 17-54). The judge refers in her reasons to all of the relevant material,*

> *including the material filed by AstraZeneca that, in the view of Apotex, established that AstraZeneca understood that Apotex was raising a new point of patent construction, and that AstraZeneca addressed or attempted to address that new point in the material filed in support of its application for prohibition. In the end, the judge accepted the submission of AstraZeneca that the notice of allegation was not sufficient to raise the new issue.*
>
> ***19*** *In my view, the judge's conclusion on this point was reasonably open to her on the record. Having reviewed the same material that she did, and the arguments of counsel, I can find no error of law or any other error that would justify adopting an interpretation of the notice of allegation that departs from the judge's interpretation. This ground of appeal must fail.*

[18] The Federal Court of Appeal made a very important observation as to the limited nature of NOC proceedings and the opportunity always open to a party to an action under the *Patent Act*, R.S.C. 1985,c. P-4, at paragraph 28:

> ***28*** *It is apparent that Apotex disagrees with the point of patent construction adopted in AB Hassle 2003, and remains of the view that the '693 patent is invalid. If so, Apotex is not without a possible remedy. It is well established that proceedings under the NOC Regulations cannot result in decisions that are conclusive for all purposes on questions of validity and infringement. It is open to parties to proceedings under the NOC Regulations to obtain a full trial on such issues by commencing an action under the Patent Act.*

[19] The third proceeding, T-766-03 and, on appeal, A-51-06, is the one that gives rise to the current motions. That proceeding involves the same parties as the two previous proceedings but different patent, Canadian Patent 2,186,037 (the ’037 patent).

[20] This third proceeding was also heard by Justice Layden-Stevenson who in her decision released January 4, 2006 (neutral citation 2006 FC 7) dismissed the application. The principal claim at issue was claim 1 which the she reproduced at paragraph 28 of her Reasons:

> ***28*** *Before turning to the arguments of the parties, since this issue turns on the construction of claim 1, it is useful, again, to reproduce that claim.*
>
> *1. An oral pharmaceutical dosage form comprising:*
>
> *(a) a core material that contains a proton pump inhibitor and an alkaline reacting compound;*
>
> *(b) an enteric coating layer comprising an enteric coating polymer; and*
>
> *(c) a water soluble separating layer that is formed in situ as a water soluble salt between the core material and the enteric coating layer by a reaction between the enteric coating polymer and the alkaline reacting compound.*

[21] One of the main controversies between the parties was with respect to construction as to element (a), above, which was whether the core needed to contain both a proton pump inhibitor (PPI) and an alkaline reacting compound (ARC), which was the position taken by Apotex (see paragraph 34) or whether one ingredient could serve as both a PPI and an ARC, which was the position taken by AstraZeneca (see paragraph 31).

[22] After a thorough analysis, Layden-Stevenson J. concluded that a proper construction of claim 1 was that PPI and ARC were to be separate substances. She said at paragraph 47:

> ***47*** *At the end of the day, it seems to me that the word "and", as used in claim 1 of the '037 patent, is intended to be conjunctive. I agree that the claim does not preclude the PPI and ARC from being*

> *the same substance. However, the inquiry is to ascertain what the claim says, not what it fails to say. I recognize that the experts for both parties agree that a skilled formulator would endeavour to use as few ingredients as possible in order to keep a formulation as simple as possible. They also agree that it is possible, all things being equal, for an ingredient to serve more than one function in a formulation.*

[23] Given that construction and the evidence before her, Layden-Stevenson J. concluded at paragraph 52 that the Apotex product did not contain separate ARC and PPI substances thus would not infringe:

> ***52*** *It is not disputed that the Apotex tablets do not contain an ARC that is separate and distinct from the magnesium omeprazole PPI. If I am correct in my construction of claim 1, it is dispositive of the application. Apotex's tablets cannot infringe claim 1 because the tablets do not contain both a PPI and an ARC. However, patent construction is a matter of law. In the event that I am wrong, I will, alternatively, consider the issues with respect to the other allegation of non-infringement.*

[24] Layden-Stevenson J. nonetheless went on to consider alternative grounds for non-infringement raised by Apotex. They are summarized at paragraph 81 of her Reasons:

> ***81*** *In sum, Apotex asserts that, to meet the specifications of claim 1 of the '037 patent, the separating layer must be continuous, water soluble and inert. Any separating layer that may be found in its tablet meets none of these requirements.*

[25] The parties each engaged experts who conducted detailed testing on samples furnished by Apotex of its proposed product. Layden-Stevenson J. found that AstraZeneca had failed to persuade her that Apotex's allegations as to non-infringement were not justified. On the matter of non-infringement she said at paragraph 112:

> ***112*** *Turning to Astra's failure to satisfy me, on a balance of probabilities, that Apotex's allegation of non-infringement is not*

> *justified, I do not intend to engage in a microscopic dissection of the various criticisms levelled by each of the parties regarding the experimental techniques employed by the other's expert. Rather, I will focus on what I consider to be the central factors that lead to my conclusion. I have not considered submissions made at the hearing that were not contained in the written memoranda of fact and law.*

[26] Again, the matter went to the Federal Court of Appeal. That Court in an unanimous decision given by Sharlow J.A. released October 16, 2007 (neutral citation 2007 FCA 327), dismissed the appeal. In so doing that Court gave consideration only to the first topic dealt with by Layden-Stevenson J., namely whether the claim required two substances, a proton pump inhibitor and an alkaline reacting compound, and whether the Apotex proposed product had one or two such substances. They held that the claim required two and that Apotex had only one. At paragraphs 3 to 5 Sharlow J.A. said:

> ***3*** *Justice Layden-Stevenson construed element (a) as requiring the proton pump inhibitor and the alkaline reacting compound to be two different substances. The appellant argues that this construction is incorrect, and that the material described in element (a) could be a single substance that is both a proton pump inhibitor and an alkaline reacting compound.*
>
> ***4*** *The main argument for the appellant is that Justice Layden-Stevenson, having recognized that the language of element (a) could include a single substance that functions as both a proton pump inhibitor and an alkaline reacting compound, was not entitled to consider any other interpretation. We do not accept that argument. Justice Layden-Stevenson was faced with a situation where the claim language was capable of bearing more than one meaning. To resolve the ambiguity, she considered the language of the patent claim and the disclosure, informed by a detailed analysis of conflicting expert evidence. We can find no error in her analysis or her conclusion.*
>
> ***5*** *It is undisputed that the Apotex product will have a core that does not contain an alkaline reacting compound that is separate*

> *from the proton pump inhibitor. It follows that Justice Layden-Stevenson was correct to find that the non-infringement allegation is justified, and to dismiss the prohibition application.*

APOTEX'S ARGUMENT

[27] Apotex's argument that the earlier prohibition Orders of Kelen J. (T-1747-00) and Layden-Stevenson J. (T-1878-02) should be set aside in view of the later decision of Layden-Stevenson J. (T-766-03) can be summarized by repeating paragraphs 40 and 41 of Apotex's memorandum filed on these motions:

> *40. Layden-Stevenson J.'s decision in the 2003 Application determined, in effect, that there is no basis for a prohibition order in the protection of AstraZeneca's patent rights with respect to the Subcoat Patents. In particular, her Ladyship determined that AstraZeneca has not met its burden of disproving Apotex's allegation that its Apo-Omeprazole tablets contained no subcoat, either separately applied or created in situ. In light of the determination of this issue, the prohibition order herein issued by Layden-Stevenson J. simply has no foundation. In light of all of the jurisprudence canvassed above, there is, thus no juridical basis upon which the prohibition order can be maintained.*
>
> *41. The evidence supporting Apotex's allegation that Apo-Omeprazole tablets contain no subcoat in the 2003 Application was not considered in the 2002 Application because of Layden-Stevenson J.'s finding of issue estoppel. Her Ladyship held that, in the particular circumstances, Apotex was barred from arguing and leading evidence that its Apo-Omeprazole tablets would not contain a subcoat. It would not derogate from that purely procedural disposition to apply Rule 399(2) and the "continuing jurisdiction" of the Court to invoke her Ladyship's substantive finding from the 2003 Application, that Apo-Omeprazole tablets do not contain a subcoat, and to dismiss the within application on that basis.*

[28] AstraZeneca opposes these motions and says that the previous Orders are final and that there is no basis for reopening them.

ANALYSIS

[29] A final judgment of this Court is a disposition that determines in whole or in part any substantive right of any party to the proceeding (*Federal Courts Act,* R.S.C. 1985, c. F-7, s. 2(1)). Once a judgment becomes final, whether the rights of appeal having been exhausted or the time for appealing has expired, it is not intended that a party to the proceeding can return to the Court and seek to re-open or set aside that judgment except in very limited circumstances. Readily recognizable are circumstances related to clerical slips and errors and to Judgments obtained by fraud. Judgment obtained *ex parte* or without proper notice to proper persons can be set aside in appropriate circumstances when a proper person comes forward. The circumstances where final judgments can be set aside where new evidence comes to light or later events transpire are carefully scrutinized before a judgment having the effect of finally disposing of a matter, is varied or set aside.

[30] Apotex argues that the earlier prohibition Orders can be re-opened on two bases. The first, Apotex argues, is an inherent jurisdiction of the Court in respect of orders like prohibition in NOC proceedings to retain what Apotex calls a continuing jurisdiction over orders issued in such proceedings such that if there is a material change in circumstances, the Order can be varied or vacated. The second basis relied upon by Apotex is an argument that Rule 399 permits the Order to vacated or varied in the circumstances of this case.

[31] The first basis argued by Apotex arises from statements made by Reed J. of this Court in *Hoffman-LaRoche Ltd. v. Canada (Minister of National Health and Welfare),* [1999] F.C.J. No.

662. In that case, a prohibition Order had issued in an NOC case prohibiting the Minister from issuing an NOC to a generic "until the expiry of (the '671 patent)". That patent was subsequently held to be invalid and the formulation at issue (Apotex's formulation) was found not to infringe (*Apotex Inc. v. Syntex Pharmaceuticals International Limited*, April 23, 1999, T-2870-96) a decision also by Reed J.

[32] Apotex then moved before Reed J. in respect of the prohibition Order which she gave in the NOC proceedings, the patent having been declared invalid. In her disposition of the matter [1999] F.C.J. No. 662 she vacated the Order. She said at paragraphs 14 to 16:

> ***14*** *I turn then to my analysis. I am not persuaded that the order that is being sought is necessary to allow the Minister to issue a Notice of Compliance. The order that was given in T-2870-96 declared the '671 patent to be "invalid, void and of no force and effect". In my view, this entitles the Minister to treat the patent as a nullity for section 4 purposes. The Minister is entitled to proceed as though the patent had never been listed. In addition, the March 20, 1996, order of prohibition that issued in this case stated that it would continue "until after the expiration of Canadian Letters Patent 1,204,671". The patent has now been declared invalid, that is for all practical purposes an expiration of the patent. Thus, I think the order by its own terms ceases to have any operative effect with the issuance of the order in T-2870-96 declaring the patent invalid.*
>
> ***15*** *I can understand, however, why the Minister's legal advisers are being cautious. The spectacle of a Minister being accused of not obeying a Court order is not one they would wish him to encounter. Accordingly, I am prepared, for greater certainty, to grant the order that is requested.*
>
> ***16*** *I have been persuaded that the Court has jurisdiction to set aside the March 20, 1996, order in a situation such as the present, not on the ground that it was void when given, but as a result of changed circumstances. That is, I accept that the Court has a continuing jurisdiction, as exists in the case of injunctions, to*

> *modify the order of prohibition. I am not persuaded that the present motion is a collateral attack on Mr. Justice Evans' decisions. The foundation of the March 20, 1996, order no longer exists, thus, the orders requested must be granted.*

[33] Apotex on these motions relies on the reasoning appearing at paragraph 8 of the same decision to argue that if the there are “changed circumstances” the Court has “inherent continuing jurisdiction” to revisit on earlier Order of the kind that deals with prohibition or an injunction:

> ***8*** *I recognize that an order of prohibition does not have the same historical roots as an injunction; one is an equitable remedy, the other a remedy at law. The rules relating to each differ, for example, the courts have greater discretion when granting or withholding equitable remedies than when granting or withholding prerogative writs. Nevertheless, the two types of orders are found together in section 18 of the Federal Court Act; and more importantly, the effect of both types of orders is the same. It would be artificial for different consequences to follow depending upon whether the Court "enjoined" a respondent or "prohibited" that person from doing the act to which the order related. In addition, the jurisprudence has held that a proceeding under the Patented Medicine (Notice of Compliance) Regulations is not a final determination of a patentee's rights; it clearly contemplates that a decision in a patent action may lead to a decision that either undercuts or supplants a decision given with respect to the justification, or lack thereof, of a Notice of Allegation (see Eli Lilly & Co. v. Novopharm Ltd. [1998] 2 S.C.R. 129 at 184). If the Court is without jurisdiction to grant the order sought, the respondent's success in the patent action is a hollow victory and injustice occurs. I am of the view that the Court has an inherent continuing jurisdiction, in the case of an order of prohibition issued pursuant to the proceedings set out in the Patented Medicine (Notice of Compliance) Regulations, to amend or annul that order in response to changed circumstances in the same manner as the case of an injunction.*

[34] It is easy to see how such thinking would be applicable to a situation where a prohibition Order was expressed in terms that the Order would endure “until the expiry of the patent” and

circumstances arose where the patent was declared to be invalid before the expiry of its term. That subsequent event goes to the heart of the Order. I do not understand Reed J. to have said that the Court may re-open a prohibition Order because evidence adjudicated upon in another case, in respect of another patent, even if closely related, appears to be more favourable to a party in an earlier case than the evidence that was or could have been adduced by that party in the earlier case, or could have been considered if the party had framed its Notice of Allegation more properly. Apotex has asserted no authority for such a proposition. I find that the Orders under consideration here cannot be re-opened on that basis. I will examine the matter more fully when considering Rule 399 below.

[35] The second basis raised by Apotex invokes Rule 399 of this Court (Federal Court Rules, (SOR/98-106)). That Rule sets out a process by which an order, which is defined in Rule 2 to include a judgment, can be set aside:

Setting aside or variance	***Annulation sur preuve prima facie***
399. *(1) On motion, the Court may set aside or vary an order that was made*	***399.*** *(1) La Cour peut, sur requête, annuler ou modifier l'une des ordonnances suivantes, si la partie contre laquelle elle a été rendue présente une preuve prima facie démontrant pourquoi elle n'aurait pas dû être rendue :*
(a) ex parte; or	*a) toute ordonnance rendue sur requête ex parte;*
(b) in the absence of a party who failed to appear by accident or mistake or by reason of insufficient notice of the proceeding,	*b) toute ordonnance rendue en l'absence d'une partie*
if the party against whom the order is made discloses a prima facie case why the order	

should not have been made.	*qui n'a pas comparu par suite d'un événement fortuit ou d'une erreur ou à cause d'un avis insuffisant de l'instance.*
Setting aside or variance	*Annulation*
(2) On motion, the Court may set aside or vary an order	*(2) La Cour peut, sur requête, annuler ou modifier une ordonnance dans l'un ou l'autre des cas suivants :*
(a) by reason of a matter that arose or was discovered subsequent to the making of the order; or	*a) des faits nouveaux sont survenus ou ont été découverts après que l'ordonnance a été rendue;*
(b) where the order was obtained by fraud.	*b) l'ordonnance a été obtenue par fraude.*
Effect of order	*Effet de l'ordonnance*
(3) Unless the Court orders otherwise, the setting aside or variance of an order under subsection (1) or (2) does not affect the validity or character of anything done or not done before the order was set aside or varied.	*(3) Sauf ordonnance contraire de la Cour, l'annulation ou la modification d'une ordonnance en vertu des paragraphes (1) ou (2) ne porte pas atteinte à la validité ou à la nature des actes ou omissions antérieurs à cette annulation ou modification.*

[36] Where a matter of the type referred to in paragraph 399(2)(a) already was in existence but was only discovered after the judgment was issued, the Court has established a stringent three-fold test which a party must meet before consideration is to be given to setting aside a judgment. The Federal Court of Appeal set out such a test in *Ayangma v. Canada*, 2003 FCA 382 at paragraph 3:

> ***3*** *The jurisprudence establishes three conditions which must be satisfied before the Court will intervene:*

> *1- the newly discovered information must be a "matter" with the meaning of the Rule;*
> *2- the "matter" must not be one which was discoverable prior to the making of the order by the exercise of due diligence; and*
> *3- the "matter" must be something which would have a determining influence on the decision in question.*

[37] In the present circumstances, Apotex argues that a subsequent decision of this Court in T-766-03 (2006 FC 7 and 2007 FCA 327, *supra*) respecting a different patent, which was the first proceeding in which Apotex made a substantive disclosure as to the technical specifications of its product and supplied samples is a new "matter" which is sufficient to enable it to re-open the earlier judgments, affirmed on appeal, in T-1747-00 and T-1878-02.

[38] I reject that argument.

[39] A subsequent judgment in another proceeding is rarely if ever a circumstance which would permit re-opening of a judgment in an earlier proceeding. Where the subsequent judgment results in a change in the law, a Court will not re-open an earlier judgment. Rothstein J.A. for the Federal Court of appeal in *Metro Can Construction Ltd. v.* Canada, 2001 FCA 227 put it this way at paragraph 4:

> ***4*** *Reconsideration is a narrow exception to the doctrine of res judicata. In Jhajj v. Canada (M.E.I.), [1995] 2 F.C. 369 (T.D.), it was determined that subsequent decisions of a higher court do not constitute "a matter that arose [...] subsequent" as those words are used in paragraph 399(2)(a). The same principle would apply to subsequent decisions of the same Court. In Jhajj, it was decided that reconsideration on the basis of subsequently decided jurisprudence was not reconcilable with the res judicata doctrine*

> *and that taken in this context, "a matter" did not include subsequent decisions of a higher court. If "a matter" included subsequent decisions, reconsideration could be sought in any previous case whenever there was a change in the law that would result in a different disposition of that previous case. Further, it would create unacceptable uncertainty for litigants and the public who must be satisfied that, once a judgment is rendered, it is final. We see no reason to depart from this analysis and conclusion.*

[40] Where the subsequent event is a change in circumstances the Court is reluctant to engage in speculation as to what might have happened if that circumstance had been present at the time of the earlier event. The Federal Court of Appeal recently considered this situation in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 407. This was an NOC proceeding in which a generic, Ratiopharm, was by a final judgment prohibited from obtaining an NOC until the expiry of a certain listed patent. That patent was subsequently de-listed. Ratiopharm sought to set aside the Order of prohibition. The Federal Court of Appeal refused to do so saying that the course of events proposed by Ratiopharm was too speculative. Letourneau J.A. for this Court said at paragraphs 21 and 22:

> ***21*** *Beyond this, the course of events proposed by Ratiopharm is too speculative to give rise to a new "matter" within the meaning of Rule 399(2)(a) or to justify the invocation of this Court's inherent jurisdiction in order to set aside this Court's prior decision. Ratiopharm assumes, amongst other things, that if the '493 patent had not been improperly listed, the Minister would have issued a NOC with respect to its Besylate tablets prior to the time when Pfizer's appeal before this Court was to be heard and in any event, before the Court rendered its decision with the result that the Court would have exercised its discretion against disposing of the appeal and a prohibition would not have been issued.*
>
> ***22*** *There are an infinite number of intervening events which could have altered the scenario painted by Ratiopharm. It is simply impossible to assume that the events would have unfolded as Ratiopharm suggests or to give this scenario the certainty that*

> *would be required in order to justify the setting aside of the earlier decision of this Court.*

[41] The same situation prevails in this case. Apotex has not demonstrated, on the evidence, that the product at issue in the third NOC proceeding was in fact the same product as that considered in either or both of the two earlier proceedings under consideration here.

[42] Even if the products were identical, the findings by Layden-Stevenson J. in the third proceedings were *obiter* to her principal finding, which was the finding upon which she was upheld in the Federal Court of Appeal. That finding was that the patent at issue in the third proceeding, which was not at issue in the two earlier proceedings, required two substances to be present in the core material and Apotex only had one. Apotex has not demonstrated on this motion that such a finding is material or conclusive in respect of the patents at issue in the two earlier proceedings. Further, in view of Rothstein J.A.'s construction of the patent principally at issue in the earlier proceeding at paragraph 24 of 2003 FCA 409, that patent requires only a core, no particular formulation of substances in that core is required:

> ***24*** *I conclude that patent claim 1 describes a pharmaceutical preparation which, in its finished product form, contains a subcoating or separating layer between the core and enteric coating, however the subcoating or separating layer is formed.*

[43] Further, even if one were to consider the alternate grounds discussed by Layden-Stevenson J. in the third NOC namely, whether the Apotex product at issue there had a subcoat that was continuous, water soluble and inert it is not clear from Rothstein J.A.'s construction of the claim in the two earlier proceedings that such criteria were essential to the claim. I do not intend to say more

about that since it is clear that Layden-Stevenson J.'s findings in that respect were based on the evidence before her and her assessment of that evidence which lead her to conclude that, in that proceeding, AstraZeneca had failed to discharge its burden of proving that Apotex's allegation of non-infringement of the patent in that case was not justified. Whether or not AstraZeneca and Apotex's evidence in the earlier proceedings would have been the same we do not know. What we do know is that in the first of the earlier proceedings, Apotex failed to put in a sufficient allegation to put the question of non-infringement into play and in the second proceeding Apotex failed to persuade the Court that its conduct in the first proceeding did not preclude it from making such allegations and leading evidence in the second proceeding.

[44] It is evident that Apotex is endeavoring through the present motions, to do what it did not do in the first proceeding and could not do in the second. I find that the determinations of this Court in the third proceeding, and the affirmation on one of those determinations by the Federal Court of Appeal, does not constitute a new "matter" as contemplated by Rule 399(2)(a) such that this Court should set aside or vary the Judgments made in proceedings T-1747-00 or T-1878-02.

[45] I digress at this point to comment upon the evidence led by the parties on this motion. Rule 82 precludes a solicitor for a party from furnishing an affidavit and also arguing the matter without leave. In *Cross-Canada Auto Body Supply (Windsor) Ltd. v. Hyundai Auto Canada*, 2005 FC 1254, aff'd 2006 FCA 133, this Court and the Federal Court of Appeal held that it was improper for a solicitor to argue a case where another member of his firm, a paralegal, filed an affidavit in support of the position being argued.

[46] In general, the Court does not object to affidavits from members of the firm of solicitors arguing a motion where the affidavit is restricted to non-controversial matters such as the furnishing of undisputed documents or recitation of undisputed facts. However, where such affidavits go further and include matters that are disputed or controversial or are expressions of opinion or state of mind, the Court will be reluctant to accept or give weight to such evidence.

[47] Here the Respondent Apotex, Applicant on the motions, submitted as its only evidence the affidavit of Di Paolo, a law clerk in the offices of Apotex's solicitors, Goodmans LLP. She provided as exhibits, the Notices of Allegation in the three proceedings under consideration here and other non-controversial material. However, in paragraph 6 of her affidavit she purports to opine as to a "substantive issue of non-infringement", in paragraph 7 she opines as to what a patent claims, and in paragraph 10 she opines that certain evidence in one proceeding was "much the same" as evidence in another proceeding. Such opinion goes beyond what is non-controversial and is certainly beyond the expertise of a law clerk.

[48] The Applicants AstraZeneca, Respondents on the motion, filed as their only evidence the affidavit of Dr. Scott Beeser, an associate in the law firm representing these parties on the motion Smart & Biggar. Dr. Beeser says that he is not only a lawyer but has a B.Sc. in biochemistry and a Ph.D. in biology. At paragraph 1 he says "Given my scientific training, I understand the science and the various analytical techniques described in evidence (in the NOC proceedings)". He says that he attended at the Court of Appeal proceedings in respect of the third NOC and purports, in

paragraph 7, to say what he heard as to submissions made by Apotex's counsel and, in paragraph 8, what was not said by either counsel. He says in paragraph 9 that he read the Di Paolo affidavit and in paragraphs 10, 11 and 12 disputes for various reasons, that the evidence in the earlier proceedings was the same.

[49] We see in these two affidavits, Di Paolo and Dr. Beeser, evidence given by persons associated with the firms of solicitors arguing these motions. The evidence is opinion and controversial. Such persons should not have been the persons giving the evidence. I have put no weight upon any of this evidence. In the future, the parties should avoid this practice. If such evidence is necessary it should be given by persons not associated with the relevant solicitor's firm.

[50] The motions will be dismissed with costs to the Applicants (Respondents in these motions) to be taxed at the middle of Column III in each proceeding.

ORDER

For the Reasons given:

1. The motions in each of T-1747-00 and T-1878-02 are dismissed;

2. The Applicants (Respondents in these motions) are awarded costs in each proceeding to be taxed at the middle of Column III.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1878-02
STYLE OF CAUSE:	**AB HASSLE ET AL. V. APOTEX INC. ET AL.**
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	February 12, 2008
FURTHER REASONS AND JUDGMENT:	Hughes, J
DATED:	February 13, 2007

APPEARANCES:

	FOR THE APPLICANTS
Mr. Mr. Gurnas A. Gaikis	AB HASSLE
Ms. Yoon Kang	ASTRAZENECA CANADA INC.
Mr. Andrew Brodkin	FOR THE RESPONDENT
Mr. John Simpson	APOTEX INC.
Mr. Eric Peterson	FOR THE RESPONDENT THE MINISTER OF HEALTH.

SOLICITORS OF RECORD:

Smart & Biggar Toronto, Ontario	FOR THE APPLICANT
Goodmans LLP Toronto, Ontario	FOR THE RESPONDENT APOTEX INC.
John H. Sims, Q.C. Deputy Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENT THE MINISTER OF HEALTH