Date: 20091019

Docket: T-794-09

Citation: 2009 FC 1053

Ottawa, Ontario, October 19, 2009

PRESENT: The Honourable Mr. Justice Martineau

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

APOTEX INC.
and THE MINISTER OF HEALTH

Respondents

and

ELI LILLY AND COMPANY LIMITED

Respondent/Patentee

REASONS FOR JUDGMENT AND JUDGMENT

[1] The Court is asked to decide whether Apotex Ltd. (Apotex) or Eli Lilly Canada Inc. and Eli Lilly and Company Ltd. (together Eli Lilly) should be precluded from pursuing their Notice of Allegation (NOA) or prohibition application under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (the NOC Regulations).

[2] For the reasons that follow, I have determined that Apotex is precluded by the doctrine of issue estoppel from pursuing their current NOA which is null, void and of no effect.

I. BACKGROUND

[3] Olanzapine is used in the treatment of disorders of the central nervous system. Eli Lilly markets three forms of olanzapine pharmaceutical products: olanzapine tablets in 2.5mg, 5mg, 7.5mg, 10mg, 15mg and 20mg doses (marketed as ZYPREXA); orally disintegrating olanzapine tablets in 5mg, 10mg, 15mg and 20 mg doses (marketed as ZYPREXA ZYDIS); and an olanzapine injection formula in a 10mg/mL dose (marketed as ZYPREXA INTRAMUSCULAR).

[4] The products above have all been issued Notice of Compliances (NOC) in connection with Canadian Patent No. 2, 041, 113 (the '113 Patent) which is included on the Patent Register maintained by the Minister of Health (the Minister).

[5] The '113 Patent is a selection patent from the class of compounds covered by the 1, 075, 687 (the '687 Patent) and is said to have "atypical anti-psychotic properties and an improved side effect profile over the genus of compounds as claimed [by the '687 Patent]".

Previous NOA

[6] This is not the first time Eli Lilly is before this Court defending the validity of the '113 Patent with respect to an NOA served by Apotex.

[7] On December 16, 2004, Apotex served Eli Lilly with an NOA claiming that in relation to the conventional olanzapine tablet, "all of [Eli Lilly's] claims [pursuant to the '113 Patent were] void and of no effect" due to anticipation, obviousness, double patenting and fraud pursuant section 53 of the *Patent Act*, R.S.C. 1985, c. P-4 (*Patent Act*).

[8] A further NOA was served by Apotex on March 21, 2005 to specifically incorporate the 10 mg strength tablet marketed by Eli Lilly into their original NOA. This second NOA incorporated by reference all the factual and legal arguments that were set out in the original NOA, and the two NOAs were consolidated to form one single NOA (the previous NOA).

Prohibition Order

[9] In accordance with subsection 6(1) of the NOC Regulations, Eli Lilly applied to this Court for an order "prohibiting the Minister from issuing a notice of compliance until after the expiration of the ['113 Patent]."

[10] On April 27, 2007, the Court granted Eli Lilly's prohibition application (*Eli Lilly Canada Inc. v. Apotex Inc*, 2007 FC 455, aff'd 2008 FCA 44 (*Eli Lilly*)).

[11] In granting the prohibition order, Justice Gauthier found that Apotex failed to substantiate their allegations. With regard to the argument on the basis of sufficiency put forth by Apotex at the hearing, the Court found that unlike new use compounds, where the patent hinges on the use of the invention, "in selection patents where the selected compound is only generally described or

encompassed within a known genus or class of compounds, it is the selected compound itself that is new" (*Eli Lilly*, at paragraph 95).

[12] Furthermore, the Court noted that it would be allowing Apotex to challenge the validity of the patent on the basis of sufficiency if it accepted the argument that the '113 Patent was not a valid selection patent because it did not provide the benefits promised in the disclosure (*Eli Lilly*, at paragraph 106). Since sufficiency was not pleaded in its NOA, Apotex was prohibited from relying on it during the hearing (*Eli Lilly* at paragraph 119).

[13] Apotex appealed to the Federal Court of Appeal on the grounds that Justice Gauthier ought to have considered the sufficiency of the '113 Patent in making a determination on its validity. In dismissing the appeal, the Federal Court of Appeal held that "the applications judge correctly held that the sufficiency of the disclosure is a stand alone ground which ought to have been raised in the NOA" (*Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FCA 44 at paragraph 3 (*Eli Lilly* 2008)).

Other proceedings

[14] On November 13, 2007, Apotex began impeachment proceedings against Eli Lilly seeking a declaration that the '113 Patent is invalid. As of the hearing date in these proceedings, nothing beyond the pleadings had been submitted to the Court (see file T-1971-07).

[15] In a different proceeding before this Court, Eli Lilly also sought an order of prohibition against another generic pharmaceutical company, Novopharm Ltd. (Novopharm), who had served

Eli Lilly with an NOA alleging that the '113 Patent was invalid on the grounds of anticipation, obviousness, double-patenting, utility, sufficiency and fraud, as understood in section 53 of the *Patent Act*.

[16] On June 5, 2007, 2 months after the *Eli Lilly*, *supra*, decision, the Court found that Novopharm's allegations with respect to everything except sufficiency were not justified. With regards to sufficiency, Justice Hughes stated that:

> [T]he '113 patent fails to provide sufficient disclosure in its specification as to the invention, if any, in selecting olanzapine from a previously disclosed group of compounds… [n]o data was given. We are left only with rhetoric such as "high level of efficicency" and "mild and transient" and "lower" side effects.
>
> […]
>
> The Court finds that Lilly has not demonstrated that Novopharm's allegations as to sufficiency are not justified and for that reason the application is dismissed…

(*Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596 at paragraphs 162 and 191 (*Novopharm* decision))

[17] As a result of the Federal Court's decision above, Novopharm was issued an NOC by the Minister, and as a result of this, on November 6, 2007, the Federal Court of Appeal dismissed Eli Lilly's appeal on grounds of mootness (*Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359).

[18] Consequently, Eli Lilly brought an action against Novopharm for infringement with respect to the '113 Patent. At the time of this hearing, the decision was still under reserve (see file number T-1048-07).

The current proceedings

[19] This brings us to the current proceedings.

[20] In compliance with the NOC Regulations, Apotex, after having filed on November 28, 2008 a Supplemental Abbreviated New Drug Submission (supplemental ANDS) for an NOC in relation to orally disintegrating olanzapine tablets, served Eli Lilly with an NOA by way of a letter dated March 27, 2009 (the current NOA).

[21] Apotex now alleges that in relation to the orally disintegrating olanzapine tablet, "each and every one of the claims of the '113 Patent are invalid, void, of no force and effect and unenforceable…for insufficiency as not complying with the requirements of subsection 27(3) of the *Patents Act*."

[22] In support of their allegation of invalidity of the '113 Patent, Apotex now exclusively relies on Justice Hughes' *Novopharm* decision and the subsequent dismissal of Eli Lilly's appeal to the Federal Court of Appeal.

[23] Eli Lilly filed a Notice of Application on May 15, 2009 (the current application) seeking: (1) a declaration that the current NOA is an abuse of process and/or not a proper NOA and detailed statement; and/or (2) an order to prohibit Apotex from being granted an NOC by the Minister.

[24] On June 23, 2009, Apotex filed a Notice of Motion seeking an order pursuant to subsection 6(5)(b) of the NOC Regulations dismissing Eli Lilly's current application on the ground that it is "redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents" since Eli Lilly has already defended these allegations in the *Novopharm* decision, and lost.

Bifurcation of Issues

[25] Upon motions by Eli Lilly seeking orders to set a schedule for the completion of pre-hearing steps and for the separate determination of issues, Prothonotary Tabib ordered a bifurcation of issues, such that a hearing would be set down for the determination of:

1. whether Apotex's current NOA is an abuse of process, not a proper notice of allegation and detailed statement as contemplated by the NOC Regulations; and
2. whether Eli Lilly's current application is an abuse of process.

[26] Since the final determination of whether Apotex's current NOA is an abuse of process or not would be determinative of all proceedings currently brought under the NOC regulations, and given that Eli Lilly's application was triggered by the Apotex's current NOA, it follows that this issue should be dealt with first (see *Sanofi-Aventis Canada Inc. v. Pharmascience Inc.*, 2007 FC 1057 at paragraph 28, aff'd 2008 FCA 213 (*Pharmascience*)).

II. PRELIMINARY OBJECTION

[27] Apotex has taken the position that neither the bifurcation order nor the current NOA make explicit reference to the issue estoppel doctrine. Thus, this Court cannot examine the argument made by Eli Lilly that Apotex is precluded from pursuing the current NOA on the basis of the application of the doctrine of issue estoppel.

[28] The preliminary objection made by Apotex is dismissed.

[29] The present instance is readily distinguishable from the situation contemplated in *AstraZeneca AB v. Apotex Inc.*, 2006 FC 7 at paragraphs 10-11 and 17-18 and upon which Apotex relies.

[30] Prothonotary Tabib, the case manager in this proceeding, bifurcated the issues in order to have the Court finally determine at the outset of the present proceedings whether, *inter alia*, Apotex's letter dated March 27, 2009 is an abuse of process, not a proper notice of allegation and detailed statement as contemplated by the NOC Regulations, as amended and it therefore a nullity. (emphasis added)

[31] Upon reading Eli Lilly's NOA, it is apparent that the factual basis for pleading issue estoppel and abuse of process is the same, and that in both cases, as mentioned in paragraph 15 of the NOA, Eli Lilly's complaint is that "[b]y its actions, Apotex is seeking to relitigate its case on the

‘113 Patent, contrary to principles of law and equity”. As such, Eli Lilly does not need to amend their NOA to plead the doctrine of issue estoppel before the Court.

[32] The application of the doctrine of issue estoppel is fully addressed by Eli Lilly and Apotex in their respective memorandum of fact and law. That said, rule 75 of the *Federal Court Rules*, SOR/98-106, provides that the Court may, on motion at any time, allow a party to amend a document, on such terms as will protect the rights of all parties.

[33] To deny Eli Lilly the opportunity to invoke the doctrine of issue estoppel would be to prefer form over substance. In practice, this would serve only to further delay the proceedings, as Eli Lilly has no intention whatsoever to abandon their argument and, if necessary, would be formally seeking from the Court the authorization to amend their notice of application accordingly.

[34] Indeed, upon receiving Eli Lilly’s memorandum of fact and law, Apotex became aware that issue estoppel was raised especially in light of Eli Lilly’s assertion that Apotex’s current NOA is a nullity under the doctrine or *res judicata*, issue estoppel and abuse of process. No adjournment has been sought by Apotex to deal with the issue estoppel argument and I am therefore entitled to consider the matter today (*Abbott Laboratories v. Canada (Minister of Health)*, 2007 FCA 140 at paragraph 23 (*Abbott*)).

III. ISSUE ESTOPPEL

[35] When a generic pharmaceutical company seeks immediate permission to market a drug that is either directly or indirectly comparable to a drug already patented by another innovator company, they must serve the company with an NOA asserting either that the proposed product does not infringe the patent and/or that the patent itself is invalid (NOC Regulations, s. 5(1)).

[36] This in turn triggers the right of the innovator company to seek an order from the Court prohibiting the Minister from issuing a NOC to the generic which would permit them to market said drug (NOC Regulations, s. 6(1)).

[37] Within the realm of such NOC proceedings, it is essential that both the generic and the innovator company "put forward their entire case, complete with all relevant evidence, at first instance" or risk having their subsequent proceedings on the same issues dismissed for abuse of process (*Sanofi-Aventis Inc. v. Novopharm Ltd.*, 2007 FCA 163 at paragraph 50 (*Sanofi-Aventis*)).

[38] The relationship between the doctrines of abuse of process and issue estoppel was canvassed by Justice Arbour in *Toronto (City) v. Canadian Union of Public Employees (C.U.P.E.), Local 79*, 2003 SCC 63 at paragraphs 37 and 38 (*CUPE*):

> **37** […] the doctrine of abuse of process engages "the inherent power of the court to prevent the misuse of its procedure, in a way that would ... bring the administration of justice into disrepute" (*Canam Enterprises Inc. v. Coles* (2000), 51 O.R. (3d) 481 (C.A.), at para. 55, *per* Goudge J.A., dissenting (approved [2002] 3 S.C.R. 307, 2002 SCC 63)). Goudge J.A. expanded on that concept in the following terms at paras. 55-56:

The doctrine of abuse of process engages the inherent power of the court to prevent the misuse of its procedure, in a way that would be manifestly unfair to a party to the litigation before it or would in some other way bring the administration of justice into disrepute. It is a flexible doctrine unencumbered by the specific requirements of concepts such as issue estoppel. See *House of Spring Gardens Ltd. v. Waite*, [1990] 3 W.L.R. 347 at p. 358, [1990] 2 All E.R. 990 (C.A.). One circumstance in which abuse of process has been applied is where the litigation before the court is found to be in essence an attempt to relitigate a claim which the court has already determined. [Emphasis added.]

As Goudge J.A.'s comments indicate, Canadian courts have applied the doctrine of abuse of process to preclude relitigation in circumstances where the strict requirements of issue estoppel (typically the privity/mutuality requirements) are not met, but where allowing the litigation to proceed would nonetheless violate such principles as judicial economy, consistency, finality and the integrity of the administration of justice. (See, for example, *Franco v. White* (2001), 53 O.R. (3d) 391 (C.A.); *Bomac Construction Ltd. v. Stevenson*, [1986] 5 W.W.R. 21 (Sask. C.A.); and *Bjarnarson v. Government of Manitoba* (1987), 38 D.L.R. (4th) 32 (Man. Q.B.), aff'd (1987), 21 C.P.C. (2d) 302 (Man. C.A.).) This has resulted in some criticism, on the ground that the doctrine of abuse of process by relitigation is in effect non-mutual issue estoppel by another name without the important qualifications recognized by the American courts as part and parcel of the general doctrine of non-mutual issue estoppel (Watson, *supra*, at pp. 624-25).

38 It is true that the doctrine of abuse of process has been extended beyond the strict parameters of *res judicata* while borrowing much of its rationales and some of its constraints. It is said to be more of an adjunct doctrine, defined in reaction to the settled rules of issue estoppel and cause of action estoppel, than an independent one (Lange, *supra*, at p. 344). The policy grounds supporting abuse of process by relitigation are the same as the essential policy grounds supporting issue estoppel (Lange, *supra*, at pp. 347-48):

The two policy grounds, namely, that there be an end to litigation and that no one should be twice vexed by the same cause, have been cited as policies in the application of abuse of process by relitigation. Other policy grounds have also been cited, namely, to preserve the courts' and the litigants' resources, to uphold the integrity of the legal

> system in order to avoid inconsistent results, and to protect the principle of finality so crucial to the proper administration of justice.

[39] Therefore, the policy underlying the two doctrines is very similar. It may even be said that the doctrine of issue estoppel is more restrictive since it only operates when specific criteria have been met. Abuse of process, on the other hand, is a residual power granted to the Court to prevent abuse of the Court's process (*CUPE* at paragraph 35). For the purposes of the present case, it is important that, as noted above, the doctrine of abuse of process operates in circumstances "where allowing the litigation to proceed would nonetheless violate such principles as judicial economy, consistency, finality and the integrity of the administration of justice," but the criteria required for issue estoppel have not been met (*CUPE* at paragraph 37).

[40] Issue estoppel applies where: (1) the same question has been decided; (2) the decision which is said to create the estoppel was final; and (3) the parties to the judicial decision or their privies were the same persons as the parties to the proceedings in which the estoppel is raised or their privies (see *Angle v. Canada (Minister of National Revenue – M.N.R.)*, [1975] 2 S.C.R. 248).

[41] As indicated by the Supreme Court's decision in *Danyluk v. Ainsworth Technologies Inc.*, 2001 SCC 44 at paragraph 33 (*Danyluk*), the first step is to determine whether the moving party has established the preconditions to the operation of issue estoppel set out by Dickson J. in *Angle, supra*. If successful, the Court must still determine whether, as a matter of discretion, issue estoppel ought to be applied: *British Columbia (Minister of Forests) v. Bugbusters Pest Management Inc.* (1998), 50 B.C.L.R. (3d) 1 (C.A.), at paragraph 32; *Schweneke v. Ontario (2000)*, 47 O.R. (3d) 97

(C.A.), at paragraphs 38-39; *Braithwaite v. Nova Scotia Public Service Long Term Disability Plan Trust Fund* (1999), 176 N.S.R. (2d) 173 (C.A.), at paragraph 56.

[42] In *Abbott*, *supra*, at paragraph 2, Justice Sexton found that:

> … generics should in most circumstances be precluded by the doctrine of issue estoppel from alleging for a second time that a patent is invalid, unless the basis relied upon for the subsequent allegation could not be determined with reasonable diligence at first instance, or some special overriding circumstance exists to warrant a judge exercising her discretion not to apply issue estoppel on the facts of the particular case.

[43] In *Pharmascience*, *supra*, the Court followed the *Abbott* decision. In that case, Pharmascience had previously served Sanofi-Aventis with an NOA alleging that the patent in question was invalid. Upon an application for a prohibition order by Sanofi-Aventis, this Court found that Pharmascience's allegations were not justified. After this determination, another generic successfully served Sanofi-Aventis with an NOA challenging the same patent on the basis of invalidity. In light of that decision, Pharmascience issued a second NOA, again alleging invalidity, and Sanofi-Aventis applied to this Court to have them estopped.

[44] In granting Sanofi-Aventis' application, the Court found at paragraph 7:

> Pharmascience's initial allegation of invalidity has been finally determined, and issue estoppel should operate to preclude it from making further allegations of invalidity, albeit on different grounds. I further decline to exercise my discretion to allow Pharmascience to proceed with its allegations of invalidity.

[45] Apotex argues that issue estoppel is not applicable in the present circumstances because the current application will not decide the same question as was determined in *Eli Lilly*, *supra*. Specifically, Apotex contends that because the product at issue in each proceeding is different (the conventional tablet was litigated before Justice Gauthier; whereas, it is the orally disintegrating tablet at issue in the present application) the cause is fundamentally different and therefore issue estoppel does not apply.

[46] According to Apotex, it is significant that in the *Abbott* decision, Justice Sexton, at paragraph 41 provides that "multiple NOAs from the same generic relating to a particular pharmaceutical and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each" (emphasis added).

[47] With respect to the current NOC proceedings, Apotex argues that what is being determined is not the validity of the patent, as Eli Lilly submits, but rather, whether or not the Minister may grant a given party an NOC for a given product. In support of this submission Apotex refers to *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588 at paragraph 13 (C.A.).

[48] The arguments made by Apotex are not convincing.

[49] In the current proceedings, as in *Eli Lilly*, the allegations made in the current NOA by Apotex are with regards to the invalidity of the '113 Patent. Therefore it is an oversimplification to

categorize the issue on an NOC as whether or not the Minister should grant an NOC to the product in question.

[50] In *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, 2003 FCA 467 at paragraph 25 (*P&G)*, Rothstein J.A. (as he then was), speaking for the Federal Court of Appeal, approved the following passage from page 9 of Lord Denning's decision in *Fidelitas Shipping Co., Ltd. v. V/O Exportchleb*, [1965] 2 All E.R. 4 (C.A.):

> But within one cause of action, there may be several issues raised which are necessary for the determination of the whole case. The rule then is that, once an issue has been raised and distinctly determined between the parties, then, as a general rule, neither party can be allowed to fight that issue all over again. The same issue cannot be raised by either of them again in the same or subsequent proceedings except in special circumstances….*And within one issue, there may be several points available which go to aid one party or the other in his efforts to secure a determination of the issue in his favour. The rule then is that each party must use reasonable diligence to bring forward every point which he thinks would help him. If he omits to raise any particular point, from negligence, inadvertence, or even accident (which would or might have decided the issue in his favour), he may find himself shut out from raising that point again, at any rate in any case where the self-same issue arises in the same or subsequent proceedings.*[Emphasis added.]

[51] More recently, the Federal Court of Appeal in *Abbott*, *supra*, referred to the above passage, at paragraph 39, before moving on to look at the "question" that is addressed in NOC proceedings. Again at paragraph 41, Justice Sexton speaking for the Court of Appeal notes:

> In other words, the "issue" to be addressed is invalidity or non-infringement. The specific grounds on which the second person wishes to demonstrate invalidity, whether that be by obviousness, anticipation, overbreadth or lack of sound prediction, do not constitute separate issues for the purpose of issue estoppel but are

> merely different bases on which the second person may address the issue of invalidity.

[52] Other key remarks were made by Justice Sexton, at paragraph 46, where reference is made to the prior decision of the Federal Court of Appeal in *AstraZeneca AB v. Apotex Inc.*, 2005 FCA 183 (*AstraZeneca*). In *AstraZeneca*, the Court found that a second NOA submitted by the generic was not an abuse of process. In distinguishing *Abbott* from that case, Justice Sexton notes:

> The second difference between *AstraZeneca* and the present case is of vital importance. In *AstraZeneca*, the NOAs at issue both alleged non-infringement, rather than invalidity. As Layden-Stevenson J. explained in *AB Hassle*, where different formulations of the generic drug are at issue, multiple NOAs alleging non-infringement may be permissible. It is intuitive that if a generic makes material changes to its formulation in an attempt to avoid infringing the listed patent, it may submit a new NOA alleging non-infringement by the new product. Similarly, if it was the process for making the generic drug that infringed the patent, a new process adopted by the generic may give rise to a subsequent NOA alleging non-infringement of the patent. That is not to say that minor variations to the formulation or process will be sufficient to permit a new NOA. Only where the change is of significance might a new NOA be permitted. Multiple NOAs alleging invalidity, in contrast, are not permissible because the factual basis does not change depending on the circumstances of the generic. Unless a material fact could not be uncovered by reasonable diligence at the time of the first NOA, subsequent NOAs alleging invalidity will generally not be permitted. In *AstraZeneca*, Evans J.A. appreciated this distinction. From his reasons, it appears that Apotex made a significant change to the formulation of its drug product between the first and second NOAs. The second NOA was therefore permitted because the factual basis for the allegations in it was separate and distinct from that in the first NOA. (Emphasis added.)

[53] It is clear that all three criteria required for issue estoppel have been met in this case. The issue to be determined in the current application is the same as that which was determined in *Eli Lilly*, *supra*, namely whether or not the ‘113 Patent is invalid as alleged in the previous NOA.

Justice Gauthier's decision is final, as it was affirmed by the Federal Court of Appeal, and the parties in the *Eli Lilly* case are the same as the ones in the present application.

[54] Since Apotex served the previous NOA on the basis of invalidity, I find that the same issue is being addressed in the current application.

[55] In view of the Federal Court of Appeal's pronouncement in *Abbott*, it is of no importance that Apotex is currently alleging invalidity on the basis of sufficiency, a particular ground of invalidity which was not raised the first time in the previous NOA. In *Pharmascience*, the Court also found that the issue in common was the validity of the Sanofi-Aventis patent (*Pharmascience*, *supra* at paragraph 36).

[56] Apotex has consistently attacked each and every claim in the '113 patent as being invalid; they do no limit themselves to particular claims. This is evidenced in the wording of the previous NOA which, as set out above, provides that "we [Apotex] allege that all of its [the '113 Patent] claims (claim 1-22) are invalid, void and of no effect" (emphasis added). Furthermore, in their further NOA submitted by way of a letter dated March 21, 2005, Apotex reiterated that "…those allegations [in the previous NOA] are allegations of invalidity of the '113 Patent, and thus, necessarily address the '113 Patent in respect of each and every listing on the Patent Register" (emphasis added).

[57] I do not accept that the cause is fundamentally different today simply because the formulation or form of the pharmaceutical product to which a NOC is sought by the generic is slightly different. For the purpose of the doctrines of issue or abuse of process, what really matters are the claims of the ‘113 Patent with respect to drugs containing olanzapine.

[58] Apotex has submitted that regardless of whether the criteria for issue estoppel are met, since both abuse of process and issue estoppel are discretionary doctrines, the Court may still choose not to apply it in the circumstances because no court has ever specifically considered whether Apotex should receive market approval for the orally disintegrating olanzapine tablets.

[59] Again, I believe the emphasis on the product made by Apotex is misplaced.

[60] While no court has considered this specific issue, this Court has considered the validity of the ‘113 Patent in light of allegations brought by Apotex. As Justice Mactavish noted in *Pharmascience*, *supra* at paragraph 2, “a generic drug manufacturer who wishes to challenge the validity of a patent owned by an innovator company by means of the *PM(NOC) Regulations* must do so by "putting its best foot forward".” The fact that Apotex has failed to do so does not entitle them to a second chance.

[61] There has been no evidence put forth to suggest that Apotex could not have raised the issue of sufficiency in the previous NOA and that Justice Gauthier in *Eli Lilly*, *supra*, refused to accept Apotex’s sufficiency argument pleaded at the hearing. This is not a case where there is some special

overriding circumstances that would warrant the judge exercising his discretion not to apply issue estoppel on the facts of the particular case.

[62] In refusing to exercise her discretion in *Pharmascience, supra*, Justice Mactavish noted that *Pharmascience* would not be without remedy since it remained open to them to begin an impeachment action in relation to the patent in question.

[63] Given that Apotex has already commenced an impeachment action, I do not feel that the circumstances of the present case warrant an exercise of my discretion not to apply the doctrine of issue estoppel.

IV. CURRENT NOA NULL, VOID AND OF NO EFFECT

[64] I find that Apotex is precluded from pursuing with their current NOA.

[65] Eli Lilly has taken the position that there was no need for the Court to make a new prohibition order if Apotex was precluded from pursuing with their current NOA and/or same was declared to be null, void and of no effect.

[66] I agree with Eli Lilly.

[67] In accordance with section C.08.004 of the *Food and Drug Regulations*, C.R.C., c. 870 the Minister shall, after completing an examination of, *inter alia,* a supplemental ANDS, issue a NOC

with respect to the supplemental ANDS, but only if that submission complies with section C.08.003. Section C.08.003 requires Apotex to file a supplemental ANDS where any of a number of listed changes have been made to its drug product.

[68] This provision can only be relied upon where a notice of compliance has previously been issued. Thus, where there is no issued NOC based on the previous submission, Apotex cannot rely upon, and the Minister cannot issue a NOC, unless and until the parent NOC expires. As the Minister is prohibited until expiry of the ‘113 Patent from granting such an NOC, there is no ability for the Minister to issue an NOC on the supplemental ANDS.

[69] For all these reasons, Apotex’s current NOA seeking a NOC for a supplemental abbreviated new drug submission for olanzapine is null, void and of no effect.

V. CONCLUSION

[70] In conclusion, Eli Lilly is entitled to a declaration to the effect that Apotex is precluded by the doctrine of issue estoppel from pursuing their current NOA dated March 27, 2009 which is null, void and of no effect. As a result, the current prohibition application made by Eli Lilly and related motion to dismiss made by Apotex are terminated. Costs shall be awarded in favour of Eli Lilly.

JUDGMENT

THIS COURT DECLARES, ADJUDGES AND ORDERS that Apotex is precluded by the doctrine of issue estoppel from pursuing their current NOA dated March 27, 2007 which is null, void and of no effect. As a result, the current prohibition application made by Eli Lilly and related motion to dismiss made by Apotex are terminated. Costs are awarded in favour of Eli Lilly.

"Luc Martineau"

Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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