

**SUPERIOR COURT OF JUSTICE - ONTARIO**

**RE:** ALLERGAN INC. and ALLERGAN, INC.,

**AND:**

APOTEX INC.,

**BEFORE:** CHIAPPETTA, J.

**COUNSEL:** *S. Batner and M. Graham*, for the Plaintiffs

*D. Cohen and M. Anderson*, for the Defendant

**HEARD:** December 21, 2012

**ENDORSEMENT**

**Overview**

[1] Apotex Inc ("Apotex") is seeking to strike the Statement of Claim ("claim") of Allergan Inc. and Allergan, Inc. ("Allergan") for disclosing no reasonable cause of action. Allergan's claim alleges that Apotex infringed its patents covering the compound bimatoprost. Apotex submits that the claim is devoid of material facts, consists of bald conclusions or speculative pleas of patent infringement and because, certain pleadings involve intended future acts, falls short of the requirements of a *quia timet* action. The claim should, therefore, be struck for having no reasonable cause of action or for being scandalous, vexatious or an abuse of process. In the alternative it is seeking an order compelling Allergan to deliver particulars as it has previously requested.

[2] Counsel agree and together submit that there are no issues with jurisdiction in that the claim is properly before the Superior Court and the Superior Court has jurisdiction to determine the within motion.

[3] For reasons set out below, I find that the claim as pleaded discloses a reasonable cause of action and is not an abuse of process. I further find that on the record before me there is no evidence warranting an Order for Particulars.

**Background**

[4] Allergan is a Canadian pharmaceutical manufacturer with rights (through its US counterpart) to patents related to the LATISSE product, including rights under Canadian Patent No 2,144,967 (“the 967 patent”) and Canadian Patent No 2,46,106 (“the 106 patent”). The 967 patent and the 106 patents protect the invention underlying LATISSE. LATISSE contains the active medicinal ingredient bimatoprost at a concentration of 0.03% W/V which is indicated to treat hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness.

[5] Apotex is a generic pharmaceutical manufacturer and markets products in Canada and the US. Apotex has filed an abbreviated new drug submission seeking a Notice of Compliance (“NOC”) with the Canadian Minister of Health for its generic version of LATISSE (“Apotex Product”).

[6] Allergan commenced the claim against Apotex on July 26<sup>th</sup>, 2012, seeking declarations that certain claims in its 967 and 106 patents are valid and that Apotex infringed them. Allergan is also seeking an injunction to prevent Apotex from making, using, selling, offering to sell, importing and exporting the Apotex Product, an order requiring Apotex to destroy infringing stockpiles of the Apotex product in its power or possession and damages for lost profits or an accounting for Apotex products.

**Patent Act, R.S.C., 1985, c. F-7**

[7] The analysis is somewhat more complicated given s. 55.2(1) of the *Patent Act*. Section 55.2(1) of the *Patent Act* reads:

It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction use or sale of any product.

Counsel for Apotex submits and I agree that s. 55.2(1) of the *Patent Act* and the common law “experimental use” exception to infringement render non infringing activities that are taken solely for uses reasonably related to the development and submission of information required under any law of Canada, a province, or any other country that regulates the manufacture, construction, use or sale of any product. Such activities are not an infringement of a patent.

[8] Apotex filed an abbreviated new drug submission with Health Canada on March 30<sup>th</sup>, 2012 seeking regulatory approval for the Apotex Product. Further, it filed an abbreviated new drug application with the United States Food and Drug Administration seeking approval to manufacture market and sell the Apotex Product. Thirdly, Apotex made an application under s. 505 (j) of the *Federal Food, Drug and Cosmetic Act* seeking approval to engage in commercial

manufacture, use, importation, offer for sale or sale of the Apotex Product prior to the expiration of certain held US patents (paragraphs 45, 48 and 49 of the claim).

[9] Counsel for Apotex walked the Court through the relevant sections of the Food and Drug Regulations C.R.C., c. 870 and reviewed what was reasonably related to regulatory activity and therefore outside the scope of an infringement.

[10] The determination of whether or not the pleading discloses a reasonable cause of action or is devoid of particulars must be assessed therefore in the context of the noted exceptions to an act of patent infringement as set out at s. 55.2(1) of the *Patent Act* and the common law "experimental use" exception.

#### Analysis

- Rule 21.02(1)(b) of the Rules of Civil Procedure

[11] Counsel agree that the test on a motion to strike a pleading pursuant to Rule 21.01(1)(b) is well settled. The moving party bears the onus of proving it is plain and obvious, assuming the facts pleaded to be true, that the pleading discloses no reasonable cause of action (*R. v. Imperial Tobacco Canada Ltd.*, [2011] 3 S.C.R. No. 45). Counsel for Apotex reviewed the narrow exception to assuming the facts to be true and submits that the material facts are based on assumptive or speculative conclusions which are incapable of proof. Accordingly, he submits the narrow exception is applicable. Upon reviewing the case law relied upon in support of this submission, I agree with counsel for Allergan that the exception which stems from the Supreme Court case of *Operation Dismantle Inc. v. Canada*, 1 S.C.R., 44, has no application to the within claim. The claim before me contains no such assumptive or speculative conclusions which are on their face incapable of proof as those pleaded in *Doe v. Metropolitan Toronto (Municipality) Commissioners of Police* (1990), 74 O.R. (2d) 225 (H.C.J.), and *Pearson v. Ontario*, 2006 Carswell Ont. 1895, [2006] O.J. No. 1269 (S.C.), aff'd on appeal.

[12] Allergan's claim for patent infringement must plead facts by virtue of which the law recognizes a defined right as belonging to it and facts that constitute an encroachment by Apotex on that defined right (*Dow Chemical Co. v. Kayson Plastics & Chemicals Ltd.*, [1967] 1 Ex. C.R. 71).

[13] In terms of a legally defined right Allergan claims a declaration of validity of its 967 and 106 patents. Counsel for Apotex submits that to the extent that Allergan is seeking a declaration of validity or infringement *in rem*, this relief ought to be struck as this Court has no jurisdiction to grant such relief. As submitted by counsel for Allergan, however, pursuant to s. 43(2) of the *Patent Act*, Allergan's patents are presumed by statute to be valid upon issuance in the absence of any evidence to the contrary. There is no evidence before me to the contrary. For the purposes of this motion, therefore, the patents are presumed by statute to be valid as issued.

[14] In terms of encroachment, Allergan alleges that Apotex has not made, constructed, used or sold the patented inventions under those patents solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction use or sale of any product

(paragraph 43). Further it alleges that all of Apotex's activities with respect to bimatoprost and the Apotex Product as described within the claim is beyond any amount which may be subject to an experimental use exception in s. 55.2(1) of the *Patent Act* (para. 44). These two paragraphs are generalities and conclusions of infringement. If the claim ended there, I would agree with Apotex that the material facts deemed true disclose no reasonable cause of action.

[15] The claim continues, however, to include particulars that go beyond the above noted generalities and when read together and assumed to be true, allege sufficient material facts by which Apotex has infringed the respective patents by having committed and continuing to commit acts that fall outside the scope of experimental or regulatory activity. Allergan particularized the actions it alleges Apotex engaged in at paragraph 55 "not solely for uses reasonably related to" regulatory filing requirements and "beyond any amount which may be subject to an experimental use exception" as follows:

- Continuing to purchase and import raw bimatoprost into Canada;
- Continuing to manufacture the Apotex Product at its Richmond Hill address;
- Continuing to stock pile raw bimatoprost and manufacture the Apotex product;
- Continuing to formulate sterile solutions containing the imported bimatoprost;
- Exporting from Canada to the United States of America topical solutions containing the compound bimatoprost.

And further and more particularly:

- Imported at least 1,300 kg of bimatoprost as active ingredient into Canada and stock piling it at its Richmond Hill facility (paragraph 56);
- Made at least 7,500 bottles containing 3ml of bimatoprost 0.3% topical solution and stockpiling the infringing material (paragraph 57);
- Made at least 7,500 kits containing 3ml of bimatoprost 0.3% topical solution and a dispenser for external application of the topical solution to the skin and stockpiling the infringing kits (paragraph 58) ;
- Created marketing plans, a launch plan and sales projections for the United States and Canadian markets (paragraph 60);
- Prepared packaging, labeling, package inserts, monographs and consumer information (paragraph 61);
- Made agreements with retailers and pharmacies to stock and distribute the Apotex Product in Canada and the United States (paragraph 62).

[16] I conclude therefore that the claim alleges sufficient material facts by which Apotex is alleged to have infringed the relevant patents. Apotex may have evidence which may protect some of its conduct as pleaded. This evidence if available and put before the Court may be relevant in assessing a genuine issue or serious issue to be tried. Both counsel agree with the statement of law in *Hunt v. Carey Canada*, [1990] 2 S.C.R. 959, however, in that the existence of even a strong defence to a claim does not justify an order striking the claim.

[17] Counsel advised of the absence of precedent jurisprudence in the Superior Court. In making this decision, therefore, I have been guided by precise attention to the within claim, the statutory regimes referred to above and the law of the Federal Court and Federal Court of Appeal as submitted and relied upon by counsel, particularly *Eli Lilly Canada Inc. v. Nu-Pharm Inc.*, [2011] F.C.J. No. 41 (F.C.) (“Eli Lilly”), *AstraZeneca Canada Inc. v. Novopharm Ltd.*, [2009] F.C.J. No. 1692, aff’d [2010] F.C.J. No 526 (“AstraZeneca”) and *Apotex Inc. v. Allergan Inc.*, [2011] F.C.J. No. 580 (C.A.) (“Apotex 2011”).

[18] Apotex 2011 considers each of the *AstraZeneca* and *Eli Lilly* decisions. Apotex appealed an interlocutory order of a judge of the Federal Court which dismissed a motion brought by Apotex for an order striking out the statement of claim (“Claim”) filed by Allergan. Apotex alleged that the judge erred when he declined to strike out the pleading as disclosing no reasonable cause of action because the Claim improperly consisted of bald or speculative pleas of patent infringement and because the plea regarding its intended future action fell short of the required standard when pleading a *quia timet* (because one fears) action.

[19] Counsel for Apotex submits that Apotex 2011 is not applicable to the within matter as unlike the within matter particulars were provided after the Claim was served and were necessarily read together with the Claim. Moreover, commercial purposes and sale activity were specifically pleaded. Despite these factual differences, for reasons more particularly set out below, I agree with counsel for Allergan that Apotex 2011 is directly applicable to the within matter and is properly relied upon.

[20] The Appeal Court at paragraph 4, agreed with Apotex, as I do in the within case, that “the mere fact that a defendant pharmaceutical company has sought regulatory approval to market a medicine does not by itself support an action for patent infringement” and that “an allegation of past infringement made without evidentiary foundation is an abuse of process.” Reading the Claim with the additional particulars provided by the plaintiffs however the judge concluded the Claim alleged facts beyond the scope of regulatory activity.

[21] Allergan refused Apotex's request for particulars in the within claim. Counsel for Allergan provided the Court with the Claim in Apotex 2011. Unlike in the Apotex 2011 Claim, the claim herein included sufficient particulars upon filing, necessary to conclude that the claim alleged facts beyond the regulatory activity. The claim does not allege commercial purposes or the selling of the Apotex Product. Even sale activity is protected however if done solely for s. 55.2(1) uses. There is no magic therefore in specifically pleading sale activity or commercial purposes. Rather, the claim must plead, as set out above, particular activity outside the noted exceptions to an act of patent infringement.

[22] Further, the Appeal Court distinguished *Eli Lilly*, as I do in the within case, as there was nothing pleaded therein beyond the regulatory scope and moreover, there was sworn evidence from the moving party defendant therein that it has done nothing other than meet the requirements of the applicable regulatory scheme. There is no such evidence on the record before me. Rather, the claim deemed true alleges that particular actions were taken for reasons not solely related to meeting the requirements of the regulatory scheme.

[23] Finally, The Appeal Court rejected the characterization of the pleading, as I do in the within case, as a *quia timet* action. As set out above, the claim is not one based merely upon the fear of future infringements. Rather, the claims of past and continuing infringement support the claim of future continuing infringement, particularly in light of the injunctive relief sought.

[24] Relying substantially on the same reasons articulated by the Federal Court of Appeal in *Apotex 2011*, it cannot be said to be plain and obvious that the pleading discloses no reasonable cause of action. It should therefore not be struck in whole or in part.

- Rule 25.11 of the Rules of Civil Procedure

[25] In the alternative Apotex is seeking to strike Allergan's claim as "scandalous, vexatious or an abuse of process" pursuant to Rule 25.11. Again counsel agreed that the applicable law in assessing whether a claim should be struck pursuant to this Rule is well settled. As relied upon by counsel for Allergan, the Ontario Court of Appeal has stated that it must only be exercised in the clearest of cases, cautioning as follows in *Wernikowski v. Kirkland, Murphy & Ain* 50 O.R. (3d) 124 (C.A.):

Like other rules (e.g. Rule 21.01), this provision is designed to allow for an early and expeditious determination of claims that cannot succeed. As the exercise of the power set out in Rule 25.11 denies a litigant a full trial of the merits of the claim, it must be exercised only in the clearest of cases. Claims that are doubtful in law or factually weak should not be foreclosed. Allowance must also be made for inadequacies in the drafting of pleadings.

[26] There is nothing in Allergan's claim as pleaded that meets the high standard required to establish a pleading is "scandalous, frivolous, vexatious or an abuse of process." As noted above the elements of the cause of action have been sufficiently pleaded with material facts. The pleading alleges no facts that I would deem wholly immaterial or designed solely to cast negative aspersions upon Apotex.

- Rule 25.10 of the Rules of Civil Procedure

[27] Apotex requested that Allergan provide particulars by way of a Demand for Particulars dated August 15<sup>th</sup>, 2012. On August 27, 2012 Allergan advised that it would not provide the particulars sought.

[28] Apotex has led no evidence on this motion. Rather, it is asking the Court to conclude that the need for particulars is obvious from the pleading itself. It submits that it is clear on the face of the pleading that the claim fails to provide Apotex with the requisite level of particularity as to the acts of alleged infringing activity levied against it. I disagree. Allergan does not have all of the details of Apotex's alleged infringing activities. It has pleaded that full particulars lie with Apotex. It has pleaded specific grounds for bringing the claim of patent infringement, it has detailed the infringing conduct it alleges and most significantly, it has particularized the specific infringing activity, the quantities, and the location. There is no evidence before me sufficient to conclude that the particulars requested are not within the knowledge of Apotex or that they are necessary to enable Apotex to adequately plead. To this end, I am guided by the Ontario Court

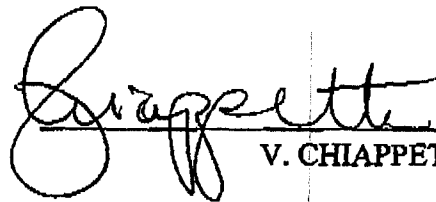
of Appeal in *Physicians' Services Inc. v. Cass* (1971), 2 O.R. 626 (C.A.) as submitted and relied upon by counsel for Allergan and decline Apotex's request for an Order for Particulars.

**Disposition**

[29] The motion is dismissed. Apotex is to deliver its Statement of Defence within 20 days.

**Costs**

[30] The costs of the motion are payable within 30 days by Apotex to Allergan fixed as agreed between counsel at \$9,000.00.

  
V. CHIAPPETTA, J.

**Date:** January 16, 2013