Federal Court  Cour fédérale

Date: 20131011

Docket: T-1555-12

Citation: 2013 FC 1036

Toronto, Ontario, October 11, 2013

PRESENT: Kevin R. Aalto, Esq., Case Management Judge

BETWEEN:

PFIZER CANADA INC.
AND G.D. SEARLE & CO.

Applicants

and

APOTEX INC.
AND THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] This case is a poster child for why reversal orders ought not to be granted except in the most exceptional of circumstances in proceedings under the *Patented Medicines (Notice of Compliance) Regulations (Regulations)*. Exceptional circumstances might include a situation in which counsel for the respective parties willingly consent to reversing evidence. It is the parties' case and if they wish to provide their evidence on an issue before they are required to under the *Federal Courts*

Rules, they should have that option so long as it is justifiable and will not lead, for example, to contested motions for reply or sur-reply.

[2] In general, it appears that reversal orders do not achieve the goal anticipated by the December 7, 2007 Practice Direction of simplifying proceedings under the *Regulations*. The Practice Direction was intended to outline approaches to proceedings under the *Regulations* for discussion which might lead to the just, most efficient and least expensive determination of the matter on its merits.

[3] This is particularly so in the context of a partial reversal of evidence which has led to the mischief in this case. The Applicants (Pfizer) delivered its fact evidence in support of the patent in suit first, followed by the Respondent's (Apotex) evidence on validity, followed by Pfizer's evidence on validity. The mischief which has arisen is that the Pfizer experts have now relied on an extensive number of clinical studies, monographs and other documents which Apotex argues are facts and should have been disclosed as part of the "fact" evidence.

[4] Thus, the motion before the Court is brought by Apotex to strike substantial portions, including exhibits, of the affidavits of three of the experts filed on behalf of the Pfizer. The evidence sought to be struck is evidence upon which the respective experts of Pfizer rely for their opinions.

[5] The portions of the affidavits sought to be struck is extensive:

(a) Dr. Fennerty, sworn August 2, 2013, paragraphs 16, 17, 35, 36, 37 (second sentence), 39 (second to fourth sentences), 40, 41 (first sentence), 43, 44, 45, 46, 47, 48, 55 (second last sentence), 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 105 (last two sentences), 112, 121 (fifth sentence), 163 (last two sentences), and exhibits D, E, F, G, I, J, M, N, O, P, R, T and V;

(b) Dr. Abramson, sworn August 6, 2013, paragraphs 14(e), 86, 101, 102, 103, 104, 105, 106, 120, 121, 122, 123, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 156 (first sentence), 177, 179 (second last sentence), 210 (last two sentences), 223, 224, 225, 227 (to the extent the *Lancet 2013* article is mentioned), 228, and exhibits D, E, F, G, H, L, M, Q, R, S, T, U, V, W, Y and BB; and,

(c) Dr. Tugwell, sworn August 6, 2013, paragraph 17, 38 (second last sentence), 44, 45, 46, 47, 48, 51, 65, 66, 67, 68, 69, 70, 71, 72, 73, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 173, 197, 198, 199, 200, 206, and exhibits G, H, I, J, O, P, U, V, W, X, Y, Z, AA, BB and CC;

[6] In large part, striking this much of these affidavits amounts almost to a re-writing of the affidavits.

Background

[7] This application involves the drug celecoxib and Pfizer's patent (the '576 Patent). Apotex delivered a Notice of Allegation (NOA) on July 3, 2012. The NOA refers to utility and sound prediction as two of the main grounds for attacking the validity of the '576 patent.

[8] On August 16, 2013, Pfizer commenced this proceeding under the *Regulations*. In this application Pfizer seeks as part of its relief that there be a reversal of evidence.

[9] As with all proceedings under the *Regulations*, it is case managed. A case management conference was held in November 2012 to "address" [the word used in the Practice Direction dated December 7, 2007] the issue of reversal of evidence and the schedule for the proceeding. Apotex as part of its schedule was seeking a hearing date in conjunction with another application commenced prior to this one dealing with the same patent [the Mylan Proceeding]. A reversal of evidence was consented to by the parties in the Mylan Proceeding. However, in this case, Apotex was opposed to any reversal of evidence and strongly expressed that view at the November case conference.

[10] Pfizer indicated they would therefore bring a motion for reversal of evidence. Such a motion would be for the purpose of persuading the Court that reversal would result in the just, most expeditious and least expensive determination of this application on the merits. Because the Court could not accommodate a date for such a motion for a number of months, Apotex acquiesced to a partial reversal of evidence. The parties agreed to a schedule which included the partial reversal and contemplated a hearing date in conjunction with the Mylan Proceeding.

[11] The Court issued a Direction encompassing the schedule as proposed by Pfizer as acquiesced in by Apotex. Thus, Apotex expected that it would receive all of Pfizer's fact evidence before putting forward its evidence on invalidity with particular focus on inutility.

[12] Pfizer delivered its "fact" evidence on January 15, 2013 which was comprised of the Affidavits of Drs. Manuela Berger (Berger Affidavit) and Karen Seibert (Seibert Affidavit). The Berger Affidavit was the main affidavit dealing with inutility. It contains fact evidence relating to three specific studies: CONDOR, GI REASONS and SUCCESS.

[13] Thereafter, on April 29, 2013, Apotex served its evidence including four expert affidavits three of which addressed the issue of inutility raised in the NOA. These affidavits dealt with the issues in the NOA and responded to the factual evidence in the Berger Affidavit. Several of Apotex's experts opine on issues of utility and in the affidavit of one of their experts, Dr. Flowers, the following statement is found:

> I am informed by counsel for Apotex that the Seibert Affidavit includes the factual information related to the development of the subject matter of the '576 Patent, including celecoxib, which the Applicants intend to rely upon in this proceeding. [para. 33]

[14] On August 6, 2013, Pfizer served five expert affidavits. Three of these affidavits addressed the issue of inutility: Drs. Fennerty, Tugwell and Abramson. In these affidavits there are references to 25 pieces of literature (the Impugned Evidence) which are nowhere to be found referred to in the Berger Affidavit or referred to in the notice of application. Only one of the references appears to be a study which was published after Pfizer delivered its first tranche of evidence: the Lancet 2013 meta-analysis.

[15] It is recognized by Pfizer that because of the way the Impugned Evidence has been raised that Apotex should have a right of reply. In a rare gesture of magnanimity, not often seen in these types of proceedings, Pfizer has served a "with prejudice" offer to resolve this motion on the basis of the Court granting a right of reply to Apotex subject to some restrictions. While this magnanimous gesture goes somewhat along the way to cure the mischief created by the partial reversal, it does not provide a complete answer.

[16] While there was some suggestion in argument that because it was only a Direction of the Court regarding the schedule and not a formal order it has less impact. In my view, that is not the case. Breach of an order may bring a wider range of remedies but Directions of the Court nevertheless carry the weight of judicial decision making and are not mere suggestions as to what should happen in the conduct of a case but are the expectation of what shall happen.

[17] On this motion, the parties have filed extensive materials including the various lengthy affidavits in dispute and the affidavit of a lawyer for Pfizer explaining his understanding of the meaning of "fact" evidence within the context of a proceeding under the *Regulations*. He was cross-examined at length. Because of the general rule that a lawyer should not appear as counsel and witness on a matter, and because Apotex raised this as an issue, outside counsel was retained by Pfizer to argue this motion.

Apotex's Position

[18] Apotex argues that:

> Complex, high-stakes intellectual property proceedings are governed by procedural rules aimed at fairness, full and timely disclosure, and efficiency. Purposeful, strategic conduct involving non-disclosure, non-clarification or inaction, as the Prothonotary and the Federal Court judge found here, disrespects these rules and their aims. Those who disrespect the rules and their aims can hardly expect courts to smile upon them when they look for a favourable exercise of discretion under those rules.
>
> [*Bristol-Myers Squibb Co. v. Apotex Inc.*, 2011 FCA 34 per Stratas J.A. at para. 37]

[19] To that end, it is argued that Pfizer, having made decisions regarding its "fact" evidence, it ought not now be able to effectively split its case and pour in new "fact" evidence in the guise of opinion evidence. There is obvious prejudice if a party splits its case. A party is required to put its best foot forward at the first opportunity [see, for example, *Merck-Frosst-Schering Pharma GP v. Canada (Minister of Health)*, 2009 FC 914 at para. 25].

[20] Apotex further argues that since the Impugned Evidence falls outside the scope of the intention of the Court's Direction regarding reversal, no prejudice by Apotex need be shown. Indeed, the evidence of Pfizer goes beyond replying to Apotex's evidence and introduces the Impugned Evidence. As there is obvious prejudice, I agree that Apotex need not demonstrate prejudice by way of evidence on this motion.

[21] Apotex argues that the Impugned Evidence is filed in contravention of the Court's Direction. However, there appears to be a considerable difference of opinion between counsel on the meaning of "fact" evidence. It cannot be definitively said, therefore, that the Impugned Evidence contravenes the Court's Direction.

[22] Apotex seeks as well to have adverse inferences drawn against Pfizer given matters which transpired at the cross-examination on Pfizer's affidavit in support of the motion. There was much sparring on the cross-examination over what is or is not a "fact". The general Pfizer position being that it is the expert that relies on a particular study to support an opinion so that it is not Pfizer that is relying on the fact but the expert. In my view this is just sophistry. An example is as follows:

Q. In support of the assertion that Celecoxib is, in fact, useful does your client intend to rely upon the study represented in column 2 of schedule A to Apotex's representations, namely the Emery study?

A. As support for the expert's opinion that Celecoxib is, in fact, useful.

Q. Good. Document 3, Goldstein. Is it Pfizer's intention to rely upon as a fact that the study conducted and described in Goldstein was, in fact, conducted and the results obtained were, in fact, obtained?

A. I think I would just characterize it in a slightly different way, Mr. Brodkin. All the studies listed here support the expert's opinion as to the utility of Celecoxib.

Q. Do you accept that the studies themselves are facts?

Mr. Mason: Well, that's an improper question.

Mr. Brodkin: Why?

Mr. Mason: What he accepts or doesn't accept is not relevant.

Mr. Brodkin: Good, and what he says or doesn't say is a fact or not is equally irrelevant.

Mr. Mason: No. What he accepts or doesn't accept is irrelevant. It's not a proper question. If you want to rephrase your question, I'm happy to let him answer.

Mr. Brodkin: I think the question was fine, but the objection is noted.

Q. Is that the study that run by Goldstein in schedule A, row 3, a fact?

A. Are you asking me an abstract whether or not Goldstein ran a study?

Q. Is that a fact?

A. Is that a fact? Um, well –

Q. Goldstein ran a study, is that a fact?

A. Whether Goldstein ran a study or didn't run a study?

Q. Yes?

A. Yes, it's not the type of fact that we understood would be necessary to put in amount with our factual evidence because it's the type of fact that support the expert's opinion.

Q. Are the results obtained by Goldstein a fact?

A. Same answer.

[23] The transcript is replete with cat and mouse exchanges such as this. There are also seemingly endless colloquies between counsel as to the scope and propriety of questions. The cross-examination is also punctuated with pointed exchanges between counsel and between counsel and the witness over the timing of evidence produced in the Mylan Proceeding. The expert affidavits of Pfizer in that case were delivered in a time frame that would have required Pfizer to be aware of much of the Impugned Evidence and would have known about the experts' intended use of the Impugned Evidence at the time the expert affidavits of Pfizer were delivered to Apotex in this proceeding.

[24] At the hearing of the motion, counsel for Apotex provided a summary of points from the cross-examination to demonstrate that efforts to obtain relevant information on the cross-examination were thwarted by the witness' failure to make inquiries and abide by the Direction to Attend and to properly inform himself. Twenty-two separate points are raised by Apotex to demonstrate how Pfizer has obfuscated the process and failed to properly respond to questions and the Direction to Attend.

[25] It is disappointing that this case has spawned this level of misbehaviour. It is largely based on two competing views among counsel as to the extent of "fact" evidence. There is no doubt that there are facts which form part of the Impugned Evidence which were known to Pfizer at the time it

delivered its "fact" evidence. The differences between counsel deals with how one categorizes those facts.

[26] In all, there is much merit to some of Apotex's complaints. The question is the appropriate remedy which is discussed in greater detail below.

Pfizer's Position

[27] Pfizer argues that their understanding of the Court's Direction and of the partial reversal of evidence was that it was Pfizer's internal factual evidence that was required and that it would be impossible to provide all of the references which experts might reasonably require to support their opinions.

[28] In Pfizer's Written Representations, Pfizer "understood the term 'fact evidence' in the agreed schedule to refer to the evidence of the fact witnesses that Pfizer was seeking to lead and 'non-factual evidence' to refer to the evidence of expert witnesses that Pfizer was seeking to lead" [para. 16]. It was argued that this is consistent with the approach in partial reversal orders and provides a respondent with facts it could not otherwise access.

[29] Pfizer further argues that had it understood that Apotex expected that all of the publicly available literature relating to Celecoxib that might be referred to by its experts be provided, it would not have proposed reversal of evidence. Pursuant to section 3 the Code of Conduct for Expert Witnesses [Schedule to Rule 52.2] an expert's report shall include (g) the reasons for each

opinion expressed; and, (h) any literature or other materials specifically relied on in support of the opinions.

[30] The affidavit in support of Pfizer's position explains the basis for not providing information relating to the Impugned Evidence relied upon by their experts as follows:

> . . . the applicant is in no better position to identify and provide publicly available literature, professional guidelines, reports or professional experience that supports an expert's opinion than a respondent. In my experience (and in this case, in respect of the applicant's expert evidence) this type of information is usually found be the experts themselves, as support for their opinion. Indeed, it is precisely this type of publicly available scientific information that expert witnesses routinely rely on in support of their opinions, and, under the *Code of Conduct for Expert Witnesses*, are required to attach. [para. 8]

[31] In respect of this observation it can certainly be said that it would be impossible for counsel to know all of the publicly available literature that an expert might rely upon in support of their opinions. However, in this case there was some significant amount of knowledge which Pfizer's counsel had concerning the literature to be relied upon by their experts. Of particular note is the fact that there was a concession on the cross-examination that preparation of the affidavits in the Mylan Proceeding was well underway at the time the first tranche of Pfizer evidence was served in this case.

[32] Pfizer also argues that the Impugned Evidence under attack is both admissible and relevant and that the Court on the hearing should have the benefit of a full record not a truncated record which would result from the striking of the Impugned Evidence. Pfizer argues to do so would cause enormous prejudice to Pfizer. There is no doubt that the Impugned Evidence is relevant and is

admissible. But that is not the issue. The issue is whether Pfizer has split its case and caused such prejudice to Apotex that it should be struck.

[33] In somewhat of an about face, Pfizer also argues the approach of Apotex is impractical. They point to the Supreme Court's decision in *Graat v. R.*, [1982] 2 S.C.R. 819 at p. 835 wherein it is noted that "there is little, if any, virtue, in any distinction resting on the tenuous, and frequently false, antithesis between fact and opinion. Since "the line between 'fact' evidence and 'opinion' evidence is not clear". They argue that the paragraphs of the Impugned Evidence intertwine both "fact" and "opinion". One wonders how partial reversal of evidence could possibly lead to a simplification of the proceeding and provide Apotex with a greater understanding of the case it had to meet. Such an order is an invitation to reply evidence or even sur-reply.

[34] Pfizer also argues that the striking of affidavits is an exceptional remedy. Again, this is true. It applies in cases where the affidavits are scandalous, abusive or clearly irrelevant. The jurisprudence of this Court dictates that only in those exceptional circumstances should affidavits be struck. In *Merck & Co. v. Canada (Minister of Health)*, 2003 FC 1511, Madam Justice Elizabeth Heneghan stated that "relying on the jurisprudence of this Court which makes it clear that interlocutory motions to strike affidavits should not be brought and the question of admissibility of evidence should be left to the judge hearing the application" [at para. 6; see also *Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc.* 2005 FCA 50 at para. 16; and *Proctor & Gamble v. Canada (Minister of Health)*, 2009 FC 113].

[35] Finally, there is the issue of prejudice to Pfizer. It argues that to strike the Impugned Evidence will significantly prejudice the right of Pfizer to support the utility of its patent. The record before the hearings judge will be incomplete as the experts have relied on publicly available literature to which Apotex also has access and could, but chose not to, refer to it in their evidence attacking utility.

Disposition

[36] In the end, this motion is about remedy in the face of the mischief created by a partial reversal of evidence, acquiesced to by Apotex. Misunderstandings about what is or is not "fact" evidence underlie the positions of the parties. Thus, my conclusion that this is all about remedy not admissibility.

[37] Pfizer's proposed remedy is that Apotex's complaint can be solved by way of filing reply evidence. To that end, as noted, Pfizer has served a "with prejudice" offer to Apotex permitting Apotex to file reply evidence.

[38] The remedy which Apotex seeks is to strike the Impugned Evidence in its entirety.

[39] Apotex strenuously argues that this is a case where the dictum of Justice Stratas ought to be applied and the Impugned Evidence be struck. However, it is necessary to consider the context in which Justice Stratas determined not to allow the amendment in the *Bristol-Myers* case. That case was not a proceeding under the *Regulations*, but an infringement/invalidity action which had been

ongoing for over a decade. The circumstances giving rise to this draconian result occurred because of the factual background in that case. As Justice Stratas observed at para. 34:

> For roughly an entire decade, Apotex has conducted itself in a way that suggested that the issues of lack of sound prediction and the broad inutility of nefazodone and its salts were not real questions in controversy. If they were real questions in controversy, they would have been addressed meaningfully at least at some time, if not constantly, during this decade-long litigation. Instead, those questions were no part of the discoveries or the pre-trial memoranda. Now, only at this late date – years after the exchange of pre-trial memoranda – and without any significantly new developments in the litigation, Apotex seeks a further and better affidavit of documents from Bristol-Myers and embarks upon what the Prothonotary called a "fishing expedition" concerning "the length and breadth of the development of nefazodone." Finally, as the Prothonotary also found, even now on the eve of trial Apotex cannot articulate these supposedly "real questions in controversy" with acceptable particularity. [para. 34]

[40] And further at para. 38:

> The result in this case is even clearer if we apply the admonition in *Merck*, *supra*, that the burden under the *Canderel* test is heavier when "the amendments at issue…would result in a radical change in the nature of the questions in controversy." In light of the Prothonotary's interpretation of Apotex's 2004 amendments as being restricted to liver issues and in light of the foregoing analysis, the proposed amendments would indeed result in a radical change to the nature of the questions in controversy.

[41] The *Bristol Myers* case turns on exceptional circumstances and is distinguishable in large part from this proceeding under the *Regulations*.

[42] In all, this proceeding at this juncture given that cross-examinations are planned for November 2013 and a hearing in March 2014, is in most unsatisfactory state of affairs.

[43] Both remedies proposed are on the extreme ends of the spectrum. In grappling with the two requested remedies it seems to me that there is some middle ground which will remove the prejudice and allow Apotex an opportunity to provide a fulsome reply to this Impugned Evidence which is not struck. While this case comes close to the exceptional circumstances requirement, a remedy can be fashioned to recognize the Court's approbation of the circumstances under which this state of affairs arose.

[44] Some of the opinion offered in the Pfizer expert affidavits is critical of Apotex's experts. There are comments such as: "Surprisingly, Apotex's witnesses have not addressed this meta-analysis. They have also not addressed the relevant Canadian and U.S. Guidelines on long-term NSAID drug therapy and the need for gastroprotection which also support this conclusion" [Fennerty, para. 17]; "and it is surprising to me that none of Apotex's witnesses have considered this publication" [Fennerty, para. 40]. Similarly, in paragraphs 113 through the first sentence of 116 of the Fennerty Affidavit comments are critical of Apotex's experts. All of these portions of the Fennerty Affidavit will be struck.

[45] The Abramson Affidavit is also critical of Apotex's failures to address the literature referred to for the first time in Pfizer's affidavits. For example, paragraph 89 and particularly in paragraph 138 which states: "A scientist considering this issue would certainly know about and take into consideration the Cochrane meta-analysis, and I was surprised that Apotex's experts did not do so in considering whether Celecoxib has significantly less harmful side effects than nonselective NSAIDs." Paragraphs 153, 154 and the latter half of paragraph 156 commencing with the word "Thus" are of a similar ilk. All of these portions of the Abramson Affidavit are struck.

[46] In the Tugwell Affidavit there are similar attacks on the Apotex experts. For example, in paragraph 73, Dr. Tugwell muses as follows:

> 73. As an aside, I find it curious that Apotex's witnesses chose not to review these two studies, but chose to criticize the CONDOR study primarily for elements of its design that had been based on the results of these two studies (Dr. Chan is one of the co-authors of CONDOR). In my view, Apotex's witnesses do not look at the CONDOR trial in its proper context and, in so doing, unjustly undermine the importance of its findings.

[47] It is indeed curious since Apotex had no indication that any of the studies upon which Dr. Tugwell founds his opinions would be referred to. In the circumstance of this case, it is not enough to say "Oh well, Apotex should have known about all of theses studies and commented on them". Paragraphs 85, 86 and 173 are also critical of Apotex. Thus, these paragraphs including paragraph 73 will be struck.

[48] The remainder of the affidavits are not struck. If I have missed any references in these lengthy affidavits which are critical of Apotex's experts and their failure to refer to or deal with any of the Impugned Evidence as identified in the chart attached to Apotex's Written Representations they should be brought to the attention of the Court to determine whether they should also be struck.

[49] The remaining part of the remedy is the issue of costs. It is my view that much of the mischief that has transpired has been the result of Pfizer's initial demand that there be a full reversal of evidence which resulted in only a partial reversal. The "with prejudice" Offer to Settle this motion is not a complete answer to the problem caused. Pfizer is not entitled to costs. Indeed, it is my view that Apotex should have its substantial indemnity costs of this motion. If the parties

cannot agree on the quantum, written submissions limited to three pages each may be made as to quantum within 15 days of the date of this decision.

[50] As well, Apotex should be compensated for the extra reasonable costs which are to be incurred in preparing reply affidavits. Apotex must contact these experts again and review all of this additional material with them. It is not enough to say that Apotex would have had to do it anyway had there been no reversal. Thus, the legal fees and expenses (e.g. travel costs, if any, to meet experts etc.) relating to the reply affidavits (though not the expert fees) should also be recovered by Apotex. Those costs are in any event of the cause and subject to assessment if the parties are unable to agree on the quantum.

ORDER

THIS COURT ORDERS that:

1. Paragraphs 17, 40, 113 through the 1st sentence of 116, of the Affidavit of Dr. Fennerty, sworn August 2, 2013 are struck without leave to amend.

2. Paragraphs 89, 138, 153, 154 and the latter half of paragraph 156 commencing with the word "Thus" of the Affidavit of Dr. Abramson sworn August 6, 2013 are struck without leave to amend.

3. Paragraphs 73, 85, 86 and 173 of the Affidavit of Dr. Tugwell, sworn August 6, 2013 are struck without leave to amend.

4. Apotex is granted leave to serve Reply Affidavits in response to the portions of the Impugned Evidence which has not been struck.

5. Costs on a substantial indemnity basis are payable by Pfizer to Apotex. If the parties are unable to agree on the quantum they may make written submissions to the Court within 15 days of the date of this Order, such submissions being limited to three pages (exclusive of any draft bill of costs).

6. The reasonable legal costs and reasonable disbursements of Apotex in preparing and serving any reply affidavits relating to the Impugned Evidence not struck, are to be paid by Pfizer to Apotex. Such costs do not include experts' fees.

7. In the event, the parties are unable to agree on the quantum of fees and disbursements referred to in paragraph 6, the costs shall be submitted for assessment.

8. The parties shall complete this proceeding based on the schedule established in the prior Direction of the Court.

"Kevin R. Aalto"

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

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