Federal Court  Cour fédérale

Date: 20170615

Docket: T-200-17

Ottawa, Ontario, June 15, 2017

PRESENT: Prothonotary Kevin R. Aalto

BETWEEN:

OTSUKA PHARMACEUTICAL CO., LTD., BRISTOL-MYERS SQUIBB CANADA CO., AND OTSUKA CANADA PHARMACEUTICAL INC.

Plaintiffs

and

APOTEX INC. AND APOTEX PHARMACHEM INC.

Defendants

ORDER

UPON Motion, dated the 16th day of March, 2017, on behalf of Defendants, for:

a) an order that the claims of Bristol-Myers Squibb Canada Co. ("BMS Canada") and Otsuka Canada Pharmaceutical Inc. ("Otsuka Canada") be struck from the statement of claim, without leave to amend;

b) an order striking out paragraphs 10 (second and third sentences), 12, 13 and 14 of the statement of claim, without leave to amend;

c) an order striking out the remainder of the statement of claim, without leave to amend, or, in the alternative, an order requiring the Plaintiffs (or any remaining Plaintiff(s)) to amend the statement of claim to provide material facts or particulars as follows:

(i). in paragraph 10, particulars of Apotex Inc. having made and continuing to make "in Canada tablets containing aripiprazole ("Apotex Tablets")" and the Apotex Tablets being "presently ultimately sold for consumption by patients outside of Canada", including when the Apotex Tablets were made, and to whom and where outside of Canada the Apotex Tablets are "presently ultimately sold" for consumption by patients;

(ii). in paragraph 11, particulars of Apotex Pharmachem Inc. having "made and offered to sell in Canada, and ... sold in Canada and/or exported aripiprazole", including when and to whom such aripiprazole was made, offered for sale, sold and/or exported and the destination(s) of export;

(iii). in paragraph 120, particulars of Apotex Inc. having "sold in Canada and/or exported Apotex Tablets", including when and to whom such Apotex Tablets were sold and/or exported and the destination(s) of export;

(iv). in paragraph 121, particulars of Apotex Inc. having "advertised and promoted online" Apotex Tablets, including when and where the advertising and promotion online occurred;

(v). in paragraph 122, particulars of Apotex Inc. having "made and sold in Canada and/or exported Apotex Tablets, including packaged in bottles with instructions

for use in the treatment of schizophrenia and bipolar I disorder", including when and to whom such Apotex Tablets and packages thereof were made, sold and/or exported and the destination(s) of export; and

(vi). in paragraph 123, particulars of Apotex Pharmachem Inc. having "made and offered to sell in Canada, and ... sold in Canada and/or exported (i) aripiprazole that is at least in part one or more of Hydrate A, Crystals B, C, D, E, and/or F as claimed in the Claims in Issue, and/or (ii) aripiprazole that was made from or using one or more of Hydrate A, Crystals B, C, D, E, and/or F", including when and to whom such aripiprazole was made, offered for sale, sold and/or exported and the destination(s) of export;

d) if the action is not dismissed, then an order extending the time for delivery of Apotex's statement of defence to a date twenty days after the disposition of this motion or, if an order for the delivery of an amended statement of claim pursuant to paragraph (c), above, is made, then twenty days after the delivery of an amended pleading that complies with such order;

e) an order granting to Apotex its costs of this motion, and, if the action is dismissed, its costs of this motion, and, if the action is dismissed, its costs of the action, all on a solicitor and client basis; and

f) such further and other relief as counsel may advise and this Honourable Court permit.

AND UPON reading the motion record of the Moving Parties, Apotex Inc. and Apotex Pharmachem Inc. (Apotex); and upon reading the responding motion record of the Plaintiffs

(collectively Otsuka); and upon hearing the submissions of counsel for Apotex and Otsuka; and upon considering the matter;

Apotex seeks to strike this action without leave to amend on the ground that there are no material facts contained in the statement of claim (Claim) that support the alleged causes of action. It is argued that the infringement allegations are nothing less and nothing more than bald allegations of infringement without the necessary material facts to give them life and therefore the Claim should be struck as it is nothing more than a fishing expedition. Wrapped up in this submission Apotex further alleges that the Claim seeks a *quia timet* injunction which is insufficiently pleaded and thus should be struck without leave to amend. Apotex also argues that there are insufficient facts pleaded whether the three Plaintiffs are persons entitled to claim under the Patentee, Otsuka Pharmaceutical Co., Ltd.

In the alternative, Apotex seeks particulars of various parts of the Claim or that an amended pleading be filed including the requisite material facts.

There are six patents alleged to be infringed in the Claim. Five of the patents relate to a crystal form of the active pharmaceutical ingredient (API) which is aripiprazole. The Plaintiff, Otsuka Pharmaceutical Co., Ltd. is the patentee while the other two Plaintiffs are alleged to have a business relationship with the patentee including the sale, commercialization and marketing of the patentee's product.

There is an ongoing proceeding commenced by two of the Plaintiffs in this proceeding under the *Patented Medicines (Notice of Compliance) Regulations*. That application was commenced September 21, 2016. As is the usual case, that application seeks an order

prohibiting the Ministry of Health from issuing a Notice of Compliance to Apotex for the Apotex aripiprazole tablet (Apotex Tablets). Apotex filed an Abbreviated New Drug Submission (ANDS) for the issuance of an NOC for the Apotex Tablets. Apotex also delivered a Notice of Allegation dated August 8, 2016 to Bristol-Meyers Squibb Canada Co.

The sixth patent in suit also relates to aripiprazole but is described as a "use" patent although Otsuka alleges it is more than a use patent as it also contemplates the commercial packaging for aripiprazole.

On this motion Otsuka filed an affidavit attached to which was, among other things, a copy of the Notice of Allegation which resulted in the PMNOC proceedings and printouts of internet searches regarding the Apotex tablets and photographs of a sealed bottle of the Apotex Tablets and the package insert with the bottle which clearly states that the Apotex Tablets were manufactured by Apotex Inc., Toronto, Ontario. There does not appear to be any dispute that Apotex in fact manufactures the Apotex Tablets but it appears that those tablets are exported to the United States for use by patients in the United States. Indeed, the Claim pleads "these tablets are presently ultimately sold for consumption by patients outside of Canada. Apotex also intends to sells its aripiprazole tablets for consumption by patients in Canada".

Because there are six patents involved, the Claim is quite lengthy. However, the Claim for the most part comprises descriptions of the six patents and the claims of those six patents. Of the some 130 paragraphs of the Claim, only a dozen or so deal with the substantive issues of infringement, standing, and, heads of relief.

First, dealing with the issue of the standing of Otsuka to bring this action, I am not persuaded that the Claim is insufficiently particularized to support, at this stage, that the three Plaintiffs have standing to bring the action. It is pleaded that Otsuka distribute and sell in Canada the tablets in issue containing aripiprazole. A relationship has been established and the authorities on which Apotex relies upon and support of its position that these parties do not have standing, are all authorities based on trial decisions based on a full evidentiary record as to the connections between the parties and their standing to bring the action.

Second, much of the argument by Apotex focused on the *quia timet* allegation. In its written representations, Otsuka denied it was claiming a *quia timet* injunction. However, the sentence from paragraph 10 "Apotex also intends to sell its aripiprazole tablets for consumption by patients in Canada" is argued by Apotex to be part of a *quia timet* pleading. From Apotex's perspective the *quia timet* pleading in insufficient, lacks particularity and does not meet the requirements of a *quia timet* plea. While Otsuka may deny it is not claiming a *quia timet*, in my reading of the Claim it is clear that the elements of a *quia timet* are alleged. The question is whether the Claim properly pleads a *quia timet.*

Apotex relies upon various authorities including *Pfizer Research and Development Co. v. Lilly ICOS LLC*, 2003 27 C.P.R. (4th) 86 (FCTD), in which the *quia timet* plea is discussed. The case primarily relied upon for the criteria for a *quia timet* allegation as summarized in *Connaught Laboratories Ltd. v. Smithkline Beecham Pharma Ltd.*, (1998), 86 C.P.R. (3d) 36 (FCTD) in which Justice Gibson described the necessary elements of a *quia timet* claim as follows:

> [18] From the foregoing authorities, I derive the following criteria for allegations that must be evident on the face of a statement of claim initiating a *quia timet* proceedings 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 be very substantial if not irreparable; and, finally, the facts pleaded must be cogent, precise and material. It is not sufficient that they be indefinite or speak only of intention or amount to mere speculation.
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> [19] Against the foregoing criteria, I find no facts pleaded in the Amended Statement of Claim herein that speak to a deliberate intention nor can I find facts pleaded that go to imminent damage. Rather, I determine the facts pleaded speak to speculation based solely on the facts that SKB obtained an NOC for its vaccine some two years ago, it is related to a manufacturer of the vaccine in Belgium, and the vaccine is marketed in countries other than Canada. No facts are alleged that speak to a deliberate intention expressed since the NOC was issued. No correspondence was directed to SKB following the issuance of the Connaught patent seeking advice as to SKB"s intentions based upon its NOC. Nor was any such correspondence not responded to as in the *Merck and Co.* v. *Apotex Inc.* decision, *supra*. No imminent allegedly infringing action is pleaded.

Thus, in order for the *quia timet* aspect of the Claim to survive there must be material facts relating to Apotex having a deliberate intention to engage in infringing activities; that the infringing activity must be imminent not speculative; and, that the damage suffered by Otsuka must be substantial if not irreparable.

In the Claim, Otsuka argues that they have pleaded the necessary material facts: Apotex has served a very lengthy ANDS and PMNOC proceedings have begun; damages in excess of $50,000.00 will be suffered; and, Apotex has been and is continuing to manufacture the Apotex Tablets although such Apotex Tablets are for use outside of Canada.

Thus, Otsuka argues that the Claim contains sufficient material facts as is to support the causes of action relating to infringement. There are many cases which opine on the proper

pleading of *quia timet*. On this issue Otsuka relies on a number of decisions but in particular that of *Teva Canada Inc. v Novartis AG*, 2016 FC 18 and *Gilead Sciences, Inc. v Teva Canada Limited*, 2016 FC 31, (both decisions of Madam Prothonotary Mireille Tabib).

In *Gilead*, Prothonotary Tabib stated:

> [21] Gilead's statement of claim, as currently written, only alleges past or current infringement in the vaguest and broadest of terms: "Teva has since prior to November 3, 2011 imported and/or manufactured pharmaceutical compositions including acceptable excipients comprising TDF (...)", "Teva manufactures TDF, or causes TDF to be manufactured (...)". As mentioned earlier, Teva promptly sought but was refused particulars of the facts upon which Gilead relies to support these allegations. The case law is clear that an infringement action that fails to set out sufficient material facts by which a defendant is alleged to have infringed a patent and relies solely on bald conclusions of infringement or on the mere fact that a defendant pharmaceutical company has sought regulatory approval to market a medicine constitutes an abuse of process and should be struck (*Apotex Inc. et al v Allergan Inc. et al*, 2011 FCA 134; *Astrazeneca Canada Inc. v Novopharm Ltd.*, 2010 FCA 112).
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> [31] Finally, I am satisfied that the probability that infringement will occur in July 2017 is sufficiently imminent to justify a *quia timet* action. The purpose of a *quia timet* action is to stop an event before it happens. Given that streamlined infringement actions may now be heard and determined in two years, it is neither premature nor pointless to institute such an action 22 months before the occurrence of the event to be avoided. To ask that a plaintiff wait until the event is so imminent that there is not enough time to reasonably bring the proceeding to conclusion would be to doom such actions to failure to achieve their goal or to impose unreasonably tight schedules on the parties and the Court.
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> [32] The only criterion left to be considered is that of "substantial, if not irreparable harm". Clearly, while allegations of irreparable harm would satisfy that criterion, irreparable harm is not a requirement and allegations of substantial harm will be sufficient. The case law does not offer further guidance as to what harm would be substantial enough to justify a *quia timet* claim.

> [33] The statement of claim currently only alleges that Gilead will be deprived of the statutory exclusivity to its invention, that it will suffer damages in excess of $50,000 and that Teva will make a profit.
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> [34] Any proven act of infringement constitutes a deprivation of the patent holder's exclusivity rights. Given that the Court in *Connaught Laboratories* expressly included harm as a necessary requirement for a *quia timet* claim of patent infringement, it is clear that it did not contemplate the deprivation of exclusivity rights as constituting, of itself, either irreparable or substantial harm. And while a patentee may choose to claim profits made by the infringer, the profits of an infringer do not necessarily constitute harm to the patentee, whatever their magnitude. Thus, the only allegation of harm left in Gilead's statement of claim is that it will suffer damages in excess of $50,000 (a figure which likely is not intended as indicative of the magnitude of the damages, but that the action should not proceed as a simplified proceeding). The allegation is, obviously, not precise or cogent enough to meet the requirements set out in *Connaught*. The amendments proposed by Gilead do not include any further particulars as to the magnitude of the expected loss. While Teva has generally asked for particulars of paragraph 49 of the original statement of claim (which sets out the consequences that would result from the intended infringement by their nature), it has asked no particulars of paragraph 51 (which confirms that expected damages will exceed $50,000). Given the substantial costs involved in prosecuting such complex actions, I expect that, given an opportunity to provide a better particularized estimate of the damages Gilead expects to suffer should Teva infringe the 059 Patent, the figure would be far in excess of $50,000. I am satisfied that Gilead should be afforded an opportunity to amend its statement of claim to particularize the monetary loss it might suffer from the alleged further infringement, with leave to Teva to argue that the particularized amount remains insufficient to meet the criterion of "substantial, if not irreparable" harm.

For its part, Apotex relies upon *Eli Lilly Canada Inc. v Nu-Pharm Inc. 2011 FC 255*, 2016 FC 18, (a decision of the Honourable Madam Justice Snider) and argues that the *Teva* and *Gilead* decisions do not support the position of Otsuka.

The takeaway from all of this is simply that there should be sufficient material facts pleaded so as to remove the Claim from the speculative/fishing expedition basket and place it in the "not bereft of any chance of success" basket. The latter phrase is the well-known test to be applied on motions to strike found in *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959.

Applying this to the Claim, the main thrust of the Claim is found in paragraph 10 which reads as follows:

> 10. Apotex has made and continues to make in Canada tablets containing aripiprazole ("Apotex Tablets"). These tablets are presently ultimately sold for consumption by patients outside of Canada. Apotex also intends to sell its aripiprazole tablets for consumption by patients in Canada. On April 1, 2016, Apotex filed in Canada an abbreviated new drug submission relying on a comparison to ABILIFY tablets, to seek approval to sell generic aripiprazole tablets in Canada.

Other examples of material facts are found, *inter alia*, in paragraphs 114, 118, 119, 120, 121 and 122 which make statements about the commercial package containing the Apotex Tablets; that the Apotex Tablets are sold in bottles; that Apotex has used aripiprazole in Canada to make tablets; that the Apotex tablets treat schizophrenia and manic and mixed episodes associated with bipolar 1 [the same as the Otsuka product, ABILIFY]; that the Apotex Tablets has been sold or exported in Canada and are available for consumption by patients outside Canada; and, that the Apotex Tablets are advertised and promoted online as a generic equivalent to ABILIFY.

The Claim also pleads in paragraph 128 that Otsuka has and will suffer harm and damage and lost profits and that Apotex will continue to make profits.

In all, I am not persuaded that the Claim is so bereft of material facts that the heavy burden on a party moving to strike has been met in this case. The facts outlined are stronger than those in the cases cited by Apotex. I am also not persuaded that particulars are required for Apotex to defend this case. They are privy to all of the facts pleaded and to the proceedings under the *Regulations* which they invited the Court to consider on this motion.

Thus, the motion will be dismissed with costs fixed and payable forthwith to Otsuka based on the middle column of Tariff B. If the parties are unable to agree on the quantum they may submit written submissions limited to 3 pages, double spaced with Otsuka to serve and file within 15 days of the date of this Order and Apotex within 15 days thereafter.

Given the issues in this proceeding, in my view it would benefit from being specially managed and an order to that effect will be made.

THIS COURT ORDERS that:

1. This action shall proceed as a specially managed proceeding and be referred to the Office of the Chief Justice for the appointment of a Case Management Judge.

2. The motion to strike is dismissed.

3. Costs of the motion are to be fixed and payable forthwith to Otsuka based on the middle column of Tariff B. If the parties are unable to agree on the quantum they may submit

written submissions limited to 3 pages, double spaced with Otsuka to serve and file within 15 days of the date of this Order and Apotex within 15 days thereafter.

"Kevin R. Aalto"
Prothonotary