Date: 20090415

Docket: T-482-04

Citation: 2009 FC 378

Toronto, Ontario, April 15, 2009

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

APOTEX INC.

Plaintiff

and

GLAXOSMITHKLINE INC., GLAXOSMITHKLINE PLC,
SMITHKLINE BEECHAM CORPORATION,
DOE CO. and all other entities unknown to the Plaintiff
which are part of the GLAXOSMITHKLINE group of companies

Defendants

REASONS FOR ORDER AND ORDER

[1] Each of the Plaintiff and Defendants have brought a motion by way of an appeal from an Order of Prothonotary Lafrenière dated September 23, 2008 which, in the case of the Plaintiff Apotex's appeal, he required certain questions put it by the Defendants on discovery to be answered and, in the case of the Defendants' appeal, he ordered that certain question which it put to the Plaintiff Aptoex on discovery need not be answered. I have dismissed both motions without costs to any party.

[2] This action is brought by the Plaintiff Apotex seeking relief as may be provided under the provisions of section 8 of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 as periodically amended. The Defendants GlaxoSmithKline et al. have defended the action on various grounds and have not counter-claimed.

[3] I thank counsel for each of the parties for reducing the groups of questions which are the subject of this motion/appeal to, in the case of Apotex to a single group and, in the case of GlaxoSmithKline, to two groups. Each of these groups were argued on the basis that they presented a single issue for determination. I will address these groups on that basis.

[4] The general principles respecting motions of this kind are well known. As the Federal Court of Appeal wrote in *Merck & Co. v. Apotex Inc*., [2004] F.C. 459 in restating its proposition made in *Canada v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C. 425 at paragraph 19 of the *Merck & Co.* decision:

> *Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless: (a) the questions raised in the motion are vital to the final issue of the case, or (b) the orders are clearly wrong in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.*

[5] I reviewed the law respecting discovery in some detail in *AstraZeneca Canada Inc. v. Apotex Inc.*, November 20, 2008, 2008 FC 1301 and do not propose to set out that decision at length here. I said at paragraphs 19, 20 and 23:

> ***19*** *Prothonotaries of this Court are burdened, to a large extent, with motions seeking to compel answers to questions put on*

> *discovery. Often hundreds of questions must be considered. Hours and often days are spent on such motions. It appears that in many cases the parties and counsel have lost sight of the real purpose of discovery, which is directed to what a party truly requires for trial. They should not slip into the "autopsy" form of discovery nor consider discovery to be an end in itself.*
>
> ***20*** *A determination made by a Prothonotary following this arduous process ought not to be disturbed unless a clear error as to law or as to the facts has been made, or the matter is vital to an issue for trial. Where there has been an exercise of discretion, such as weighing relevance against onerousness, that discretion should not be disturbed. The process is not endless. The parties should move expeditiously to trial.*
>
> ...
>
> ***23*** *Law establishes if a question is relevant, discretion may be applied as to whether, nonetheless, it is appropriate to Order, or not to Order, that an answer be given. Deference is to be given to a Prothonotary's Order in that regard.*

[6] I will turn to the three groups of questions before me on these motions/appeals.

[7] The first is the subject of Apotex's motion/appeal. Prothonotary Lafrenière ordered that a large number of questions be answered as to whether the Apotex product is or becomes a hemihydrate. Such questions would be relevant in considering whether that product infringes Canadian Patent 1,287,060 (the '060 patent). In earlier proceedings T-2660-96 and T-2230-97 the '060 patent was the subject of non-infringement allegations by Apotex. It was held by this Court that these allegations of non-infringement were justified hence the application for prohibition was dismissed. No action for infringement of the '060 patent has been brought.

[8] Instead, in the present action the Defendants GlaxoSmithKline have defended the action in part by a pleading which I will describe as a novel. Relying on a statement made by the Trial Judge, McGillis J. in the earlier proceedings to the effect that Apotex would suffer what she described as "*very grave consequences*" if its product did in fact convert to a hemihydrate, GlaxoSmithKline pleads, by way of a defence, that the Apotex product does contain hemihydrate in part, thus Apotex's claim under section 8 of the *NOC Regulations* should be dismissed. The Defence states, in part:

> *54. In the end, the Court determined that GSK had not met its burden to prove that Apotex's allegation was unjustified. In this regard, Madam Justice McGillis concluded that:*
>
> > *Apotex should not be prevented from taking its anhydrate tablets do convert to hemihydrate, in whole or in part it will face "very grave" consequences at that point in time.*
>
> *55. As such, the Court accepted Apotex' undertaking that its tablets would not contain the hemihydrate.*
>
> *56. However, the tablets that Apotex is marketing today do contain hemihydrate, in part.*
>
> *57. Throughout the various NOC proceedings resulting from the numerous NOAs sent by Apotex to GSK in respect to paroxetine hydrochloride, Apotex produced a number of different process documents. E ach and every one of the processes set out in these documents yields drug product and tablets containing crystalline paroxetine hydrochloride hemihydrate, at least in part. Apotex should not be entitled to any damages prior to the time it develops, if ever, a process that yields tablets completely free of hemihydrate.*
>
> *58. As such, Apotex has breached its undertaking. Under Justice McGillis's decision, they must face very grave consequences. As such, their claim for damages under Section 8 should be dismissed in its entirety.*

> *59. Apotex should not be rewarded with Section 8 damages for any delay in bringing to market a product which is infringing. This would be contrary to the intent of the NOC Regulations, which is to prevent patent infringement.*

[9] Apotex did not move to strike out this plea. Its Counsel at this hearing said that they were disheartened by having lost motions to strike in other section 8 NOC proceedings in the past. It is Counsel's job to be bold, not disheartened!

[10] Instead, Apotex pleaded over, saying in Reply:

> *7. In paragraphs 51 to 59 of the GSK Canada Statement of Defence, GSK Canada pleads a series of irrelevant allegations. More particularly:*
>
> > *(a) without admitting that Apotex infringes Canadian Letter Patent 1,287,060 (the "'060 Patent"), which it does not, any question of infringement is irrelevant to a claim pursued by a second person such as Apotex consequent upon the dismissal or withdrawal of a prohibition application brought under the Regulations;*
> >
> > *(b) any issue as to infringement of the '060 Patent is one that may only be pursued by a patentee in an action for infringement. It is only in such an action, assuming that the necessary conditions exist, which in fact do not exist in the circumstances at bar, that grave consequences may be visited upon a second person. It is significant that no action for infringement has been brought against Apotex alleging infringement of the '060 Patent;*
> >
> > *(c) without admitting that any undertaking was given and relied upon by GSK Canada or by the Court, Apotex denies that it breached any alleged undertaking and further denies that any such breach, which is not admitted, has any relevance to the claim advanced by Apotex herein.*

[11] Apotex's Counsel now says that the GlaxoSmithKline pleading is without merit, therefore questions directed to this pleading need not be answered. In so asserting Counsel relied on a number of cases each of which, on closer examination at the hearing of this motion, did not bear out that proposition. Those cases dealt with striking out a pleading, or for particulars of a pleading, or to add new subject matter to a pleading.

[12] Where a pleading itself is not the subject of a motion, a Prothonotary hearing a motion respecting questions put on discovery is quite entitled to accept the pleadings as they stand and determine whether or not a question should be answered based on such pleadings. Such a motion is not a surrogate for a motion to strike.

[13] Given the state of the pleadings, I find that the Prothonotary did not misapprehend the law or overlook any material fact. I would not interfere with the exercise of the Prothonotary's discretion in ordering this group of questions to be answered.

[14] Apotex says that to give answers to such questions, which they already have done, and respond to any follow up questions, which has not yet happened, delays this action and creates enormous expense. This is a matter to be deal with at trial in considering costs, interest and other matters.

[15] GlaxoSmithKline's motion/appeal dealt with two closely related groups of questions both of which the Prothonotary ordered did not need to be answered. Both groups deal with aspects of

alleged delaying tactics by Apotex. One deals with delays alleged in respect of disposition of numerous NOC proceedings. I repeat paragraph 60 of the Defence:

> *60. Section 8(5) of the NOC Regulations makes it clear that the conduct of the second person that contributed to delay the disposition of the NOC proceedings should be taken into account by the Court in assessing damages in accordance with Section 8. Because of the egregious conduct of Apotex throughout the various NOC proceedings as set below, including numerous delays amounting to years, Apotex should not be entitled to any damages whatsoever pursuant to Section 8.*
> (pages of particularization follow)

[16] It is to be noted that the delay alleged is "*throughout the various NOC proceedings",* not before institution of these proceedings.

[17] The second group of questions arise from Apotex's plea in paragraph 21 of its Statement of Claim:

> *21. During the currency of the proceedings with respect of the First Four Patents, GSK Canada added a further patent to the Patent Register in respect of paroxetine, namely, Canadian Letters Patent No. 2,178,637 (the "'637 Patent"). The '637 Patent we added to the Patent Register on February 17, 1998.*

[18] GlaxoSmithKline, not in its Defence or other pleading but in its Memorandum or Argument, makes the point, a tribute to ingenuity of Counsel, that Apotex's delay gave GlaxoSmithKline the opportunity to list another patent and an opportunity to institute further NOC proceedings contributing to the delay. Surely GlaxoSmithKline was not forced to list a patent nor to enforce it. If it does, can it somehow blame Apotex for the delay? In paragraph 56 of its Memorandum GlaxoSmithKline says:

> *56. Apotex' conduct in T-2660-96, T-2230-97 and T-2526-96 caused enough delay that an additional patent was added to the Patent Register before the proceedings were completed. Apotex has specifically plead that this additional patent contributed to its damages in this proceeding.*
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> *Apotex Statement of Claim, para. 21.*

[19] In summary as to delay, GlaxoSmithKline said in paragraph 123 of its Defence:

> *123. If Apotex had not delayed in sending NOAs and had consolidated the allegations in the NOAs it sent, the proceedings would have been over much sooner and Apotex would have mitigated its alleged damages. This failure to mitigate alone should disentitle Apotex to any relief sought in the Statement of Claim.*

[20] Apotex filed a Reply rebutting the allegations as to delay in some detail and concluded at paragraph 13:

> *13. In any even and without prejudice to Apotex's position that GSK's pleas of delay are irrelevant. Apotex denies that it conducted itself in any of the prohibition proceedings in a manner which caused any delay in the proceedings such as to warrant the Court to reduce the award to be made in the within proceeding. In fact, Apotex conducted the prohibition proceedings in a manner designed to expedite the proceedings, subject to the exigencies of litigation, as will be detailed in the evidence provided at trial.*

[21] Prothonotary Lafrenière dealt with these two groups of questions in his Reasons stating that the questions were of "*tenuous relevance"* and would "*serve no useful purpose".* He wrote

> *GSK has also asked a numbers of questions in regard to three mandamus proceedings commenced by Apotex in relation to the paroxetine patents held by GSK (Court File Nos. T-1635-98, T-2063-99 and T-2288-01). Being substantially in agreement with Apotex's submissions, I am not satisfied that the conduct of Apotex in the mandamus proceedings are relevant. The "matters relevant to the assessment of the amount", as defined in ss. 8(5) of the Regulations, target the conduct of the parties in relation to applications under s.*

> *6(1), and does not open the door to a far-reaching discovery on matters of tenuous relevance. In any event, delving into the motivations and legal strategies of Apotex in commencing and discontinuing mandamus proceedings would serve no useful purpose as it would not advance GSK's legal position.*

[22] I agree with the Prothonotary's disposition of these matters. He properly exercised his discretion.

CONCLUSION AND COSTS

[23] As a result, both motions/appeals are dismissed. Following discussions with Counsel and the hearing, there will be no costs ordered in respect of either motion

ORDER

FOR THE REASONS PROVIDED:

THIS COURT ORDERS that:

1. Each of the motions by way of appeal from the Prothonotary's Order of September 23, 2008 brought by the Plaintiff and Defendants respectively is dismissed;

2. No Order as to costs in respect of either motion.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-482-04
STYLE OF CAUSE:	APOTEX INC. v. GLAXOSMITHKLINE INC., GLAXOSMITHKLINE PLC, SMITHKLINE BEECHAM CORPORATION, DOE CO. and all other entities unknown to the Plaintiff which are part of the GLAXOSMITHKLINE group of companies
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