Date: 20070810

Docket: T-2113-06

Citation: 2007 FC 833

Toronto, Ontario, August 10, 2007

PRESENT: Kevin R. Aalto, Esquire, Prothonotary

BETWEEN:

GLAXOSMITHKLINE BIOLOGICALS S.A.

Plaintiff
(Moving Party)

and

NOVARTIS VACCINES AND DIAGNOSTICS, INC.

Defendant

REASONS FOR ORDER AND ORDER

[1] This is a motion to strike out the Defendant's Counterclaim without leave to amend and to strike out paragraph 7 of the Statement of Defence without leave to amend.

Background

[2] The Plaintiff (GSK), commenced this action on December 4, 2006 pursuant to s. 60 of the *Patent Act* to impeach Canadian Patent No. 2,017,507 (507 Patent) which is owned by the Defendant (Novartis).

[3] GSK seeks a declaration that the 507 Patent is invalid. The 507 Patent discloses an adjuvant for use in vaccines. The 507 Patent expires May 24, 2010. GSK bases its allegation of invalidity by reason of lack of novelty, obviousness, lack of utility, claims broader than the invention made or disclosed, and ambiguity and/or indefiniteness.

[4] As described in the Statement of Claim, the 507 Patent "relates generally to vaccine adjuvants comprising a metabolizable oil and an emulsifying agent, with or without a separate immunostimulating agent, in which the oil and the emulsifying agent are present in the form of an oil-in-water emulsion having oil droplets substantially all of which are less than one micron in diameter, and in which there is no polyoxypropylene-polyoxyethylene block co-polymer".

[5] GSK pleads in its Statement of Claim that it wishes to sell in Canada a vaccine containing an adjuvant comprising the same elements as the 507 Patent (the GSK Adjuvants). GSK further pleads that the GSK Adjuvants might be alleged by Novartis to constitute an infringement of some or all of the 507 Patent.

[6] In paragraph 7 of its Statement of Defence, Novartis pleads, *inter alia*, that "GSK intends to manufacture, import, distribute, use, offer for sale and sell in Canada Adjuvants". Novartis alleges that "making, importing, distributing, using, offering for sale, or selling of the GSK Adjuvants" is an infringement of the claims of the 507 Patent.

[7] In its Counterclaim, Novartis seeks a declaration that the 507 Patent "will be infringed" by the GSK Adjuvants and seek, *inter alia*, an injunction restraining GSK from manufacturing, distributing, offering for sale, selling, licensing, or otherwise making available or using in Canada the GSK Adjuvants. Throughout the Counterclaim, Novartis uses speculative language to describe the conduct of GSK. Novartis pleads that GSK is "proposing" to sell etc., "intends" to sell, "intends" to use", and "intends to formulate" the GSK Adjuvants.

[8] Novartis concludes that by virtue of "proposing" and "intending" to sell etc., GSK "has or will make an unlawful profit" and that Novartis "has or will suffer loss or damage". Novartis specifically pleads that the extent of GSK's infringing activities is unknown to Novartis.

Issue

[9] Neither in paragraph 7 of the Statement of Defence nor anywhere in the Counterclaim are any material facts pleaded in support of the allegations of possible infringement by GSK of the 507 Patent. These pleadings are entirely speculative.

[10] The Novartis counterclaim and paragraph 7 of the Statement of Defence are based entirely on a *quia timet action*. *Quia timet* translated from the latin means "because one fears". To obtain relief on a *quia timet* basis there must be a real or impending threat (see, Dukelow, *The Dictionary of Canadian Law*, Thomson Carswell [3d ed.] at p. 1055). Thus, the issue to be determined is whether Novartis has pleaded a reasonable cause of action to salvage the Counterclaim and paragraph 7 of the Statement of Claim from being struck.

Discussion

[11] The Court may strike out a pleading that discloses no reasonable cause of action. Rule 221(1)(a)of the *Federal Courts Rules* provides:

> 221(1) On motion, the Court may, at any given time, order that a pleading, or anything contained therein, be struck out, with or without leave to amend, on the ground that it
>
> (a) discloses no reasonable cause of action or defence as the case may be . . .

[12] It is trite law that a pleading will not be struck unless it is "plain and obvious" that the pleading discloses no reasonable cause of action (see, for example, *Hunt v. Carey*, [1990] 2 S.C.R. 959 at par. 18). Further, the material facts as pleaded must be accepted as true. The pleadings under attack are *quia timet* pleadings. A *quia timet* proceeding can allege patent infringement. A summary of the test to be applied as to whether a *quia timet* proceeding is properly pleaded is set out by Justice Gibson in *Connaught Laboratories Ltd. v. SmithKline Beecham Pharma Ltd.* (1998), 86 C.P.R. (3d) 36 at p. 42:

> From the forgoing authorities, I derive the following criteria for allegations that must be evident on the face of a statement of claim initiating a *quia timet* proceeding alleging patent infringement: the statement of claim must allege a deliberate expressed intention to engage in activity the result of which would raise a strong possibility of infringement; the activity to be engaged in must be alleged to be imminent and the resulting damage to the plaintiff must be alleged to very substantial if not irreparable; and, finally, the facts pleaded must be cogent, precise and material. <u>It is not sufficient that they be indefinite or speak only of intention or amount to mere speculation</u>. (Emphasis added)

[13] Applying this test to the pleadings in this proceeding, it is plain and obvious that no reasonable cause of action has been pleaded and both paragraph 7 of the Statement of Defence and

the Counterclaim must be struck out. The pleading speaks only to GSK "intending" or "proposing" to manufacture, formulate, use or sell. The allegations fail to support a *quia timet* action for infringement.

[14] As noted by Justice Reed in *Faulding (Canada) Inc.* v. *Pharmacia S.p.A.* (1998), 82 C.P.R. (3d) 435 at p. 439:

> Claims for infringement that are premised on indefinite acts in the future are in the realm of speculation. As such they are premature and should be struck out. [citations omitted] Similarly, pleas founded on the "intention of a party to do certain acts are improper and will be struck [citations omitted]

[15] Novartis argues that the pleadings are sufficient to support a *quia timet* case of patent infringement and that the pleading complies with the test for a *quia timet* proceeding for patent infringement. They argue that there is no basis for GSK bringing this action now to declare the 507 Patent invalid as it expires in less than three years. They argue that the only possible conclusion is that GSK plans to sell the GSK Adjuvant imminently and well before the 507 Patent expires. This is an entirely speculative argument. There are no material facts pleaded of how imminent such activity of GSK is nor any other material fact other than mere possibility of infringing acts. None of the authorities cited by the Novartis assist their cause. Material facts may come to the attention of Novartis which may support a *quia timet* action for patent infringement. There are none presently pleaded.

[16] Further, the Counterclaim and paragraph 7 should not be used as a weapon to permit Novartis to get to discovery and "bootstrap their claim" and use the discovery process improperly as

a fishing expedition (see Justice Rothstein's comments in *Merck & Co.* v. *Apotex Inc.*(1997), 72 C.P.R. (3d) 515 at p. 516).

[17] In the result, both paragraph 7 of the Statement of Defence and the Counterclaim are struck out without leave to amend. However, I echo the words of Justice Gibson in *Connaught*, *supra*, at p. 43 wherein it is noted:

> "None of my conclusions herein should be read as in any sense foreclosing a further action by Connaught, even on a *quia timet* basis, if more significant evidence of an expressed intention on the part of SKB to imminently market its vaccine in Canada, with a strong resultant probability of infringement of Connaught's patent, can be pleaded."

Similarly, if more cogent evidence of a real and imminent intention by GSK to infringe that meets the test for a *quia timet* patent infringement action surfaces, then Novartis may take such steps as it is advised to pursue such a claim. The current pleading in par. 7 and the counterclaim are insufficient. One may well speculate why GSK seeks to declare the 506 Patent invalid when there is only 3 years to go on the patent. However, at this juncture the Novartis *quia timet* pleadings in par. 7 of the Statement of Defence and the Counterclaim are only speculation.

[18] As GSK has been successful on this motion they are entitled to their costs. Counsel for the parties submitted that $2,000.00 was an appropriate amount.

ORDER

THIS COURT ORDERS that:

1. The Counterclaim is hereby struck out without leave to amend.

2. Paragraph 7 of the Statement of Defence is struck out without leave to amend.

3. This action shall continue as a specially managed proceeding.

4. The Plaintiff is entitled to its costs of this motion which are fixed in the amount of $2,000.00 and are payable forthwith.

"Kevin R. Aalto"
Prothonotary

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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