Federal Court		Cour fédérale

Date: 20101217

Docket: T-2078-00

Citation: 2010 FC 1304

Ottawa, Ontario, December 17, 2010

PRESENT: The Honourable Madam Justice Tremblay-Lamer

BETWEEN:

BRISTOL-MYERS SQUIBB COMPANY and BRISTOL-MYERS SQUIBB CANADA CO.

Applicants

and

APOTEX INC.

Defendant

REASONS FOR ORDER AND ORDER

[1] This is an appeal, pursuant to Rule 51 of the *Federal Courts Rules*, SOR/98-106 whereby Apotex Inc. ("Apotex") seeks to set aside an order of Prothonotary Aronovitch dated October 26, 2010, wherein Apotex was denied leave to serve and file an amended Statement of Defence and Counterclaim. Bristol-Myers Squibb Company and Bristol-Myers Squibb Canada Inc. (collectively, "BMS"), the plaintiffs in the main action, oppose Apotex's proposed amendment

because they allege it introduces two new defences, lack of utility and lack of sound prediction, on the eve of trial. Apotex, for its part, argues that its pleadings have always included allegations as to lack of utility and lack of sound prediction, and that the proposed amendment is merely a clarification.

BACKGROUND

[2] On November 10, 2000, BMS commenced an action against Apotex for infringement of Canadian Letters Patent No. 1,198,436 (the "'436 Patent"), alleging that Apotex had made, used, sold and offered for sale nefazodone hydrochloride in finished dosage form in violation of BMS' rights under the '436 Patent. Specifically, BMS alleged Apotex had infringed claims 1, 2, 3, 4, 7 and 8 of the '436 Patent. Claims 1 and 2 cover a broad range of compounds which include nefazodone and nefazodone hydrochloride. Claims 3, 4, 7 and 8 are more specific to nefazodone and its salts.

[3] On February 6, 2001, Apotex filed a Statement of Defence and Counterclaim (SOD) whereby it denied the allegations of infringement and asserted that the '436 Patent was invalid, void and of no force or effect. For the purposes of the current appeal, of particular interest are the following two grounds of invalidity alleged by Apotex at paragraphs 20 and 21 of its SOD:

> 20. The '436 Patent and the claims thereof are invalid on the basis that they fail to disclose an invention within the meaning of section 2 of the *Patent Act*. More particularly, the compounds which are described within the claims of the '436 Patent lack the utility promised by the specification of the '436 Patent. The claims of the '436 Patent include compounds within their scope that do not function as anti-depressants and are inoperable as medicines.

> 21. In addition, at the time of the petition for the '436 Patent and at all material times thereafter, the persons listed as the inventors of the '436 Patent did not have any sound basis for predicting that all of the compounds within the class of compounds described by Formula I and included in the claims of the '436 Patent would have the utility promised by the specification of the '436 Patent.

[4] BMS sought clarification with respect to paragraph 20. On February 15, 2001, it sent Apotex a demand for particulars requesting that Apotex indicate the specific compounds it was alleging "in paragraph 20 [did] not function as antidepressants and [were] inoperable as medicines." Apotex replied on February 22, 2001 by indicating that the compounds that it was alleging did "not function as antidepressants" and were "inoperable as medicines" were, essentially, all compounds within the '436 Patent *other than* nefazodone and its salts. In September of 2001, a similar exchange took place during examination for discovery of Apotex (between counsel for BMS, Mr. Creber, and counsel for Apotex, Mr. Radomski):

> Question 304:
>
> Mr. Creber: So this allegation is that every compound within claim 1 but for nefazodone and its salts doesn't work?
> Mr. Radomski: That would be the logical conclusion.
> Mr. Creber: And that is your plea?
> Mr. Radomski: Yes.

[5] Furthermore, during discovery in February of 2002, Mr. Radomski indicated that the allegations regarding lack of sound prediction found at paragraph 21 of the Apotex SOD did not apply to nefazodone. He indicated:

> The issue is not sound prediction as to Nefazodone because we know it was made, and we know that it was clinically tested, and we know that it appears to be a successful and workable product; but the question has to do with the other compounds.

[6] As a result of this, Mr. Creber suggested to Mr. Radomski that since the issue of lack of sound prediction was related to compounds other than nefazodone and nefazodone hydrochloride, and since Apotex was not making any of those other compounds, nor did they intend to make any of those other compounds, then there might be a way to "simplify things" so as to focus on the "real issue". Mr. Creber and Mr. Radomski then agreed to focus the action on claims 3, 4, 7, and 8 of the '436 Patent (the claims more narrowly confined to nefazodone and its salts) and drop claims 1 and 2 (the broader claims) from the action.

[7] In July of 2004, Apotex amended its SOD in two ways that are relevant to this appeal. First, it introduced two new paragraphs after paragraph 20 which read as follows:

> 20A. The '436 Patent asserts that the present invention relates to compounds, including nefazodone, and, *inter alia*, their "therapeutic use in treating depression". The '436 Patent promises that the compounds of the invention, including nefazodone, are "improved antidepressants with minimal side effect potential". The '436 Patent also asserts that the invention provides a method for treating a mammal afflicted with depression and that, in accordance with good clinical practice, the invented compounds, including nefazodone, can be administered to produce effective antidepressant effects without causing any harmful or untoward side effects.
>
> 20B. Contrary to the assertions of the '436 Patent, as aforesaid, the compounds of the '436 Patent, including nefazodone, do not meet the promise of the '436 Patent in that the compounds, including nefazodone, are not "improved antidepressants with minimal side effect potential". Thus, the compounds of the '436 Patent do not have the utility promised in the '436 Patent.

[8] The second relevant amendment was the following addition to paragraph 21:

> 21. In addition, <u>even if one or more of the compounds of the '436 Patent have the utility promised by the '436 Patent, which is not admitted, but denied</u>, at the time of the petition for the '436 Patent and at all material times thereafter, the persons listed as the inventors of the '436 Patent did not have any sound basis for predicting that all of the compounds within the

> class of compounds described by Formula I and included in the claims of the ‘436 Patent would have the utility promised by the specification of the ‘436 Patent.

[9] BMS did not oppose the Apotex amendment. Discovery was focussed on the narrow issue of lack of utility pertaining to a specific liver toxicity side effect that had been discovered to be associated with nefazodone use (which had ultimately led to the withdrawal of nefazodone products from the market in 2003).

[10] In April of 2007, Apotex delivered its answers to questions BMS had posed on continued examinations for discovery. Two of the questions and answers are particularly relevant to this appeal [emphasis added]:

> Q 973: To advise if the only allegation in respect of inutility with respect to nefazodone was in respect of liver toxicity effects and not with respect to any of the other statements made in Apotex’s product monograph.
>
> A: Liver toxicity effects <u>is not the only allegation in respect of inutility with respect to nefazodone that Apotex is pleading.</u>
>
> Q 975: To provide any other basis for inutility that we are going to plead other than liver toxicity.
>
> A: <u>The other bases for i</u>nutility that Apotex is going to plead other than liver toxicity include that, contrary to the assertions of the ‘436 Patent, nefazodone does not produce “effective antidepressant effects without causing any harmful or untoward side effects” and is <u>not an “improved antidepressant with minimal side effect potential”</u> as promised.

[11] In August of 2009, Apotex served its expert reports on invalidity. The reports included opinion evidence to the effect that nefazodone lacked the utility promised by the ‘436 Patent because it was not an “improved antidepressant with minimal side effect potential” and to the effect

that there was no basis, at the filing date, to soundly predict that nefazodone would be an improved antidepressant with minimal side effect potential.

[12] On November 2, 2009, BMS wrote to Apotex indicating that the Apotex expert reports went beyond the scope of the live issues in that they contained analysis regarding utility and sound prediction which, aside from the liver toxicity aspect, were no longer at issue between the parties. BMS further stated:

> As you are aware, we have limited our claims to claims 3, 4, 7 and 8 and, as such, the only issue in this case is the compound nefazodone. Therefore, it would appear that your pleas in Paragraphs 20 and 21 are and have been moot for some time considering that nefazodone was never alleged to lack utility or was not a sound prediction.

[13] On November 30, 2009, Apotex replied to BMS and indicated that the issues of lack of utility and lack of sound prediction in relation to nefazodone were pleaded and were being pursued in respect of more than just claims 1 and 2 of the patent. BMS protested the inclusion of the issues of inutility and lack of sound prediction in the Apotex reports, but the case management judge directed that the admissibility of that aspect of the reports would be best left to be determined by the trial judge. As such, in January of 2010, BMS served expert reports addressing the issues of inutility and lack of sound prediction as raised by Apotex.

[14] In March of 2010, BMS amended its Statement of Claim (SOC) to officially withdraw allegations of infringement regarding claims 1 and 2 of the ‘436 Patent, as had been agreed upon during discovery in 2002. On April 26, 2010, Apotex filed an amended SOD in response. The principal amendments made, and the key amendments that are at issue in this appeal, were found at paragraph 20 and 21 of the SOD. The paragraphs were amended to read as follows:

> 20. The ‘436 Patent and the claims thereof, including specifically the Asserted Claims, are invalid on the basis that they fail to disclose an invention within the meaning of section 2 of the Patent Act. More particularly, the compounds which are described within the claims of the ‘436 Patent lack the utility promised by the specification of the ‘436 Patent. The claims of the ‘436 Patent include compounds within their scope that do not function as anti-depressants and are inoperable as medicines.
>
> 21. In addition, even if one or more of the compounds of the ‘436 Patent have the utility promised by the ‘436 Patent, which is not admitted, but denied, at the time of the petition for the ‘436 Patent and at all material times thereafter, the persons listed as the inventors of the ‘436 Patent did not have any sound basis for predicting that all or any of the compounds within the class of compounds described by Formula I and included in the claims of the ‘436 Patent, including specifically the compounds of the Asserted Claims, would have the utility promised by the specification of the ‘436 Patent.

Note that “Asserted Claims” was defined in the amendment as “claims 3, 4, 7, and 8 of the ‘436 Patent.”

[15] BMS moved to strike the amendments, claiming that they did not flow from the amended SOC and that, in fact, they introduced new allegations regarding lack of utility and lack of sound prediction in relation to nefazodone that were not already in the case. On July 30, 2010, Prothonotary Aronovitch allowed the motion, and struck the amendments to paragraph 20 and 21 of the Apotex SOD. She indicated that the changes constituted a “material and radical departure from previous pleadings contrary to the admissions made by way of particulars, and repeatedly and clearly reaffirmed on discovery.” Prothonotary Aronovitch indicated that a formal motion to amend, supported by evidence to justify departure from the material facts pleaded, would be necessary to introduce the new allegations of lack of utility and lack of sound prediction. Prothonotary Aronovitch’s decision was upheld on appeal.

[16] On September 30, 2010, Apotex filed a motion requesting leave to serve and file a Sixth Amended Statement of Defence and Counterclaim to introduce the same changes to paragraph 20 and 21 it originally had attempted to introduce in response to BMS' amended SOC in April of 2010. On October 26, 2010, Prothonotary Aronovitch declined to grant leave. It is that order that Apotex seeks to have set aside.

ANALYSIS

[17] The appropriate standard of review to be applied to a discretionary decision made by a prothonotary is the standard set out in *Merck & Co v. Apotex*, 2003 FCA 488, [2004] 2 F.C.R. 459 at para. 19 [*Merck*]. There, the Federal Court of Appeal indicated that a discretionary order of a prothonotary is not to be disturbed on appeal unless: a) the questions raised in the motion are vital to the final issue of the case, in which case the matter is considered *de novo*, or b) the order is clearly wrong, in the sense that the exercise of discretion by the prothonotary was based on a wrong principle or a misapprehension of the facts, in which case, again, the matter is considered *de novo*.

[18] The questions raised in this motion are vital to the final issue of the case. The outcome effectively determines whether or not Apotex is able to advance lack of utility (with the exception of the narrow issue of liver toxicity which both parties agree is in the case) and lack of sound prediction with respect to nefazodone and nefazodone hydrochloride.

[19] At the hearing, counsel for BMS did not deny that the questions raised on this motion were vital to the final issue of the case. Instead, he simply indicated that because Prothonotary Aronovitch had case-managed this particular action for a number of years, the Court should show

deference to her findings. While I agree that it is important to show deference to the decisions of a case management judge, the current motion raises questions that are vital to the final issue of the case, and, as such, I must consider the matter *de novo*.

[20] The general rule with respect to whether or not a party should be permitted to amend its pleadings was set out by the Federal Court of Appeal in *Canderel Ltd. v. Canada* (1993), [1994] 1 F.C. 3, 157 N.R. 380 (C.A.) [*Canderel*]. An amendment should be allowed for the purpose of determining the real questions in controversy, provided that: a) allowing the amendment would not result in an injustice to the other party that is not capable of being compensated by an award of costs, and b) allowing the amendment would serve the interests of justice. Furthermore, the Federal Court of Appeal in *Merck*, above at para. 32, indicated:

> There is a burden to be met by the amending party and, while the factors to be considered are essentially the same for all amendments, the burden should be heavier when the amendments at issue purport to withdraw substantial admissions and would result in a radical change in the nature of the questions in controversy.

[21] On the current motion, then, two main questions arise. First, do the amendments at issue result in a "radical change" thus increasing the burden for Apotex to justify its proposed amendments; and second, will allowing the amendments result in an injustice to BMS that is not capable of being compensated by an award of costs?

[22] In considering the nature of the proposed change, I will address the amendments to paragraph 20 and 21 separately. BMS argues that the amendment to paragraph 20 of the Apotex SOD effectively introduces the issue of inutility with respect to nefazodone and nefazodone hydrochloride for the first time. Despite the broad wording of the original paragraph 20, BMS

argues that the particulars provided by Apotex in February of 2001 and the admissions provided by Mr. Radomski during discovery in September of 2001 limited the scope of paragraph 20 so that it only applied to the compounds in claim 1 and 2 of the '436 Patent *other than* nefazodone and nefazodone hydrochloride. It argues that, aside from the narrow issue of liver toxicity introduced at paragraphs 20A and 20B in 2004, any allegations as to lack of utility had been out of the case altogether since the parties agreed to focus the action on claims 3, 4, 7 and 8 in February of 2002.

[23] On the other hand, Mr. Radomski has submitted affidavit evidence to the effect that paragraph 20 was always intended by Apotex to allege lack of utility against nefazodone and nefazodone hydrochloride. He claims that this position is not contradicted by the particulars and admissions made in 2001, because there have always been *two* aspects to the lack of utility pleaded in paragraph 20. The first aspect, he argues, is captured by the sentence, "More particularly, the compounds which are described within the claims of the '436 Patent lack the utility promised by the specification of the '436 Patent." This, he suggests, clearly applies to *all the compounds* described in the '436 Patent – which would include nefazodone and nefazodone hydrochloride. The lack of utility alleged here, Mr. Radomski submits, is with respect to the broad promise of the patent which, in part, includes the delivery of an "improved antidepressant with minimal side effect potential."

[24] The second aspect of inutility is captured by the sentence, "The claims of the '436 Patent include compounds within their scope that do not function as anti-depressants and are inoperable as medicines." This is the aspect of paragraph 20 that Mr. Radomski claims his admissions during discovery in September of 2001 and the particulars provided in February of 2001 were addressing.

[25] It is true that the BMS demand for particulars in 2001 only requested a list of the compounds that did "not function as antidepressants" and were "inoperable as medicines". The particulars provided by Apotex in response were, thus, limited to the second aspect of inutility alleged in paragraph 20. Similarly, the admissions provided by Mr. Radomski during discovery in 2001 can also be read as being restricted to the compounds that Apotex was attacking due to lack of utility *as antidepressants*. Mr. Radomski argues, essentially, that Apotex was never asked to specify which compounds that it was alleging lacked utility in general, in terms of the broader promise of the '436 Patent – and, thus, it never provided that detail. In any event, Mr. Radomski submits that the wording of paragraph 20 is clear that Apotex was alleging that *all* of the compounds described in the '436 Patent lacked the utility promised by the broad specification of the '436 Patent in some way.

[26] I can see why, after the discovery of September 2001, BMS came away with the impression that paragraph 20 was only alleging inutility with respect to the compounds of claim 1 *other than* nefazodone and nefazodone hydrochloride. Furthermore, I suspect that Apotex was aware of this misapprehension and purposefully, for strategic reasons, decided not to clarify the matter for BMS. This type of strategic manoeuvring is directly contrary to the purpose and spirit of discovery and is looked upon very unfavourably by this Court. However, I find that in this case, by way of subsequent conduct, Apotex did make the meaning of paragraph 20 sufficiently clear such that it is difficult for BMS to now claim a sound basis for being surprised by Apotex's proposed amendments.

[27] The amendments made by Apotex in 2004 at paragraphs 20A and 20B clearly indicate that Apotex intended to attack nefazodone for lack of utility based on grounds other than nefazodone's

effectiveness as an anti-depressant or operability as a medicine. Paragraph 20B indicated, "the compounds of the '436 Patent, including nefazodone, do not meet the promise of the '436 Patent in that the compounds, including nefazodone, are not 'improved antidepressants with minimal side effect potential'" [emphasis added]. At no point did Apotex indicate that the new paragraphs were limited to the narrow issue of liver toxicity which had been discovered in 2003. If any doubt remained, it was certainly clarified on continued discovery in 2007 when Apotex set out specifically that, "Liver toxicity effects is not the only allegation in respect of inutility with respect to nefazodone that Apotex is pleading," and that, "The other bases for inutility that Apotex is going to plead other than liver toxicity include that, contrary to the assertions of the '436 Patent, nefazodone does not produce 'effective antidepressant effects without causing any harmful or untoward side effects' and is not an 'improved antidepressant with minimal side effect potential' as promised."

[28] As such, I find that the proposed amendments to paragraph 20 cannot be said to constitute a radical departure from Apotex's prior pleadings.

[29] With respect to paragraph 21, BMS points to Mr. Radomski's statement during discovery in February of 2002 as an admission that paragraph 21 did not apply to nefazodone and its salts. During that discovery, Mr. Radomski indicated that Apotex was not alleging lack of sound prediction with respect to nefazodone.

[30] Apotex argues, however, that Mr. Radomski's statement was not so much an admission as it was an agreement as to the current state of the law as it existed in February of 2002. Mr. Radomski had indicated at that time that there was no issue with respect to the sound prediction of nefazodone *because* nefazodone had, subsequent to the filing of the '436 Patent, been made, clinically tested,

and was successful. Under the governing law of the time, as established in *Apotex Inc. v. Wellcome Foundation Ltd.*, [2001] 1 F.C. 495, 262 N.R. 137 (F.C.A.), that was enough – all that was required was for an inventor to demonstrate utility or sound prediction at the time a patent was attacked. Apotex points out, however, that the law changed subsequent to Mr. Radomski's statement. In December of 2002, the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, 219 D.L.R. (4th) 660 directed that either actual utility or a sound basis for predicting utility was required as of the filing date of a patent. As such, Apotex argues that the statement made by Mr. Radomski in February of 2002 was obviously no longer applicable: the fact that nefazodone had been shown to eventually have utility as an anti-depressant no longer necessarily meant that the '436 Patent was immune to attack based on lack of sound prediction as of the filing date.

[31] While I agree that it would have been preferable if Apotex had formally withdrawn its statement in light of the change of law, I find that the amendments made by Apotex to paragraph 21 in July of 2004 sufficiently demonstrated that lack of sound prediction with respect to nefazodone and nefazodone hydrochloride was a live issue. The amendment to paragraph 21 paralleled the change of law with respect to sound prediction: it alleged that even if one of the compounds of the '436 Patent had eventually been shown to have the utility promised, there was a lack of sound prediction at the time of filing. As Apotex points out, since nefazodone was the only compound covered by the '436 Patent which had been demonstrated to have anti-depressant activity, it should have been clear that this modification was specifically targeted at nefazodone. In fact, that Apotex was amending paragraph 21 at all should have been an indication that the issue of lack of sound prediction was not out of the case as BMS claims to have thought it was. After all, why would a party take steps to add further detail to a "moot" pleading?

[32] I find that given the change of law regarding lack of sound prediction, and given the modifications made by Apotex to paragraph 21 subsequent to that change, it cannot be said that the amendments sought by Apotex on the current motion constitute a radical departure from Apotex's prior pleadings.

[33] Overall, I would agree that the amendments proposed by Apotex essentially act to clarify Apotex's position with respect to paragraphs 20 and 21. That being said, it is clear from the affidavit evidence that BMS was acting under the belief – at least until Apotex filed its expert reports in 2009 – that lack of utility (aside from with respect to liver toxicity) and lack of sound prediction were no longer live issues. It is also clear that Apotex was not as forthcoming with respect to paragraphs 20 and 21 as it could have been. Given this, it is still worthwhile to consider whether allowing the proposed amendments would result in injustice to BMS that is not capable of being compensated by an award of costs, as per the test from *Canderel*, above.

[34] The main question that arises with respect to prejudice in the current matter is, given that trial is set to begin in March of 2011, does BMS have sufficient time to adequately address the allegations of inutility and lack of sound prediction raised in paragraphs 20 and 21 of the Apotex SOD? Based on the evidence and arguments submitted by the parties, I must conclude that the answer to this question is yes. The expert reports provided by Apotex in August of 2009 particularized the claims of inutility and lack of sound prediction being advanced. Although under protest, BMS has already filed expert reports addressing the issues of inutility and lack of sound prediction as raised in the Apotex reports. Furthermore, Apotex has undertaken to make itself available for any additional discovery needed, and to provide particulars expeditiously as required by BMS so that trial can proceed as scheduled. It should be noted that the Court expects Apotex to

carry out these undertakings in good faith, and to ensure that there is no delay in bringing the action to trial in March. Having said this, there is nothing to suggest that delay will result or that BMS will have any particular difficulty pleading in response to the Apotex allegations.

[35] Given that I do not find that the amendments proposed by Apotex constitute a significant change to its pleadings, and given that I do not find that the amendments will result in injustice to BMS that is not capable of being compensated by an award of costs, and given the importance of ensuring that the substantive rights of the parties remain intact, the order of Prothonotary Aronovitch is set aside and Apotex is granted leave to serve and file the proposed Sixth Amended Statement of Defence and Counterclaim.

ORDER

THIS COURT ORDERS that the order of Prothonotary Aronovitch is set aside and Apotex is granted leave to serve and file the proposed Sixth Amended Statement of Defence and Counterclaim. Costs are in the cause.

"Danièle Tremblay-Lamer"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2078-00
STYLE OF CAUSE:	BRISTOL –MYERS SQUIBB COMPANY and BRISTOL-MYERS SQUIBB CANADA CO. Plaintiffs APOTEX INC. Defendant
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	December 14, 2010
REASONS FOR ORDER:	TREMBLAY-LAMER J.
DATED:	December 17, 2010

APPEARANCES:

Anthony Creber Jay Zakaib Jennifer Wilkie	FOR THE PLAINTIFFS
Andrew Brodkin David Lederman	FOR THE DEFENDANT

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Ottawa, Ontario	FOR THE PLAINTIFFS
Goodmans LLP Toronto, Ontario	FOR THE DEFENDANT