Federal Court  Cour fédérale

Date: 20201124

Docket: T-1184-17

Citation: 2020 FC 1087

Ottawa, Ontario, November 24, 2020

PRESENT: The Associate Chief Justice Gagné

BETWEEN:

MERCK SHARP & DOHME CORP. and MERCK CANADA INC.

Plaintiffs

and

WYETH LLC

Defendant

ORDER AND REASONS

I. Overview

[1] In their impeachment action, Merck Sharp & Dohme Corp. and Merck Canada Inc. [Merck or the Plaintiff], who are currently developing a pneumococcal conjugate vaccine with 15 serotypes [V114] , are seeking an order invalidating Wyeth LLC's Composition Patent and two Formulation Patents relating to its current pneumococcal conjugate vaccine with 13 serotypes [Prevnar 13].

[2] As the twelve-day trial is scheduled to commence on November 30, 2020, Merck brings this motion for leave to file reply expert reports from its three experts.

[3] The parties have thus far tendered the following expert reports in support of their respective positions:

(1) For Merck (filed in June 2020):

> **Dr. Paton** opines on the Composition Patent, including the credentials and common general knowledge of the skilled person, claims construction, anticipation, obviousness and overbreadth/lack of utility (his report is 136 pages);
>
> **Dr. Kasper** opines on the Composition Patent, including the credentials and common general knowledge of the skilled person, and claims construction in relation to the obviousness of certain Method/Process claims (his report is 47 pages); and
>
> **Dr. Petrovsky** opines on the Formulation Patents, including the credentials and common general knowledge of the skilled person, claims construction, anticipation, obviousness, and double patenting (his report is 118 pages).

(2) For Wyeth (filed in September 2020):

> **Dr. Ravenscroft** opines on the Composition Patent, including the credentials and common general knowledge of the skilled person, claims construction, anticipation, and obviousness. He also responds to both Dr. Paton and Dr. Kasper's opinions (his report is 215 pages).
>
> **Dr. Dagan** opines on the development of pneumococcal vaccines, including immune interference, carrier-induced suppression, and serotype selection. He also responds to both Dr. Paton and Dr. Kasper's opinion (his report is 114 pages).
>
> **Dr. Manning** opines on the Formulation Patents, including the credentials and common general knowledge of the skilled person, claims construction, anticipation, obviousness, and double patenting. He also responds to Dr. Petrovsky's opinion (his report is 208 pages).

[4] Merck is now seeking to tender reply reports from Drs. Paton and Kasper, wherein they opine on new issues raised by Drs. Ravenscroft and Dagan, as well as a reply from Dr. Petrovsky to Dr. Manning on the Formulation Patents [Reply Reports]. In addition to his reply opinion on the Composition Patent, Dr. Paton provides a rebuttal opinion on Wyeth's prosecution history with the Canadian Intellectual Property Office [the patent office], as now permitted by section 53.1 of the *Patent Act*, RSC 1985 c P-4 [Rebuttal Opinion].

II. Issues

[5] The sole issue to be determined on this motion is whether Merck should be granted leave to serve and file the Reply Reports and Rebuttal Opinion.

III. Analysis

A. *The Governing Law*

[6] The general rules governing the filing of reply evidence are well known and relatively simple. However, they are not so simple to apply on a preliminary motion, out of context, and without the full evidentiary picture that the experts' testimonies and cross-examinations will provide the Court at trial.

[7] That said, the starting point is Rule 274(1) of the *Federal Courts Rules*, SOR/98-106, which sets out the order in which the parties present their evidence:

> 274(1) Subject to subsection (2), at the trial of an action, unless the Court directs otherwise,

> (a) the plaintiff shall make an opening address and then adduce evidence;
>
> (b) when the plaintiff's evidence is concluded, the defendant shall make an opening address and then adduce evidence;
>
> (c) when the defendant's evidence is concluded, the plaintiff may adduce reply evidence.

[8] There are a few rules that govern and limit the nature of evidence the plaintiffs can adduce in reply. They all flow from the fact that a plaintiff will not be allowed to split its case (*R v Krause*, [1986] 2 SCR 466 at 473); the reply evidence must relate to issues raised in defense that were not raised in chief by the plaintiff (*Amgen Canada Inc v Apotex Inc*, 2016 FCA 121 at para 12).

[9] As stated by Justice Manson in *Janssen Inc v Teva Canada Limited*, 2019 FC 1309 at para 16, the Trial Division of the Federal Court in in *Halford v Seed Hawk Inc*, 2003 FCT 141 at para 15, had aptly broken this rule down to four principles:

> 1. Evidence which is simply confirmatory of evidence already before the court is not to be allowed.
>
> 2. Evidence which is directed to a matter raised for the first time in cross examination and which ought to have been part of the plaintiff's case in chief is not to be allowed. Any other new matter relevant to a matter in issue, and not simply for the purpose of contradicting a defence witness, may be allowed.
>
> 3. Evidence which is simply a rebuttal of evidence led as part of the defence case and which could have been led in chief is not to be admitted.
>
> 4. Evidence which is excluded because it should have been led as part of the plaintiff's case in chief will be examined to determine if it should be admitted in the exercise of trial judge's discretion.

[10] In *Merck-Frosst v Canada (Health)*, 2009 FC 914 at para 10 [*Merck-Frosst*], Justice Zinn added a few more factors to be considered when assessing whether evidence is being introduced as proper reply:

> (a) whether the further evidence serves the interests of justice;
>
> (b) whether the further evidence assists the Court in making its determination on the merits;
>
> (c) whether granting the motion will cause substantial or serious prejudice to the other side; and
>
> (d) whether the reply evidence was available and/or could not be anticipated as being relevant at an earlier date.

[11] Justice Zinn breaks down this fourth factor into a two-pronged analysis at paragraphs 23 and 25 of *Merck-Frosst*:

> (23) The first step is to ask whether the proposed evidence is properly responsive to the other party's evidence. It is responsive if it is not a mere statement of counter-opinion but provides evidence that critiques, rebuts, challenges, refutes or disproves the opposite party's evidence. It is not responsive if it merely repeats or reinforces evidence that the party initially filed.
>
> …
>
> (25) If the proposed evidence is found to be responsive, one must then ask whether it could have been anticipated as being relevant at an earlier date. If it could have been anticipated earlier to be relevant, then it is being offered in an attempt to strengthen one's position by introducing "new" evidence that could and should have been included in the initial affidavit. Such evidence is not proper reply evidence as the party proposing to file it is splitting his case.

[12] On the other hand, Rule 279 of the *Federal Courts Rules* governs the admissibility of expert evidence. No expert witness' evidence is admissible unless the issue has been defined by the pleading or in an order of the Court; the expert must have previously served and filed an

affidavit or a statement made in accordance with the *Federal Courts Rules*; and, the expert must be available at the trial for cross-examination.

[13] In *R v Mohan*, [1994] 2 SCR 9 at paragraph 20, the Supreme Court developed a useful test to determine if expert evidence should be admitted:

> (a) It should be relevant;
>
> (b) It should be necessary to assist the trier of fact;
>
> (c) It should not be subject to any exclusionary rule; and
>
> (d) A properly qualified expert should adduce it.

[14] Mindful of all these principles, I will now turn to the topics covered in Merck's Reply Reports and Rebuttal Opinion and to the contradictory positions taken by the parties regarding each one of them.

B. *Dr. Paton's Rebuttal Opinion*

[15] In his Rebuttal Opinion (3 pages), Dr. Paton responds to Dr. Ravenscroft's opinion regarding the construction of the claims of the Composition Patent. Merck submits that Dr. Ravenscroft gave opinions which are inconsistent with statements made by Wyeth to the patent office during prosecution of the patents (*i.e*. that certain claims are not limited to 13 serotypes), which triggers the application of subsection 53.1(1) of the *Patents Act*. Merck asserts that Wyeth is estopped from bringing such contradictory evidence and it submits it could not have anticipated Wyeth would take such an inconsistent position.

[16] Wyeth submits that subsection 53.1(1) is a mere evidentiary rule that does not estop a patentee from taking an inconsistent position in litigation. It further argues that Dr. Paton's opinion is unnecessary because evidence from the patent office related to patent prosecution does not require a scientific expert.

[17] Without having to dig into the interpretation of subsection 53.1(1) at this stage of the proceedings, I disagree with Wyeth. The communication between Wyeth and the patent office describes the process of creating a conjugate vaccine. In my view, the Court would benefit from expert evidence on the content and impact of this exchange. In addition, since the rebuttal evidence is only admissible after a patentee takes an inconsistent position, Dr. Paton's rebuttal report is only proper in response to Dr. Ravenscroft's opinion. Therefore, Merck could not have raised this issue before Wyeth's expert took this so-called inconsistent position in its action. Filing of the Rebuttal Opinion will therefore be permitted.

[18] Given that I see this scientific interpretation as benefiting the Court, I will also grant leave to Wyeth to file Dr. Ravenscroft's surreply, without further edit.

C. *Dr. Paton's Reply Report*

[19] In his proposed Reply Report (23 pages), Dr. Paton discusses five points raised by Drs. Dagan and Ravenscroft. The parties have different views as to whether or not they were new issues or could have been anticipated:

> First, Dr. Paton suggests that Dr. Ravenscroft raised for the first time in this litigation that a skilled person in assessing the obviousness of the Composition Patent would start with

> pneumococcal protein-only composite and not with a pneumococcal conjugate vaccine. He states that he could not have anticipated that the starting point for a conjugate vaccine would not be a conjugate vaccine.
>
> Second, Dr. Paton responds to Dr. Ravenscroft's opinion that the serotype specific conditions in Examples 1-15 of the patent are critical and required for a skilled person to make a 13 serotype conjugate composition. Dr. Paton says that this contradicts the clear terms of the Composition Patent and as such, could not have been anticipated.
>
> Third, Dr. Paton responds to the unanticipated opinion by Dr. Dagan on obviousness in relation to a later date than the priority date of the Composition Patent.
>
> Fourth, Dr. Dagan raises new prior art documents related to an aspect of obviousness and Dr. Paton could not have anticipated he would.
>
> Fifth, Dr. Ravenscroft opines that certain information was not available outside pharmaceutical companies at a relevant date and Dr. Paton disagrees based on his personal experience.

[20] I would first like to note that Dr. Paton specifically enunciates the mandate received from counsel and states that he was asked to read the reports filed in defense and identify issues that he had not raised in chief and that he could not have anticipated as relevant, prior to Dr. Ravenscroft or Dr. Dagan raising them.

[21] I agree with Merck that a plaintiff is not expected to try to anticipate every argument of the defendant; to do so would hinder the efficiency of a well-circumscribed litigation and would force a plaintiff to file unnecessary and burdensome evidence. Most of Wyeth's counter-arguments to the Court are general in nature and are related to the fact that Merck was familiar with the issues raised by its experts and that it knew of the new evidence referenced by them. I do not believe that is the test to be met.

[22] Dr. Paton's Reply Report is short and well focussed. He specifically says why he could not have reasonably anticipated the subjects discussed therein and why he disagrees with Drs. Ravenscroft and Dagan. Wyeth has not provided me with sufficient reasons to find otherwise at this stage.

[23] Merck will be granted leave to file Dr. Paton's Reply Report.

D. *Dr. Kasper's Reply Report*

[24] In his separate Reply Report (13 pages), Dr. Kasper also provides his opinions on the following:

> Dr. Ravenscroft's opinions regarding serotype-specific conditions for making conjugates;
>
> Dr. Ravenscroft's opinions regarding the common general knowledge of the Skilled Person as of April 8, 2005;
>
> Dr. Dagan's knowledge of immune interference as of April 26, 2006.

[25] Merck makes the same arguments in support of Dr. Kasper's reply evidence as it makes for Dr. Paton's reply evidence. In addition to raising similar arguments against Dr. Kasper's evidence, Wyeth submits that Dr. Kasper's evidence is duplicative of Dr. Paton's evidence.

[26] I reject Wyeth's main arguments for the same reasons I rejected them in regards to Dr. Paton's Reply Report.

[27] As for the duplicative aspect of Dr. Kasper's opinion, Wyeth states that since it is unnecessary it fails to meet the *Mohan* test. If we were to follow Wyeth's argument, two different experts with different fields of expertise could never opine on the same subject for the same party. According to Merck, Dr. Paton is a pneumococcal expert whereas Dr. Kasper is a polysaccharide-protein conjugate expert. Just as their reports in chief complement one another, their Reply Reports are not mere duplication, even if they do address the same or similar issues. I assume they will both assist the Court in understanding the science behind those issues.

[28] Merck will be granted leave to file Dr. Kasper's Reply Report.

E. *Dr. Petrovsky's Reply Report*

[29] Finally, Dr. Petrovsky's Reply Report (13 pages) responds to five issues raised by Dr. Manning. Merck submits these were not reasonably anticipated issues:

> First, Dr. Manning was asked to provide his opinion on Merck's invention story and Dr. Petrovsky could not anticipate what story Wyeth would put forward;
>
> Second, Dr. Manning says that Jones *et al*., 2005 would not have been known to the skilled person. Dr. Petrovsky responds that this is inconsistent with binding admissions made in the Formulation Patents, which specifically cite Jones *et al*., 2005;
>
> Third, Dr. Manning relied on new prior art documents regarding the use of surfactants that Dr. Petrovsky did not initially view as relevant, although surfactants were discussed in his initial report;
>
> Fourth, Dr. Petrovsky states it was inconsistent for Dr. Manning to say that the Formulation Patents only relate to physical stability since stability, as defined in the patents, refers to both chemical and physical stability;
>
> Fifth, Dr. Manning raised a new issue regarding whether certain information would have been shared outside of pharmaceutical

> companies at the relevant date. Dr. Petrovsky responds to this issue and provides specific examples of how his real-life experience in the field at the relevant date is inconsistent with the opinion provided by Dr. Manning.

[30] Merck argues that with respect to new prior art or new documents referred to by Wyeth's expert, it did not see them as relevant to its case until they were invoked to support an unanticipated position taken by Wyeth's experts. In addition, Wyeth's experts express opinions that could not be anticipated either because they contradict answers Wyeth provided during discovery or the impugned claims of the Composition Patent and the Formulation Patents.

[31] Wyeth responds that for all if not most of these prior arts or documents, they were listed in Appendix 1 to Merck's initial Statement of Claim.

[32] Again, it is not because a piece of prior art or other documentary evidence is initially known to a party or to an expert that it is considered relevant when addressing a specific issue or area of the science. It might only become relevant when linked to that issue or area of the science by the opposite party.

[33] Generally speaking, the issues raised in reply concern complicated scientific concepts that the Court requires expert evidence to clarify. As a result, it is in the interests of justice to allow the evidence where it plays an illuminating role for the Court.

[34] On the point of Jones *et al*., 2005, I believe Wyeth's submissions misrepresent the issue. While Dr. Petrovsky indeed wrote about Jones *et al*., 2005 in his initial report, he responds in the

reply evidence to Dr. Manning's position that it was not part of the common general knowledge. It is clear from Dr. Petrovsky's reponse that Dr. Manning's position was unanticipated, at least to him.

[35] Merck will be granted leave to file Dr. Petrovsky's Reply Report.

IV. Conclusion

[36] Merck is granted leave to file the Reply Reports and Rebuttal Opinion since: (a) it has not yet had an opportunity to address those issues; (b) they were not and could not have been reasonably anticipated; and (c) the new matters require a response in order for the Court to have a complete and accurate picture of the scientific issues raised on important issues in the case.

[37] There will be no prejudice to Wyeth as its experts had the opportunity to comment on all the issues raised in Merck's expert reports and it is hereby granted leave to file Dr. Ravenscroft's Response to Rebuttal.

[38] Costs on this motion are granted to Merck.

ORDER in T-1184-17

THIS COURT ORDERS that:

1. The Plaintiffs' Reply Motion is granted;
2. The Plaintiffs are granted leave to file the Reply Reports of Drs. Paton, Kasper and Petrovsky and the Rebuttal Opinion of Dr. Paton;
3. The Defendant is granted leave to file Dr. Ravenscroft's Response to Rebuttal;
4. Costs on this motion are granted to Merck.

"Jocelyne Gagné"
Associate Chief Justice

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1184-17
STYLE OF CAUSE:	MERCK SHARP & DOHME CORP., and MERCK CANADA INC. v WYETH LLC

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ORDER AND REASONS:	GAGNÉ A.C.J.
DATED:	NOVEMBER 24, 2020

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