

Federal Court



Cour fédérale

Date: 20170914

Docket: T-1056-16

Citation: 2017 FC 831

Ottawa, Ontario, September 14, 2017

PRESENT: Case Management Judge Mireille Tabib

BETWEEN:

APOTEX INC.

Plaintiff

and

**SHIRE LLC AND
SHIRE PHARMA CANADA ULC**

Defendants

ORDER AND REASONS

[1] This motion arises in the context of an action brought by Apotex Inc. against Shire LLC and Shire Pharma Canada ULC for a declaration of non-infringement and of invalidity of Canadian Patent No. 2,027,646, entitled “Abuse Resistant Amphetamine Compounds”.

[2] The trial is scheduled to take place in seven months, and discoveries are complete, except for refusals motion arising from the second round of discoveries.

[3] Apotex's original statement of claim contained extensive allegations of inutility of the patent, premised on the alleged failure of the inventors to have demonstrated or soundly predicted the promises set out in the patent. On June 30, 2017, the Supreme Court of Canada declared, in *AstraZeneca Canada Inc. v Apotex Inc.*, 2017 SCC 36, that the Promise Doctrine is not sound in law and is not the correct method of determining the utility of an invention.

[4] Apotex now moves to amend its statement of claim in light of that decision. Shire, by cross-motion, asserts that the amendments proposed do not cure the defects of Apotex's pleadings, as exposed by the Supreme Court's decision, and that all allegations related to Apotex's plea of inutility ought to be struck.

[5] With the exception of trivial observations that the activity of amphetamines in rats and dogs are "laboratory curiosities", of a sildenafil-type plea of insufficient disclosure and of a plea of willful misrepresentations, the amendments proposed by Apotex do not introduce new facts. They merely "recast" the same factual allegations that formed the basis of Apotex's inutility plea in a form that Apotex suggests accords with the state of the law as pronounced by the Supreme Court in *AstraZeneca*.

[6] To say that Apotex's proposed amendments are poorly drafted is an understatement. The amendments are slipshod, inconsistent and confusing. Although Apotex portrays its amendments as being made in accordance with the Supreme Court's teachings on the correct approach to utility, they reflect, in my view, an obtuse application of selected passages of the Supreme Court's decision, a refusal to come to terms with and embrace the essence of the Supreme Court's teachings, and a fairly desperate attempt to shoehorn Apotex's promise

allegations into each and every ground of invalidity known to law. The resulting pleading remains haunted by the ghost of the now defunct promise doctrine and is neither particularly helpful nor illuminating.

[7] That, however, is not a reason to disallow the amendments that purport to “recast” Apotex’s existing allegations of fact, or to strike the portions of Apotex’s original pleadings related to the plea of inutility.

[8] With the exception of amendments introducing new allegations of fact, which I will discuss below, Apotex’s proposed amendments are in the nature of statements or conclusions of law. They are an exercise in affixing labels to groups of facts. The jurisprudence is clear that neither the labels, nor the facts to which labels are affixed, should be struck out simply because the wrong label was chosen (*Paradis Honey Ltd. v Canada (Attorney General)*, 2015 FCA 89, at paras 113 - 114, and all cases cited therein). The Court will not strike a particular characterization of a cause of action if allegations of material facts, construed generously, give rise to any reasonably arguable cause of action. A party is not bound by the legal characterization it has used in its pleading and can present in argument at trial any legal consequence of which the facts present.

[9] Here, the essence of the facts to which the proposed amendments relate, and which I must take as proven for the purpose of this motion, is as follows: There is not a single relevant and practical use or utility for the subject-matter of the invention that does not include a reduced

potential for abuse; that reduced potential for abuse does not in fact exist, and was neither demonstrated nor soundly predicted as of the filing date.

[10] Shire makes a compelling case that Apotex's allegation that the invention can have no possible utility that does not include reduced potential for abuse is not very likely to succeed, given that only a small proportion of the 51 claims of the patent even allude to abuse-reducing characteristics. However, for the following reasons, I find that the allegations are not devoid of any possibility of success.

[11] Apotex's statement of claim also includes allegations of obviousness and anticipation in respect of the claims to the compounds and their therapeutic uses. The possibility thus exists that only those claims that include elements of abuse reduction might be found to be inventive. To the extent the Court were to find that only those claims containing an element of abuse-resistance are inventive, the allegations to the effect that the compounds do not have the claimed benefit could arguably support a plea of overclaiming, or even insufficient disclosure or inutility.

[12] I therefore conclude that the factual allegations of the statement of claim relating to inutility should not be struck as disclosing no reasonable cause of action. As Apotex's proposed amendments to "recast" those facts, despite their numerous flaws, do not raise any new facts, I am not satisfied that allowing them would cause any additional delay in the conduct and determination of this action, or cause prejudice to Shire that cannot be compensated in costs.

[13] I now turn to those proposed amendments that do allege new facts.

[14] Paragraphs 23, 85 and 87 add an allegation that “the activity of amphetamines in rats and dogs are laboratory curiosities whose only possible claim to utility are as starting material for further research”. As mentioned, this seems a rather trivial allegation that parrots a selected passage of the *AstraZeneca* decision. Neither party has suggested that discoveries would need to be reopened to explore these allegations and I am not persuaded that they would cause prejudice to Shire.

[15] Paragraphs 116(C) to (G) allege new facts in support of a Sildenafil-type plea of insufficient disclosure. The same facts are “recast” in paragraph 129D as a plea of overbreadth. Although not mentioned in its written record, Apotex’s counsel advised at the hearing that the underlying facts arose from the discovery of Shire and would not require further discovery. Shire did not pursue its objection to the amendments in its oral argument. I am not satisfied that these allegations do not disclose an arguable cause of action, nor that their addition would cause Shire prejudice that cannot be compensated in costs.

[16] Paragraphs 21A(e) and 129E to 129J recycle the factual allegations related to inutility and the Sildenafil-type plea, but add bare allegations that the unproven or unsubstantiated uses set out in the disclosure constitute material allegations, that “the applicant” for the patent knew the statements to be untrue and made them willfully for the purpose of misleading, rendering the patent and all its claims void pursuant to section 53 of the *Patent Act*. As drafted, the proposed amendments are a bare pleading that “the applicant was aware” that the inventors had not demonstrated or had no sound basis to predict a particular utility, as pleaded elsewhere. On the basis of those facts alone, the proposed amendments state the bare conclusion that the application

contains a material allegation which is untrue and was made by “the applicant” willfully for the purpose of misleading. “The Applicant” is not specifically identified, and counsel for Apotex could not even, at the hearing, state its identity. Shire’s counsel advised that it was a corporation who is not a party in this action.

[17] As mentioned in my reasons for order dated November 14, 2016 in this same action (reported at 2016 FC 1267), section 53 allegations are essentially allegations of fraud and state of mind, which require, pursuant to Rule 181 of the *Federal Courts Rules*, full particulars. The pleadings now proposed contain no particulars of exactly who made what statements to the patent office, or of any factual basis upon which the Court might be able to conclude that this person or persons knew, at the time, that the statements were false or that these persons intended to mislead the patent office by making the statements. Pleadings of fraud are a serious matter. Parties should not make them recklessly and without sufficient evidence or a reasonable belief as to their truthfulness. Especially after discovery has been had, Apotex should have been able to set out the particular facts upon which a Court might find any particular state of mind or knowledge in any particular persons at any particular time. Apotex’s failure to do so, especially in light of the admonishment contained in the order of November 14, 2016, leads me to infer that it has no reasonable basis to advance these allegations, and that it is not in the interest of justice that they be permitted.

[18] Shire opposed all of the amendments but was only partially successful. It shall have its costs of the motion, but in the amount of \$2,000.00 only. It should also be entitled to claim the

costs of any amendment to its pleadings necessitated by the extensive, but poorly drafted amendments.

ORDER

THIS COURT ORDERS that:

1. Apotex has leave to serve and file an amended statement of claim in the form of the draft included under Tab 1A of its motion record, on the conditions set out below:
2. The amended statement of claim must show the passages removed or deleted from the original by reproducing them in “strikethrough” font.
3. The amended statement of claim may not include paragraphs 21A(e) and 129E to 129J of the proposed draft.
4. Shire will be permitted to serve and file an amended statement of defence and counterclaim responsive to the amended statement of claim, and the cost thereof shall be paid by Apotex in an amount fixed at \$2,000.00, in any event of the cause.
5. Costs of this motion shall be paid by Apotex in the amount of \$2,000.00.

“Mireille Tabib”

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET: T-1056-16

STYLE OF CAUSE: APOTEX INC. v SHIRE LLC AND SHIRE PHARMA
CANADA ULC

PLACE OF HEARING: OTTAWA, ONTARIO

DATE OF HEARING: SEPTEMBER 5, 2017

**REASONS FOR ORDER AND
ORDER:** TABIB P.

DATED: SEPTEMBER 14, 2017

APPEARANCES:

Mr. Harry Radomski
Ms. Jenene Roberts

FOR THE PLAINTIFF

Mr. Adam Heckman
Ms. Jennifer Wilkie
Mr. Jay Zakaib

FOR THE DEFENDANTS

SOLICITORS OF RECORD:

Goodmans LLP
Barrister and Solicitor
Toronto, Ontario

FOR THE PLAINTIFF

Gowling WLG (Canada) LLP
Barristers and Solicitors
Ottawa, Ontario

FOR THE DEFENDANTS