Federal Court of Appeal | Cour d'appel fédérale

Date: 20141028

Dockets: A-380-13
A-95-14
A-270-14

Citation: 2014 FCA 242

CORAM: **TRUDEL J.A.**
WEBB J.A.
BOIVIN J.A.

Docket: A-380-13

BETWEEN:

JANSSEN INC.

Appellant

and

ABBVIE CORPORATION, ABBVIE DEUTSCHLAND GMBH & CO. KG AND ABBVIE BIOTECHNOLOGY LTD.

Respondents

Docket: A-95-14

AND BETWEEN:

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Appellant

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and ABBVIE BIOTECHNOLOGY LTD.

Respondents

Heard at Toronto, Ontario, on October 8, 2014.
Judgment delivered at Ottawa, Ontario, on October 28 2014
following reasons delivered on October 8th & October 28, 2014.

REASONS FOR JUDGMENT OF THE COURT BY: THE COURT

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REASONS FOR JUDGMENT OF THE COURT

[1] In a related appeal (A-95-14), Janssen Inc. appeals a judgment of the Federal Court authored by Hughes J. (the Judge) and rendered on January 17, 2014, in which he found that claims 143 and 222 of Canadian Patent No. 2,365,281 (the '281 patent) were valid and infringed (2014 FC 55). The patent is held by one of the respondent corporations, AbbVie Deutschland GmbH & Co. KG (collectively "AbbVie"). The Judge found that Janssen infringed the claims through the promotion and sale of its product STELARA® for the treatment of psoriasis in humans. The Judge then dismissed the appellant's counterclaim that the claims were invalid on the grounds of obviousness, insufficiency, overbreadth, and ambiguity. On appeal Janssen did not challenge the finding of infringement and focuses on the Judge's rejection of its invalidity arguments.

[2] Janssen has appealed two other decisions of the Judge in related proceedings. In file A-380-13, it has appealed the Judge's dismissal of its pre-trial motion to amend Schedule A to its Defence and Counterclaim (2013 FC 1148). In file A-270-14, it has appealed the Judge's post-

trial injunction order (Docket T-1310-09). The three appeals were set down to be heard on the same day. These reasons concern file A-380-13 and deal with the Judge's order dismissing Janssen's motion to amend.

[3] On a motion to amend, the applicable test is that taught by the case of Continental Bank Leasing Corp. v. R., [1993] T.C.J. No. 18, (1993) 93 DTC 298 at page 302, [Continental], cited by our Court in Merck & Co. Inc. v. Apotex Inc., 2003 FCA 488, [2004] 2 F.C.R. 459 leave to appeal to S.C.C. refused, 30193 (May 6, 2004) (see Judge's reasons in A-380-13 at paragraph 10):

> […] I prefer to put the matter on a broader basis: whether it is more consonant with the interests of justice that the withdrawal or amendment be permitted or that it be denied. The tests mentioned in cases in other courts are of course helpful but other factors should also be emphasized, including the timeliness of the motion to amend or withdraw, the extent to which the proposed amendments would delay the expeditious trial of the matter, the extent to which a position taken originally by one party has led another party to follow a course of action in the litigation which it would be difficult or impossible to alter and whether the amendments sought will facilitate the court's consideration of the true substance of the dispute on its merits. No single factor predominates nor is its presence or absence necessarily determinative. All must be assigned their proper weight in the context of the particular case. Ultimately, it boils down to a consideration of simple fairness, common sense and the interest that the courts have that justice be done. [Emphasis added.]

[4] When we apply *Continental* to the facts of this case, we are all of the view that, in the context of this particular case, the amendment sought by Janssen should have been allowed. The Judge did not give sufficient weight to all relevant considerations.

[5] Of all the factors listed in *Continental*, the Judge was satisfied that here "timeliness, extent to which amendments would delay a trial [and] the extent to which a position taken by the

party seeking the amendment would require the other party to change its position" (at paragraph 11 of the Reasons) militated against the motion. AbbVie had relied on the affidavit of its lead counsel in the underlying proceeding for evidence of its prejudice if the amendment was allowed.

[6] On the timeliness issue, we note the following. In 2009, AbbVie initially alleged that all 223 claims of the '281 patent were infringed by Janssen. This was reduced to 154 in February 2010, to 95 in October 2012, then to 94 in June 2013 and finally to 2 claims as of September 10, 2013 (Janssen's memorandum of fact and law at paragraph 9 and AbbVie's memorandum of fact and law at paragraph 2). It is noteworthy that at the time of the pre-hearing conference held by the Judge in July 2013, AbbVie was still asserting that 94 claims were infringed by Janssen. This case kept changing and the "landscape in which the person skilled in the art [was operating]" also was changing.

[7] At that time, both parties were still retaining experts to deal, at least in part, with the prior art. For instance, Dr. Chizzonite for AbbVie and Dr. Sarfati for Janssen were retained at approximately the same time around May and June of 2013. Experts' reports were exchanged between the parties in September and October 2013. In particular, Dr. Sarfati's report was served on counsel for AbbVie on September 16, 2013. That report referenced the new prior art that Janssen sought to add to Schedule A attached to its defence and counterclaim.

[8] As for the possible delay of the trial, we note that lead counsel for AbbVie opined that a two-month delay at minimum - at that time to February 2014 - would be required to have the

necessary discovery and address the 20 new references contained in Dr. Sarfati's report. (affidavit of Mr. Reddon, Janssen's compendium at tab 19, page 290 at paragraph 3p).

[9] The Judge addressed some of the *Continental* factors. However, there are other factors in this case that are important and ought to have been more fully considered by him. As stated in *Sanofi-Aventis Canada Inc. v. Teva Canada Limited*, 2014 FCA 65, [2014] F.C.J. No. 254 at paragraph 15, a party seeking an amendment must meet two independent criteria: (a) any injustice to the other party is capable of being compensated by an award of costs, and (b) the interests of justice would be served. With respect, the Judge failed to fully consider these criteria and substituting our discretion to his, we find that Janssen meets both criteria.

[10] In addressing costs, the Judge at paragraph 7 of his reasons in A-380-13, cited the case of *Montana Band v. R.*, 2002 FCT 583, [2002] F.C.J. No. 774 [*Montana Band*] but never turned his mind to why, in this particular case, AbbVie could not be compensated by costs in light of the fact that its lead counsel was advocating that possibly only a two-month delay would be necessary to conduct the required discovery and address the new references.

[11] AbbVie also relies on Hugessen J.'s reasons in *Montana Band* to support its position that it could not be compensated by costs if the amendment would have been allowed. This blind reliance on *Montana Band* is misplaced.

[12] First there were an excess of 25 parties in *Montana Band*. The style of cause takes a full page.

[13] Second, the dispute in *Montana Band* related to subsurface rights to certain Bands' reserve lands. There were nine separate lawsuits in front of the court. The issues were not only complex but also intimately intertwined.

[14] Thirdly, Hugessen J. noted that if the proposed amendment would have been allowed, it would necessitate substantial pleadings over by other parties and lengthy additional discovery. Without even factoring in re-scheduling difficulties, an adjournment of at least one year would be required. This factual background in quite different than the one at hand.

[15] In his reasons to dismiss, the Judge said little about the interests of justice. Here, it was an important factor to consider. At paragraph 9 of his reasons, the Judge acknowledges that "the amendments sought here are not trivial or merely formalistic; they go to the heart of one of the major invalidity issues raised by [Janssen]; that of obviousness, in respect of which the prior art is critical". It is uncontested that obviousness was a key issue and was raised by Janssen from the onset of the proceeding as a ground of invalidity. Findings to be made on obviousness also impacted, to a certain extent, on the issue of overbreadth - *i.e.* the connection between the human cytokine known as interleukin 12 or IL-12 and psoriasis (reasons in A-95-14 at paragraph 168).

[16] In particular, the parties' focus was on two specific references in Dr. Sarfati's report, the Ehrhardt 1999 and Yawalkar 1998 papers. In the latter case, it was agreed by the experts on both sides that the Yawalkar paper was part of the general common knowledge as of March 25, 1998. As for the Ehrhardt paper, the parties were not in agreement as to the date of publication and whether or not it formed part of the prior art. That would have been a matter for the trial judge.

[17] In the context of this case, it would have served the interests of justice that all the relevant prior art be before the Judge to allow him to fully address the issue of obviousness especially in a case where Janssen was not on a fishing expedition for "the" piece of prior art that would support its position. As stated above, the experts on both sides knew of the existence of the Yawalkar paper. It was alleged that Dr. Chizzonite, an IL-12 specialist with a purported expertise in its potential use in treating diseases, was an author of one of the additional prior art references. Yet, AbbVie had directed Dr. Chizzonite to not address the Yawalkar paper in his report.

[18] The jurisprudence on amendments teaches us that no single factor is determinative. The list of factors to be considered is not exhaustive. This is a balancing exercise and although no single factor predominates, proper weight has to be given to the relevant factors applicable to each particular case. In our view, the Judge misapplied the stated test and failed to give proper consideration to the relevant factors including the particularity of this case which involves novel technology with complex scientific and commercial realities going at the heart of the patent bargain between the inventor and the public. Had the Judge considered all of the relevant factors and applied them appropriately to the case at hand, he would have allowed the amendment. Once again, the interests of justice required that the Judge be in possession of the entire relevant prior art.

[19] In saying this, we are not suggesting that every amendment sought by a party within a few months or weeks of the commencement of a trial should be allowed. The delicate balancing exercise required to decide whether or not to allow the amendment sought by a party must be done on a case-by-case basis. We also realize the importance of this case for the parties and the

inconvenience of going back to the Federal Court with this matter. But weighed against the other factors discussed above, we reach the same conclusion. The parties are experienced litigators and will, no doubt, find solutions to shorten the next hearing. As a result, the appeal will be allowed with costs.

[20] This said and after the Court had read these reasons on record and ordered that the matter be returned to the Federal Court for a new trial, counsel for AbbVie sought a remedy different than the one sought in its memorandum of fact and law. It had originally asked that Janssen's appeal be dismissed with costs without more. Instead, it is now asking that this Court issue a declaration pursuant to subparagraph 52(*b*)(iii) of the *Federal Courts Act*, R.S.C. 1985, c. F-7. More specifically, AbbVie asks this Court to make the order that the Federal Court ought to have made on the motion to amend and to refer the matter back for a continuance of the trial on the issues of obviousness and overbreadth only. Janssen wants a new trial on all of the issues.

[21] In view of AbbVie's request, the parties were invited to submit relevant case law to assist the Court in reaching its final conclusion as to the appropriate remedy. The gist of AbbVie's submissions is that the Judge's conclusion that Janssen has infringed claims 143 and 222 is not under appeal.

[22] According to AbbVie, the remaining issues to be determined in light of our Court's judgment granting Janssen's appeal in file A-380-13 should be limited to Dr. Sarfati's statement at paragraphs 72(*a*) and (*b*) of her Witness Statement (Janssen's compendium in A-380-13 at

page 7352). Ordering otherwise would put Janssen in a better position than the one it was in before the appeal. So the declaration it seeks should be issued.

[23] The problem with the declaration sought is that here there are no remaining issues to be decided - ["les points en suspens"] in the French version of subparagraph 52(*b*)(iii) (*Democracy Watch v. Campbell*, 2009 FCA 79, [2010] 2 F.C.R. 139). The Judge made findings of law and of facts on all issues.

[24] Janssen suggests that AbbVie's request has the effect of completely dissociating the Judge's finding on infringement from his findings on obviousness and overbreadth.

[25] Although these concepts are independent and shed light on different issues, one could reasonably argue that their independence is somewhat limited as both noninfringement and validity of a patent depend on the scope of the patented invention and, as a result, on how the claims are construed. Indeed, whether STELARA® "falls within the parameters of each of claims 143 and 222" depends on what these claims mean. In like manner, invalidity grounds also depend on how the claims are construed, albeit to differing degrees. For instance, a defence of obviousness requires a comparison between the construed claims and the prior art. Once again, that comparison exercise brings to the fore the inventive concept of the claim (*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at paragraph 67, citing *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (C.A.)). In order to determine whether or not the prior art discloses any specific claim limitation, one must turn his mind to what the relevant claims' limitations are and what they mean. In the end,

the conclusion on infringement and how the Judge got there may have an impact on the rest of the analysis.

[26] AbbVie's argument that we should only send the matter back for a re-hearing on the issues that would be affected by the amendment to the pleadings would require us to receive and assess the evidence, including the fresh evidence, and draw conclusions on what findings may be affected by the new documents. To do so, our Court would need "to transform itself into a court of first instance and to make fresh findings of fact and determinations of law based on those findings" (*Canada v. Brokenhead First Nation*, 2011 FCA 148, [2011] F.C.J. No. 638). We are unwilling to assume that role.

[27] As noted by AbbVie, Janssen did not appeal the Judge's conclusion on infringement. This is evident from its notice of appeal and there is nothing in its Memorandum of Fact of Law to explain why it did not appeal this part of his judgment.

[28] However, at the beginning of the part of his brief reasons addressing the issue of infringement, the Judge noted that:

> **103** Janssen, in its Closing Submissions at paragraphs 48 and 103, essentially concedes that, if I construe claims 143 and 222 as covering human antibodies made by any method, including, for instance, the transgenic mouse method, then STELARA would fall within the scope of the claims at issue, subject to testing as to the level of stickiness and potency.

[29] In paragraph 107 of his reasons he stated that:

> **107** I find that, if claims 143 and 222 are valid, Janssen has infringed these claims.

[30] It is clear that the Judge's finding of infringement was contingent on his finding of validity in relation to claims 143 and 222. Since we have concluded that his finding of validity in relation to these claims is to be set aside, it must necessarily follow that his finding of infringement in relation to these claims must also be set aside.

[31] Once again, we realize the burden on the parties having to re-argue this matter. It is worth repeating that counsel for the parties are highly experienced lawyers and it is their duty, as officers of the Court, to take all necessary steps to reduce the numbers of issues to be addressed by the Federal Court in the new trial. Having heard the evidence, surely counsel will be able to reach agreements on some of the issues and to co-operate with the Federal Court to ensure that the new trial is conducted in an efficient manner and in the interests of justice.

[32] Therefore, Janssen's appeal from the order dismissing its motion to amend Schedule A to its Defence and Counterclaim so as to remove and add other prior art references will be allowed with costs and rendering the order that the Federal Court ought to have rendered, Janssen's motion will be allowed without costs. Janssen will be entitled to amend Schedule A to its Defence and Counterclaim as contemplated by its motion. The judgment of Hughes J. indexed as 2014 FC 55 will be set aside. As a result, the matter will be remitted back to the Federal Court for a new trial before another judge.

"Johanne Trudel"
J.A.

"Wyman W. Webb"
J.A.

"Richard Boivin"
J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-380-13
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