

Federal Court



Cour fédérale

**Date: 20100819**

**Docket: T-1787-08**

**Citation: 2010 FC 828**

**BETWEEN:**

**APOTEX INC.**

**Plaintiff**

**and**

**SHIRE CANADA INC.**

**Defendant**

**REASONS FOR ORDER**

**TABIB P.**

[1] The following are the reasons for the Order issued on June 4, 2010, granting in part the motion of the Defendant, Shire Canada Inc. (“Shire”) for leave to amend its statement of defence.

[2] The present proceeding is an action brought by Apotex Inc. (“Apotex”) for damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133) (“the *Regulations*”). Apotex filed a submission for a Notice of Compliance for its generic Apo-modafinil tablets, by comparing it to Shire’s modafinil product. Shire had listed Canadian Patent No. 2,201,967 (the “’967 Patent”) on the patent register pursuant to the *Regulations* in respect of its modafinil tablets. On March 16, 2006, Apotex served a Notice of Allegation on Shire, alleging that

the claims of the '967 Patent were invalid, void and of no effect. In response to Apotex's Notice of Allegation, Shire commenced an application for an order prohibiting the Minister of Health from issuing an NOC to Apotex. The application was dismissed on April 25, 2008, two years after the application was commenced. Having obtained its NOC shortly after the judgment issued, Apotex now seeks to recover, pursuant to section 8 of the *Regulations*, damages it has suffered as a result of the delay in issuance of the NOC resulting from Shire's unsuccessful application for a prohibition order.

[3] In its initial defence, filed January 23, 2009, Shire defended the action on the basis that Apotex delayed serving its Notice of Allegation regarding the '967 Patent, and unnecessarily delayed the conduct of the prohibition proceedings. A year later, Shire further amended its Statement of Defence to add as a defence that because of the difficulties in making modafinil, especially on a commercial scale, Apotex would not have been ready to launch its Apo-modafinil product on the alleged date of September 1, 2006. By its present motion, Shire seeks to amend again its Statement of Defence to allege two new defences, as follows:

- (a) That the owner of the '967 Patent, Cephalon Inc. ("Cephalon") has commenced an infringement action against Apotex in a different Court file and that, should the '967 Patent in that other action be found to be valid and infringed, Apotex should not be entitled to recover any damages for loss of sales ultimately found to be infringing.
- (b) That a second patent was listed on the patent register against Shire's modafinil tablets, being Canadian Patent 2,165,824 (the "'824 Patent"). That Apotex served on Shire a Notice of Allegation dated August 30, 2005 in which it alleged that it

would not infringe the '824 Patent on the basis of its Draft Product Monograph and gave an undertaking that it would not make, use or sell its tablets for the patented use of treatment of sleep apnea or ventilation problems of central origin. That, however, Apotex's Product Monograph states that Apo-Modafinil is indicated for the patented use and has been sold for that use, in breach of Shire's undertaking. Shire alleges that the breach of undertaking gives rise to the "grave consequences" alluded to by the Federal Court of Appeal in *Hoffmann-Laroche Limited et al. v. Minister of National Health and Welfare et al.* (1996) 70 C.P.R. (3<sup>rd</sup>) 206, in the form of a denial of any remedy for delayed entry into the market pursuant to section 8 of the *Regulations*.

[4] Apotex opposes Shire's motion on the grounds that the proposed amendments do not disclose a reasonable defence and ought not to be permitted.

I. The defence based on Cephalon's action

[5] Instead of directly asserting as a defence against Apotex's action a plea that the '967 Patent is valid and infringed and that Apotex should therefore not be entitled to recover damages based on the loss of infringing sales, Shire proposes to rely on the outcome of a separate infringement action commenced by Cephalon and to which it is not a party. Thus, it does not propose to bring any evidence in this action as to the validity or infringement of the '967 Patent so that the Court could make a direct determination of these issues in the context of this action. Rather, it proposes to rely strictly on the outcome of Cephalon's action, as a fact. The allegations, as proposed, recognize

clearly that the Cephalon action was only begun in April 2009 and has yet to be determined. The outcome of the Cephalon action, upon which depends the success of the proposed defence, is therefore clearly an uncertain future event which is not susceptible of being determined or even influenced in the context of the present action. In essence, Shire is alleging that if a certain event comes to pass (upon which neither the Court nor the parties have any control or any way of determining in the context of this action), then it will have a valid defence. This is the essence of a speculative and hypothetical pleading and ought to be struck (see *Bell Canada v. Pizza Pizza Ltd.* (1993), 48 C.P.R. (3<sup>rd</sup>) 129). Furthermore, if these allegations were allowed to be introduced in the Statement of Defence, the issues they raise could not be determined unless and until the proceedings brought by Cephalon against Apotex in that other Court file were resolved. This would unreasonably delay, embarrass and prejudice the trial of the present action.

## II. The “grave consequences” defence

[6] Apotex submits that because the alleged misrepresentation or breach of undertaking in respect of the ‘824 Patent did not arise in the context of the prohibition application relating to the ‘967 Patent and from which its right to claim damages flows, the misrepresentation cannot be used as a proper defence in this action. More particularly, Apotex relies on the wording of sub-section 8(5) of the *Regulations*, which provides that in assessing the amount of the compensation, regard may be had to the conduct of the parties “during the prohibition proceedings” (being, on Apotex’s argument, the prohibition proceedings relating to the ‘967 Patent) which contributed to the delay. On that view, the only valid defence to a section 8 action would be those arising exclusively in the context of the very prohibition proceeding that was dismissed or discontinued. Apotex further cites

in support of its proposition paragraph 66 of the Court of Appeal' decision in *Merck Frosst Canada Ltd. et al. v. Apotex Inc.*, 2009 FCA 187, as follows:

“[66] I would simply add, to further highlight the extent of the connection, that an award of damages under section 8 logically flows from the section 6 prohibition proceedings and would normally be adjudicated by the judge who hears the prohibition application. I refer in particular to subsection 8(5) of the *PM(NOC) Regulations* which provides that in assessing the amount of the compensation, regard must be had to the conduct of the parties during the prohibition proceedings which contributed to the delay. It is apparent that the only reason section 8 damages are adjudicated in a separate proceeding is that regard had to be had to the right of appeal.”

[7] That passage in *Merck Frosst* was written in the context of the determination of the constitutional validity of s. 8 of the *Regulations*. Not only does it appear to be an *obiter dictum* but it is not clear that it was intended to apply as a cannon for the interpretation of subsection 8(5) for all purposes. Further, the Federal Court of Appeal has, in the past, cautioned against the resolution of difficult questions involving the interpretation of section 8 in the context of preliminary or summary proceedings (*Apotex Inc. v. Eli Lilly and Co.*, 2004 FCA 358). Apotex's argument constitutes a difficult question, and should not be determined on a motion to strike. In any event, even if Apotex's interpretation of sub-section 8(5) of the *Regulations* were eventually found to be correct, it would not end the matter or make Shire's factual allegations incapable of supporting a reasonably arguable defence. In particular, I am satisfied that it is reasonably arguable that the Court could conclude, pursuant to sub-section 8(1)(a)(ii) of the *Regulations*, that Apotex's breach of undertaking in relation to the '824 Patent (if established), justifies choosing another date than the date certified by the Minister as the starting point of the period for which damages should be paid. For instance, it could be argued that but for that the alleged misrepresentation or breach of undertaking, an NOC

would not have issued to Apotex until the expiration of the '824 Patent, such that the period of liability never commenced.

[8] I am therefore satisfied that Apotex has not met the very heavy onus of showing that the proposed amendments, as to the “grave consequences” defence, are plainly and obviously devoid of any merit and stand no chance of success whatsoever.

“Mireille Tabib”

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Prothonotary