Federal Court  Cour fédérale

Date: 20110221

Docket: T-2078-00

Ottawa, Ontario, February 21, 2011

PRESENT: The Honourable Mr. Justice Crampton

BETWEEN:

BRISTOL-MYERS SQUIBB COMPANY AND BRISTOL-MYERS SQUIBB CANADA INC.

Plaintiffs

and

APOTEX INC.

Defendant

ORDER

(Motion to set aside January 11, 2011 Order re: sur-reply reports)

UPON MOTION, dated January 21, 2011, on behalf of the Defendant for: (i) an Order setting aside the Order of Prothonotary Aronovitch, dated January 11, 2011, denying the Defendant leave to serve and file sur-reply expert reports prepared by Dr. Robert McClelland and Dr. Peter Stang (the "SR Reports"); (ii) an Order granting leave to the Defendant to deliver confidential versions of the SR Reports, in the form attached as Volumes I and II to the Defendant's Motion

Record; (iii) an Order requiring the Plaintiffs to pay the Defendant's costs of this motion and the motion below; and (iv) such further and other relief as this Court may deem just;

AND UPON reading the materials filed by the parties and hearing their oral submissions;

AND UPON determining that this motion should be denied, for the following reasons:

The test applicable on an appeal of a discretionary order issued by a prothonotary is whether: (i) the questions raised in the motion are vital to the final issue of the case; or (ii) the order "is clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts" (*Merck & Co. Inc. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C. 459, at 478). More recently, the Federal Court of Appeal has stated that discretionary decisions of prothonotaries should stand unless intervention is warranted "to prevent undoubted injustices and to correct clear material errors" (*j2 Global Communications, Inc. v. Protus IP Solutions Inc.*, 2009 FCA 41, at para. 16). However, the latter statement appears to have been made solely with respect to the second prong of the test set forth above, as the Court in that case agreed with the motions judge that the issue that had been raised was not vital to the final issue of the case (*j2 Global Communications*, above, at para. 15). Based on a decision rendered three weeks ago by the Federal Court of Appeal in these proceedings, it is clear that this Court is still obliged to conduct a *de novo* review of a prothonotary's decision in respect of a question that is vital to the final issue in the case (*Apotex Inc. v. Bristol-Myers Squibb Company*, 2011 FCA 34, at paras. 6 and 9).

I am satisfied that the central question raised in this motion is vital to the final issue in this action. That question is whether to the Defendant should be granted leave to deliver the SR Reports. In my view, on the very particular facts of this case, that question is vital because: (i) an important issue addressed in the SR Reports is whether nefazodone free base ("NFB") is formed during one or more of the processes ("Processes") that the Defendant used to produce nefazodone and nefazodone hydrochloride; and (ii) NFB is a molecule that allegedly reacts *in situ* with hydrochloric acid, and that reaction process is alleged to be protected by claims 7 and 8 of Canadian Letters Patent 1,198,436 (the "'436 Patent"), which is owned by one of the Plaintiffs and licensed by the other Plaintiff (collectively, "BMS"). I am therefore obliged to conduct a *de novo* review of Prothonotary Aronovitch's decision, notwithstanding that I am attracted to the view that deference should be given to the factual findings and assessments of a Prothonotary, even where they raise a question vital to the final issue of the case (*Apotex Inc. v. Bristol-Myers Squibb Company*, above, at paras. 8 and 9).

The principles governing applications to file reply and sur-reply evidence were established in *Halford v. Seed Hawk Inc.* (2003), 24 C.P.R. (4th) 220, at paras. 14 and 15 (F.C.T.D.). As Prothonotary Aronovitch observed in her reasons, those principles may be summarized as follows: the evidence sought to be adduced must not be simply confirmatory of evidence already before the Court, and it must be new and not merely adduced for the purpose of contradicting an opposing party's witness. In addition, it cannot be evidence that could have been anticipated, and thus, lead in chief. That said, even if the Court finds that the evidence sought to be adduced as reply (or sur-reply) could have been adduced in chief, the Court retains discretion to grant leave to admit such evidence.

Apotex acknowledges that the thrust of the SR Reports is that BMS's reply expert evidence is scientifically incorrect. In short, those reports opine that the Processes cannot, as a matter of science, infringe the '436 Patent in the manner claimed in the reply reports of BMS's experts (the "BMS Reply Reports"). Apotex submits that, in the SR Reports and on cross-examination, Drs. McClelland and Stang stated that they could not have foreseen that BMS's experts would advance the theory of infringement that is set out in the BMS Reply Reports. Apotex asserts that Prothonotary Aronovitch erred by ignoring this evidence and reaching the opposite conclusion. It also maintains that it would be manifestly unfair and contrary to the interests of justice for it to be denied an opportunity to address BMS's theories of infringement, through the SR Reports. I disagree.

Apotex was aware of BMS's intention to rely upon the presumption set forth in section 55.1 of the *Patent Act*, R.S.C. 1985, c. P-4 from the time it was served with BMS's Statement of Claim, in November 2000. Accordingly, it should have foreseen the distinct possibility that BMS would not adduce expert evidence in chief regarding the Processes. It should therefore have ensured that Drs. McClelland and Stang: (i) turned their minds to the potential ways in which the Processes might be alleged to infringe the '436 Patent; and (ii) addressed those possibilities in their 2009 expert reports ("2009 Reports"), assuming that there was not such a large number of such possibilities that it would have been unreasonable for this Court to expect all of those possibilities to be addressed in the 2009 Reports.

I do not read anything in the pre-trial Order dated April 23, 2008 which could reasonably be interpreted as contemplating that BMS: (i) would be required to adduce in chief any evidence that it might wish to lead in respect of the Processes; and (ii) would not be permitted to adduce reply evidence in respect of the Processes.

Based on the evidence submitted on this motion, I am not satisfied that there was such a large number of potential ways in which the Processes might be alleged to infringe the '436 Patent that it would be unreasonable for this Court to expect those possibilities to be addressed in the 2009 Reports. On the contrary, I am satisfied that, in preparing the 2009 Reports, one or both of Drs. McClelland and Stang should have anticipated that BMS's experts would opine that one or more of the Processes

infringe the ‘436 Patent because NFB is produced at some point in one or more of the Processes.

For greater certainty, I am satisfied that this is so even if, as alleged in the SR Reports: (i) the specific conditions under which the Processes run are not conducive to the production of NFB; and (ii) the theory that might permit NFB to be produced, if followed through to completion, would predict an incorrect result, rather than the infringing nefazodone hydrochloride. In this regard, I am mindful that the Processes were developed subsequent to the processes protected by the ‘436 Patent, such that careful attention would have been given to attempting to ensure that the Processes do not infringe the ‘436 Patent. I am satisfied that Drs. McClelland and Stang should have known that one of the ways in which BMS might allege that the Processes infringe the ‘436 Patent is on the basis that NFB is produced at some point in one or more of the Processes. Even if, at the time they prepared their 2009 Reports, they truly believed what is described in clauses (i) and (ii) above in this paragraph, they should have anticipated that BMS’s experts would opine that NFB is produced during one or more of the Processes.

The explanations that this possibility was not relevant to the presentation and discussion of the Processes that were the focus of the 2009 Reports, and that there was no obligation to address issues such as the role of the excess triethylorthopropionate (“TEOP”) in the Processes, are not acceptable justifications. It was incumbent upon Drs. McClelland and Stang to go beyond simply describing the basic steps and general strategy of the Processes and comparing them with the basic steps and general strategy contemplated by the claims in the ‘436 Patent. Keeping in mind that the 2009 Reports were prepared in the context of a patent infringement action, Drs. McClelland and/or Stang should have gone further and addressed some of the ways in which BMS might allege that the Processes infringe the ‘436 Patent, even if those ways were not considered to be scientifically reasonable.

Based on my review of the draft SR Reports and the excerpts of the transcripts of the cross-examinations of Drs. McClelland and Stang that were included in Apotex’s Motion Record, I am not satisfied that those experts did not anticipate the theory of infringement that has been advanced in the BMS Reply Reports. Notwithstanding their assertions that they could not have anticipated that theory of infringement, I am satisfied that the basic parameters of the theory relied on in the BMS Reply Reports were known by Drs. McClelland and Stang and that they simply chose not to address that theory.

Indeed, I agree with Prothonotary Aronovitch’s finding that Drs. McClelland and Stang: (i) knew of the disputed purpose and functions of the reagents and solvents at issue; and (ii) acknowledged that they were aware that there is excess TEOP in one of the Processes, and that this molecule has dual functionality, one of which is being an acid scavenger. I further agree with Prothonotary Aronovitch that it is difficult to accept that Drs. McClelland and Stang could not have anticipated that BMS’s

experts might well rely on one of those functions to support their theory, particularly given that Canadian Letters Patent No. 2,182,241 (the "'241 Patent"), owned by Apotex, teaches that a reaction can occur in the manner proposed in the BMS Reply Reports, albeit perhaps at a higher temperature and with a different kind of solvent. The fact that Dr. McClelland may not have considered this reaction to be "relevant to the issue that [he] was addressing" is not a sufficient justification for his failure to address that issue anywhere in his initial report.

Drs. McClelland and Stang had every opportunity to address a greater number of steps in the Processes, and to explain why the '436 Patent was not infringed at any of those steps. It bears underscoring that they should have anticipated that BMS's experts might advance a known theory predicated on reactions alleged to occur at some of the steps that they failed to address in their 2009 Reports, and involving one or more of the reagents or solvents that they failed to sufficiently address in those reports. I do not accept Apotex's assertion that the substance of the SR Reports "would be neither understandable nor admissible in the absence of BMS's reply expert reports."

In summary, Drs. McClelland and Stang should have anticipated that the issue of whether NFB is converted in the Processes to nefazodone and nefazodone hydrochloride would be potentially important in this action, as it may essentially determine literal infringement of one of the claims in the '436 Patent. Having specifically considered the issue of whether NFB is formed during the Processes, Drs. McClelland and Stang should have gone further and addressed the reactions and conditions that would be required for NFB to be produced in the Processes, as they have now done in the SR Reports. They should have also addressed in greater detail the purpose and functions of the reagents and solvents of the Processes. Instead, Dr. McClelland simply denied that NFB is formed at any stage of the Processes, while Dr. Stang baldly stated that NFB could not be produced in the Processes because that would require reaction conditions that included a base, and no base is used in the Processes. Unfortunately, having apparently anticipated this potential issue, they did not elaborate. Apotex must now bear the consequences, as it has not met its burden of demonstrating why leave should be granted to permit it to deliver the SR Reports.

As Dr. Stang observed in his cross-examination (at p. 181 of Apotex's Motion Record): "[Y]ou never know what another side [might say], realistic or unrealistic, chemically sensible or not sensible, relevant or not relevant, until you see it." However, this does not absolve a defendant from completely or largely failing to anticipate the basis upon which its processes may be alleged to infringe the plaintiffs' patent, particularly where the defendant's processes may have been specifically designed to avoid infringing the plaintiffs' patent. To allow otherwise would be to sanction the very type of case-splitting that is discouraged by the Rules and the general principles set forth in *Halford*, above.

Particularly in cases in which the defendant has been put on notice of the plaintiffs' intention to rely on s. 55.1, I am concerned that if the type of approach that was taken in the 2009 Reports is permitted, it would imply that the Court would have to be much more receptive to allowing sur-reply expert reports in this context than is currently contemplated by the Rules and by the general principles set forth in *Halford*, above

Given the foregoing, it is not necessary for me to address the other errors alleged to have been committed by Prothonotary Aronovitch. In short, the fact that the thrust of the new evidence sought to be adduced in the SR Reports should have been anticipated in the 2009 Reports is a sufficient basis upon which to deny Apotex leave to deliver the SR Reports.

I do not consider it appropriate to exercise my discretion to grant such leave in this case for several reasons. First and foremost, I am not satisfied that the SR Reports are likely to be of assistance to the Court at the upcoming trial of this matter. I agree with Prothonotary Aronovitch's view that the SR Reports are: (i) to a significant degree, either unresponsive to the BMS Reply Reports or repetitive of material already addressed in the 2009 Reports; and (ii) likely to unnecessarily protract and confuse issues, rather than assist the Court. Second, Apotex waited until the eve of the trial in this action, approximately five months after the BMS Reply Reports were filed, before bringing this motion. Finally, Apotex will have a full opportunity to attempt to impugn, in cross-examination at trial, the theories set forth in the BMS Reply Reports. Accordingly, BMS's theories will not be "shielded from scrutiny by Apotex's experts" and I do not believe that the dismissal of this motion is likely to cause significant prejudice to Apotex.

THIS COURT ORDERS that:

1. The motion is denied with costs, payable in any event of the cause, to BMS.

"Paul S. Crampton"

Judge