

Federal Court



Cour fédérale

**Date: 20090703**

**Docket: T-656-09**

**Citation: 2009FC693**

**Ottawa, Ontario, July 3, 2009**

**PRESENT: Madam Prothonotary Mireille Tabib**

**BETWEEN:**

**APOTEX INC.**

**Plaintiff**

**and**

**ELI LILLY CANADA INC.**

**Defendant**

**REASONS FOR ORDER AND ORDER**

[1] The present motion is brought in the context of an action taken by Apotex Inc. (“Apotex”) against Eli Lilly Canada Inc. (“Lilly”), for damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (the “*Regulations*”). Lilly seeks an Order pursuant to Rule 221 of the Federal Courts Rules striking out paragraphs 1(b) and 22 to 28 of Apotex’ statement of claim, in which Apotex seeks disgorgement of Lilly’s revenues in application of the principles of unjust enrichment.

[2] Lilly's motion further seeks an Order either extending the time within which to file its statement of defense or staying the action until the determination of its application for leave to appeal to the Supreme Court of Canada the Order of the Federal Court of Appeal upholding the dismissal of Lilly's application for a prohibition order, extending to the final determination of the appeal, if leave is granted.

### **Motion to strike**

[3] Lilly submits that as a result of the decision of this Court in *Apotex Inc. v. Merck and Co. Inc.*, 2008 FC 1185, upheld by the Court of Appeal in *Merck Frosst Canada Ltd. et al v. Apotex*, 2009 FCA 187, it is now plain and obvious that, at law, a generic such as Apotex is precluded, in a claim pursuant to section 8 of the *Regulations*, from asserting a claim for disgorgement or accounting of a first person's profits.

[4] Apotex argued at the hearing that the decision in *Apotex v. Merck* is not determinative of whether a second person may assert a claim for unjust enrichment, as it is specifically mentioned at paragraph 11 of that decision that Apotex' claim for unjust enrichment was dropped at trial and was therefore not considered.

[5] In *Apotex v. Merck*, the Court held as follows:

“97 Turning to section 8(4) of the *PMNOC Regulations* it is immediately apparent that the generic is not a patentee, in fact it escaped charges of infringement of somebody else's patent by demonstrating that the patent was invalid (as in the present case) or

not infringed. The generic cannot claim damages or an account of profits for infringement. What the generic can claim is "compensation" for "loss" having been kept off the market for a period of time. That "compensation" takes the form of "damages or profits". The reasonable interpretation of those words "damages or profits" is that the generic can seek, as a measure of its damages in the alternative, the profits that it would have made if it had been able to market its product at an earlier time.

(...)

101 Having regard to all of the foregoing discussion, including but not limited to what Professor Sullivan has said, I conclude that the proper interpretation of section 8(4) of the *PMNOC Regulations* is to find that the words "damages or profits" are to be interpreted to include only "compensation" for the "loss", if any, suffered by a generic, and that those words do not provide for a right of a generic to elect for a disgorgement or account of a first person's profits.

102 Section 20(2) of the *Federal Courts Act* does not expand upon the remedies afforded by section 8 of the *PMNOC Regulations*. It enables the Regulations to include equitable remedies, but such remedies must be found in the Regulation. As I have stated above, I cannot find such a remedy in the *PMNOC Regulations*."

[6] It is clear from that analysis, with which the Federal Court of Appeal agreed, that the proper interpretation of section 8 of the *Regulations* is that it includes only remedies that would compensate the generic for the loss it has suffered. From the discussion in *Bayer AG v. Apotex Inc.*, (2001) 10 C.P.R. (4<sup>th</sup>) 151, cited in *Jay-Lor International Inc. v. Penta Farm Systems Limited*, 2007 FC 358 and relied upon by the Court in *Apotex v. Merck*, it is clear that the remedy of an accounting of profits has the same remedial aim as the remedy of unjust enrichment, in that it would return to the Plaintiff what rightly belongs to it, being the revenues or profits earned through the infringing use of its intellectual property:

“12 The remedy of an accounting of profits is equitable in origin and its goal is compensatory. The purpose is not to punish the defendant for its wrongdoing: *Beloit Canada Ltd. v. Valmet Oy* (1994), 55 C.P.R. (3d) 433 at 455 (F.C.T.D.), var'd on other grounds (1995), 61 C.P.R. (3d) 271 (F.C.A.); *Lubrizol Corp. v. Imperial Oil Ltd.* (1996), 71 C.P.R. (3d) 26 at 33 (F.C.A.). Like an award of damages, an accounting of profits is designed to compensate the patentee for the wrongful use of its property. While the goal of each remedy is the same, the underlying principles are very different. An award of damages seeks to compensate the plaintiff for any losses suffered by the plaintiff as a result of the infringement. The amount of profits earned by the infringing party is irrelevant. An accounting of profits, on the other hand, aims to disgorge any profits improperly received by the defendant as a result of its wrongful use of the plaintiff's property. Such profits, having been earned through the use of the plaintiff's property, rightly belong to the plaintiff. The aim is to remedy the unjust enrichment of the defendant by transferring these profits to their rightful owner, the patentee: *Beloit Canada Ltd. v. Valmet Oy* (1994), supra, at p. 455 (F.C.T.D.).”

(emphasis added)

[7] As discussed by the Court, at paragraph 97 of *Apotex v. Merck*: “It is immediately apparent that the generic is not a patentee. (...) The generic cannot claim damages for an accounting of profits for infringement.” The reasoning of the Court is to the effect that the compensatory provisions of section 8 of the *Regulations* do not include disgorgement of a patentee's profits because that type of remedy only has compensatory effect where the claimant is a patentee claiming for infringement. I cannot see how this reasoning could possibly be construed as still allowing *Apotex* to claim, from a patentee, the disgorgement of the same kinds of profits or revenues, as compensation for the same kind of harm, of being kept off the market, merely by invoking the more general principles of unjust enrichment.

[8] Counsel for Apotex further argues that even if remedies for unjust enrichment were unavailable pursuant to the restricted interpretation of section 8 of the *Regulations*, it is still not plain and obvious that an independent claim for unjust enrichment could not be asserted by Apotex against Lilly outside the scope of section 8. I disagree. What Apotex would then be asserting is a cause of action entirely based on unjust enrichment arising from the unjustified commencement and prosecution by Lilly of proceedings under the *Regulations*. The fatal flaw in Apotex' argument is that a cause of action between private parties based on unjustified enrichment or abuse of process is simply outside the jurisdiction of this Court. Outside the statutory scheme provided by the *Regulations*, there is simply no body of Federal law creating a cause of action for unjust enrichment or abuse of process between private parties. Apotex' reliance on Section 20(2) of the *Federal Courts Act* is misguided, as the cause of action asserted by Apotex is clearly not "respecting any patent" but respecting solely the conduct of the Defendant in the prosecution of an application under the *Regulations*. Further, as stated by the Court at paragraph 102 of *Apotex v. Merck*: "Section 20(2) of the *Federal Courts Act* does not expand upon the remedies afforded by section 8 of the *Regulations*. It enables the *Regulations* to include equitable remedies, but such remedies must be found in the *Regulations*."

[9] Finally, I should add that Apotex' reliance on the jurisprudence of this Court prior to the *Apotex v. Merck* decision is misplaced. The cases cited stand for the proposition that it is not appropriate to entertain motions to strike proceedings brought under s. 8 of the *Regulations* based on the interpretation of the scope of that provision. These decisions reflect the state of the law as it existed at that time. There had yet been no judicial determination as to the interpretation

of section 8, as to the type of remedies that could be sought and awarded thereunder and as to the period of time for which relief could be claimed, and it was properly held that these questions should not be resolved as simple questions of law without context and a full evidentiary record. Now that such judicial determination has been made in *Apotex v. Merck* as to the available remedies, in the context of a trial and on a full argument and evidentiary record, this line of cases is no longer applicable to these issues. Apotex placed particular reliance on the unreported decision of *Apotex v. Merck & Co., Inc et al*, a decision issued by Justice Pinard on February 18, 2002 in Court file T-411-01, wherein a motion to strike a claim for unjust enrichment was also dismissed. It appears that the moving party had specifically pleaded that a claim for unjust enrichment could neither be sustained pursuant to section 8 of the *Regulations* nor as an independent claim as the Court did not have jurisdiction over the latter. The dismissal order, which contains no reasons, cannot be held as a vindication of Apotex' argument that jurisdiction does arguably exist for this Court to hear a claim for unjust enrichment independently from section 8: It is clear that the statement of claim in that matter also advanced the same claim pursuant to section 8 of the *Regulations*; as the claim was allowed to proceed on the basis of section 8, it would have served no purpose to pronounce as to whether or not it could also arguably be maintained independently.

[10] In conclusion, I find that it is plain and obvious that any claim made by Apotex in its statement of claim seeking a disgorgement of the profits or the excess revenues realized by Lilly cannot succeed, and must be struck.

**Motion for a Stay or an Extension of Time**

[11] It was the dismissal of Lilly's application for a prohibition order which paved the way for Apotex to obtain an NOC for its raloxifene product and gave rise to the present action. Lilly therefore contends that if it is successful in having that dismissal overturned by the Supreme Court, the action will automatically fail, and all time, efforts and costs expended in prosecuting the action in the interim will have been wasted.

[12] In support of its motion for a stay of proceeding or an extension of time, Lilly asserts that its motion for leave to appeal to the Supreme Court presents a reasonable chance of success, notwithstanding previous determinations by the Federal Court of Appeal to the effect that appeals from judgments dismissing a prohibition application become moot once the relevant NOC is issued, and that the prospect of further litigation arising from the earlier dismissal, such as an action pursuant to section 8 of the *Regulations*, is not sufficient to militate in favour of exercising the discretion to hear the appeal (see *Eli Lilly Canada Inc. v. Novopharm Ltd.*, (2007), 62 C.P.R. (4<sup>th</sup>) 161, 2007 FCA 359). Lilly suggests that, contrary to the conclusions of the Federal Court of Appeal in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, an appellate Court does have the power, on appeal of a prohibition application, to set aside the NOC issued pursuant to the earlier dismissal and issue a prohibition order.

[13] Lilly further contends that, if it is ultimately successful before the Supreme Court on that argument, it will suffer irreparable harm in that the solicitor and client costs which it will have

expended in defending this action in the interim will not be fully recoverable, since any award of costs would be limited to party and party costs.

[14] Even if I were to agree with Lilly's argument on the issues set out above, but without making any determination either way, I would still decline to exercise my discretion to issue the order sought by Lilly.

[15] Even assuming that Lilly's appeal to the Supreme Court raises an arguable case, it remains that Lilly's chances of success on the motion for leave to appeal are very remote: leave to appeal to the Supreme Court on the issue of mootness has already once been denied (in the specific *Lilly v. Novopharm* matter already cited) and there is clearly ample opportunity for the substantive issues raised in the appeal to be put before and considered by the Supreme Court in the context of other proceedings. The realization of the harm feared by Lilly is, accordingly, equally remote. In addition, the steps which Lilly will be required to take in defending this action are expected to be relatively straightforward, at least until the beginning of oral discoveries, at which time it is likely that the Supreme Court will have ruled on Lilly's motion for leave to appeal. To the extent there is a discrepancy between the amounts which Lilly might recover for those steps on a party and party basis and the amounts in fact expended, the amounts at stake are unlikely to be very large. It is, in my view, this relatively manageable and remote prejudice which is to be weighed against the prejudice caused to Apotex in simply being prevented or delayed in pursuing a recourse which it is, at law, entitled to pursue. The interest of justice, in ensuring that actions proceed before it expeditiously and without delay, especially in



the context of recent policy initiatives of this Court in this regard, must also be taken into consideration.

[16] On balance, at this time, I would decline to stay these proceedings. Should Lilly's motion for leave to appeal to the Supreme Court be successful, the balance of convenience may well shift, and it would then be appropriate to consider in detail and determine the validity of Lilly's arguments as to a serious question to be tried and irreparable harm. In the circumstances as they currently exist, that exercise is unnecessary.

**ORDER**

**IT IS ORDERED THAT:**

1. Sub-paragraphs 1(b) and 22 to 28 of the Statement of Claim are hereby struck.
2. The motion is otherwise dismissed.
3. The time within which the Defendant is to serve and file its Statement of Defence is extend to 30 days from the date of this Order.
4. Costs of the appearance on May 19, 2009 are awarded to the Plaintiff; no costs are otherwise awarded.

“Mireille Tabib”

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Prothonotary

**FEDERAL COURT**

**NAME OF COUNSEL AND SOLICITORS OF RECORD**

**DOCKET:** T-656-09

**STYLE OF CAUSE:** APOTEX INC. v. ELI LILLY CANADA INC.

**PLACE OF HEARING:** Ottawa, Ontario

**DATE OF HEARING:** June 25, 2009

**REASONS FOR ORDER:** MADAM PROTHONOTARY MIREILLE TABIB

**DATED:** July 3, 2009

**APPEARANCES:**

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