Federal Court Cour fédérale

Date: 20210222

Docket: T-1004-18

Citation: 2021 FC 171

Ottawa, Ontario, February 22, 2021

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

AKEBIA THERAPEUTICS, INC.
OTSUKA CANADA PHARMACEUTICAL INC.

Plaintiffs

and

FIBROGEN, INC.

Defendant

ORDER AND REASONS

UPON hearing this motion by videoconference from Halifax on Monday the 25th day of January, 2021;

AND UPON reading the parties motion records and hearing from counsel;

AND UPON deciding the motion for the following reasons, given orally from the bench on the day of the hearing:

[1] This is a motion by the Plaintiffs seeking leave under Federal Courts' Rule 279 to file expert evidence in reply to the Defendant's expert reports delivered on November 30, 2020. The Plaintiffs had previously filed their expert reports on August 31, 2020 dealing with invalidity issues, including claim construction, obviousness, inutility/overbreadth, double patenting and insufficiency.

[2] The Defendant opposes the introduction of this material on the basis that it is repetitive, argumentative, or that it ought to have been anticipated and led in chief. Any new issues that the Plaintiffs seek to address in reply were, according to the Defendant, known to be of potential relevance to the Plaintiffs' counsel and should have been put to their experts at the time their reports in chief were being prepared. The Plaintiffs suggest that no meaningful prejudice will befall the Defendant if this evidence is admitted and that reasonable sur-reply is available if required.

[3] The Plaintiffs propose to file four brief reply reports, one from each of its expert witnesses: Dr. Semenza, Dr. Ward, Dr. Fishwick and Dr. Haase. The reply reports are attached as exhibits to the affidavit of a law clerk employed by Plaintiffs' counsel and contain the author's explanation as to why they were unable to anticipate the evidence they each now seek to respond to.

[4] The Defendant objects to this approach on the basis that it shields the experts from being cross-examined and allows their unsworn justifications into the motion record. This, it says, is mere argument. I am told, however, that this problem was not directly raised by the Defendant before the motion was briefed. It is also noteworthy that the Defendant seeks to bolster its position on the merits by relying on the same type of unsworn references from its own expert reports.

[5] The practice of presenting this type of evidence in this way appears to be fairly common and unobjectionable – at least where a cross-examination of the witness is not sought, and the authority for that can be found in *Merck-Frosst - Schering Pharma GP v Canada (Minister of Health)*, 2009 FC 914 paras 19-20, [2009] FCJ No 1092:

> 19 It is certainly true that the proposed reply affidavit of Dr. Sutherland was unsworn; however, that is not an uncommon or objectionable way of proceeding in such motions. Therefore, that fact alone ought not to have been fatal to Novopharm's application. Moreover, the unsworn affidavit was an exhibit to a sworn affidavit that attested that if reply evidence was allowed, it would be sworn, served and filed in the form that was before the Prothonotary. Accordingly, it was entitled to be given more consideration than a mere unsworn statement alone.
>
> 20 Although the burden was on Novopharm to show why reply evidence was required, the Applicants do not appear from the record to have indicated any desire to cross-examine Dr. Sutherland on the proposed affidavit prior to the motion. It is simply inappropriate to suggest, as it was, that he was "shielded from cross-examination" by Novopharm.

Although in *The Regents of the University of California and Tearlab Corporation v I-MED Pharma Inc*, T-300-16, Prothonotary Tabib described this type of information as more in nature

of argument, she was still willing to take it into account along with the rest of the so-called objective record. I will adopt the same approach.

[6] The onus is, of course, on the Plaintiffs as the moving parties to establish that their reports are proper reply in the context of the applicable legal principles. The Court must always be mindful of case-splitting and the serious prejudice it can create for a Defendant. Proposed reply that merely confirms positions addressed in chief is also objectionable – even though repetition does not add any probative value to a witness' initial evidence. Reply that amounts to a bare rebuttable of a defence report is also often refused. Proper reply addresses matters that are raised for the first time in the defence case that could not have been reasonably anticipated by the plaintiff. These principles must be applied with some flexibility. Ultimately the resolution of this type of motion will substantially turn on the judge's view of what best serves the interests of justice and whether the evidence assists the Court in making its decision on the merits, subject, of course, to the avoidance of undue prejudice to a defendant. In some cases the introduction of reply evidence can be helpful to the Court and the opposing side because it clarifies areas of apparent confusion or misunderstanding and it can also forewarn the Defendant of issues that are likely to arise under cross-examination. Where the issues presented in reply concern complex issues of science the discretion to admit it may be enlarged. That can be a particular problem for the Court where a plaintiff expert offers an untested science-based justification for why an issue was not addressed in chief at a point in time when the Court lacks a clear understanding of the relevant science.

[7] I have to say that I do not fully understand the concern expressed by some colleagues that the opportunity to present reply evidence can be denied on the basis that the issue in dispute can be tested under cross-examination. If that was the case, reply evidence would never be admissible. A plaintiff is entitled to present proper reply evidence in support of its case AND to cross-examine on the same issues. The idea that cross-examination is a sufficient measure applies, I think, to proposed reply that merely points to shortcomings or disagreements with the Defendant's evidence and nothing more. This point was made by Justice Michael Manson in *Janssen Inc v Teva Canada Ltd*, 2019 FC 1309 at para 17, [2019] FCJ No 1221, where he said:

> … Mere disagreement with statements made by another witness is not proper subject matter for reply evidence. Disagreements between experts can be addressed by cross-examination.

[8] So with these principles in mind, I will now turn to the content of the reply reports, all of which is objected to by the Defendant. I will begin with Dr. Haase. Dr. Haase's reply deals with the issue of the use of cobalt chloride to treat anemia. It appears to be common ground that cobalt chloride had been an accepted treatment in the past but was withdrawn from use because of toxicity concerns. The issue of present concern seems to me to be whether this would have been part of common knowledge of the person of skill at the relevant date. It may be that the initial reports have sufficiently framed this issue to permit it to be fully canvassed in testimony at trial. Dr. Haase's reply may turn out to be unnecessary to that exercise but out of an abundance of caution I will permit it. I am of the view that Dr. Haase's reply concerning the use of ESA and EPO as treatments for anemia is proper. The Defendant argues that this issue arises out of a mischaracterization of Dr. Wish's report touching on "off-label" use. I will admit that this distinction is not entirely clear to me at this point based on the arguments made and it will be

helpful to me to hear further evidence explaining it from both Dr. Wish and Dr. Haase. I will, therefore, allow Dr. Haase's reply report – so Dr. Haase's report will, therefore, be admitted.

[9] Turning to Dr. Fishwick, I do not accept that Dr. Fishwick's "surprise" about Dr. Gazaryan's unfamiliarity with the so-called Marven software is relevant or a proper reply. Dr. Fishwick is entitled to discuss the reliability and ubiquity of this software in his testimony but he is in no position to directly challenge Dr. Gazaryan's statement that she was not familiar with the software and was not, as seems to be agreed, provided with a copy. Paragraph 13 of Dr. Fishwick's reply is also not proper reply. It is bare argument. Dr. Gazaryan can, of course, be cross-examined on these issues. The rest of Dr. Fishwick's reply is unobjectionable. Dr. Gazaryan cast doubt on the reliability Dr. Fishwick's calculation and he is entitled to defend his work. I do not agree with the Defendant that this vaguely asserted criticism, "the data appeared to be flawed", should have been anticipated. On this point I adopt the view of Justice Russel Zinn in *Merck-Frosst - Schering Pharma GP v Canada (Minister of Health)*, above, at para 30:

> 30 However, to the extent that the Applicants' evidence is that claim 21 was not obvious and they set out reasons why that is so, those reasons and the facts behind them are likely to warrant reply evidence, as they are new. Further, where the Applicants' evidence is that Novopharm's expert is wrong in his opinion and they are not merely challenging his science but are raising new matters by way of different science, different authorities, different assumptions, and the like, that too at first blush will raise new matters that may require reply. While this type of evidence may be said to respond to the evidence of Novopharm in a very general and overarching manner, the detail of it may well be new. Novopharm could anticipate that some science and argument would be put forward for the inventiveness of the claim and challenging its expert's evidence, however, it need not deal with every argument it can anticipate being put forward because, until the Applicants put forward their evidence Novopharm has no way of knowing which

> of the possible arguments and supporting evidence it may have anticipated are truly relevant. To require it to do so earlier will result in lengthy affidavits containing many irrelevant paragraphs of "anticipatory evidence".

[10] To the extent that this issue may be the result of a misunderstanding of Dr. Fishwick's work, it should be fully addressed as was the case in *Bristol-Myers Squibb Canada Co v Pharmascience Inc*, 2020 FC 897 at para 21, again a decision by Justice Zinn:

> [21] In paragraphs 5-10 of the Laskar Reply, he says that Dr. Davies has mischaracterized his evidence in chief. I agree with the Plaintiffs that Dr. Laskar does restate his initial evidence; however, this alone does not make these paragraphs inadmissible because this is not a mere disagreement between experts; rather it is the first asserting that the second has misinterpreted his opinion. In my view, that evidence is admissible <u>for that purpose</u>. [Emphasis in original]

[11] Turning to Dr. Ward's reply report, he addresses what appears to be an important assertion made by Dr. Gazaryan that "the key to these patents is the pharmacaphore". Dr. Gazaryan opines that the pharmacaphore is a common structural feature in the claimed compounds that a person of skill would understand to be responsible for the mechanism of action and supportive of the sound prediction of utility. According to Dr. Ward, the patents do not discuss this theory let alone demonstrate anything about a proposed mechanism of action. He goes on to explain in some detail why Dr. Gazaryan's opinion is scientifically unsound and unsupported by the patents.

[12] I take the Defendant's point at paragraph 58 of its Brief that there is some repetition between Dr. Ward's two reports but these overlaps appear to be of minor significance to the central issue in dispute. They also provide some context. I also do not accept that the evidence

elicited on discovery by the Plaintiffs was sufficiently on point or illuminating that the Plaintiffs ought to have anticipated Dr. Gazaryan's detailed opinions on this issue. This disagreement is so fundamental to what appears to be one of the central issues on this case that it needs to be fully explored. The science around this issue is also markedly abstruse, including Dr. Ward's explanations for why Dr. Gazaryan's theory was unexpected. To deny the Plaintiffs a full reply to Dr. Gazaryan would potentially create a significant evidentiary imbalance. The issue is now fully joined on the evidence and I can identify no serious prejudice to the Defendant by allowing Dr. Ward's reply into the record. If the Defendant seeks a right of a surreply, it can make its case to do so.

[13] The second issue raised by Dr. Ward in reply concerns a very discreet measurement of inhibition values as an indication of biological activity. Dr. Gazaryan accepted as valid any measured inhibition value above zero. Dr. Ward is of the view that this approach is scientifically untenable. He nevertheless went on to do his own testing using Dr. Gazaryan's thesis and came up with a different analysis of the data. I accept that the Plaintiffs had no sound basis to anticipate that Dr. Gazaryan would adopt what Dr. Ward says was a controversial approach to the measurement of compound activity for the purpose of proving sound prediction. I will accordingly accept this evidence as appropriate reply.

[14] Dr. Semenza's reply report addresses certain unresolved questions raised by Dr. Ivan concerning the mechanism of action through which HIF-PH degraded HIF-alpha. Dr. Semenza states that these questions would be irrelevant to the person of skill based on what was, in fact, known. Dr. Semenza also states that the subject patents provide no guidance in answer to

Dr. Ivan's questions. Paragraphs 5 to 12 of Dr. Semenza's reply add some helpful clarity to a new point raised by Dr. Ivan and I will permit it.

[15] I am also satisfied that paragraph 13 to 22 in Dr. Semenza's report are appropriate responses to points raised by Dr. Ivan and which could not have been reasonably anticipated. This evidence is important and necessary to a full evaluation of Dr. Ivan's opinion. I am satisfied that Dr. Semenza's reply will assist the Court in its understanding of what is very, very complicated science.

[16] So, those are my conclusions. The only problems that I have identified here are from the reports are those of Dr. Fishwick's reports. I am not sure how you want to address that and I have read the material obviously. I do not know if someone wants to have those passages redacted or removed – that may be unnecessary under the circumstances. I certainly will not take them into account.

[17] The other technical point that I will bring up is that if either party wishes to have a copy of these Reasons; I will reserve the right to make corrections to grammar, correct citation and quotations. So, subject to those comments and a final point is costs. The parties agreed that the costs should be in the cause and it shall be so ordered.

ORDER IN T-1004-18

THIS COURT ORDERS that:

1. The motion is allowed with the exception only of the references in Dr. Fishwick's reply report identified above which are not allowed; and

2. The costs of the motion shall be in the cause.

"R.L. Barnes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1004-18
STYLE OF CAUSE:	AKEBIA THER.APEUTICS, INC. v FIBROGEN, INC.
PLACE OF HEARING:	HALIFAX, NS TORONTO, ON
DATE OF HEARING:	JANUARY 25, 2021
REASONS FOR ORDER AND ORDER:	BARNES J.
DATED:	FEBRUARY 22, 2021

APPEARANCES:

Steven G. Mason Sarit Batner Michael D. Burgess	FOR THE PLAINTIFF
Brian Daley	FOR THE DEFENDANT

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Barristers & Solicitors Toronto ON	FOR THE PLAINTIFF
Norton Rose Fulbright Canada LLP Montréal, QC	FOR THE DEFENDANT