Federal Court Cour fédérale

Date: 20140919

Docket: T-1364-14

Toronto, Ontario, September 19, 2014

PRESENT: Madam Prothonotary Milczynski

BETWEEN:

BRISTOL-MYERS SQUIBB CANADA CO., BRISTOL-MYERS SQUIBB HOLDINGS IRELAND AND NOVARTIS AG

Applicants

and

THE MINISTER OF HEALTH AND TEVA CANADA LIMITED

Respondents

ORDER

UPON Motion dated the 11th day of August, 2014, on behalf of the Applicants, Bristol-Meyers Squibb Canada Co., Bristol-Myers Squibb Holdings Ireland and Novartis AG (together "BMS") for:

1. An Order that the schedule for the delivery of evidence be partially reversed, as set out in the proposed timetable attached as Schedule "A" to the Notice of Motion; or

2. In the alternative, should a partial reversal not be granted, an Order implementing the timetable attached to the Notice of Motion as Schedule "B";

3. An Order granting leave to the Applicants to amend their Notice of Application to reflect BMS's narrowing of the relevant issues and patent claims in a form of draft Amended Notice of Application that will be provided to the Court at or in advance of the hearing of this motion on September 16, 2014, after consent from Teva as to form and content has been sought;

4. Costs of this motion; and

5. Such further and other relief as to this Honourable Court may seem just.

AND UPON reviewing the motion records filed on behalf of the parties and hearing submissions of counsel at the hearing of the motion on September 16, 2014;

AND UPON noting that the partial reversal sought contemplates BMS delivering its fact evidence relating to the invention of each the patents in issue first, followed by Teva Canada Limited ("Teva") delivering its evidence on all issues and then BMS delivering its evidence in response to Teva's evidence on invalidity;

BMS commenced the within application in respect of the Notice of Allegation ("NOA") that was delivered by Teva on or about April 22, 2014. As reflected above in the prayer for relief, in addition to seeking a partial reversal of the usual order of delivery of evidence, BMS seeks to amend the notice of application, which is not objected to, and which will result in the proceeding being restricted to the issue of whether Teva's allegations asserting the invalidity of Canadian Patent No. 2,250,840 (the "840 Patent) and Canadian Patent No. 2,317,736 (the "736

Patent") are justified. The 840 Patent generally contains claims covering the anti-HIV compound atazanavir and its uses. The 736 Patent generally contains claims covering the bisulfate salt of atazanavir. Teva does not contest infringement of the claims of the 840 and 736 Patents. Thus, the application will be limited to the invalidity allegations in respect of claims 20-25, 28 and 29 of the 840 Patent and claims 1-2 of the 736 Patent.

With respect to the partial reversal sought by BMS, BMS submits that by knowingly drafting its NOA without critical details regarding the legal and factual basis that it intends to rely on to support its invalidity allegations, Teva has left BMS with a "mystery". As such, BMS submits that Teva is seeking some tactical procedural advantage (essentially splitting its case) by having BMS albeit the Applicant, not knowing the case to meet, proceed first with all their evidence. BMS also submits that without partial reversal, it is nearly inevitable that there will be a motion for reply evidence and a request for sur-reply.

Teva makes the same argument as against BMS – asserting that it is BMS that seeks the tactical and procedural advantage through this motion, by unfairly shifting the burden from Applicant to Respondent to go first with service of evidence, which Teva argues is particularly unfair in the context of a notice of application that it says provides little detail as to what BMS' position and arguments are on the application. Teva submits the onus is on BMS to establish that the allegations of invalidity contained in the NOA (which they say are sufficiently clear, including the legal and factual basis upon which they rely) are unjustified. Teva also adds that it is virtually guaranteed that there will be further rounds of evidence for which leave will be sought if the partial reversal is granted, and notes that already, with the order of evidence

proposed by BMS, there is the extra step of BMS delivering its factual evidence relating to validity.

I cannot conclude who (if anyone) would bring or resist a motion to gain some procedural or tactical advantage, but strongly suspect that on the matter of whether or not there will be further motions relating to additional evidence, both parties are correct.

Nonetheless, the specific complaints lodged by BMS regarding the NOA that BMS submits make clear that a partial reversal is necessary for the proper conduct of this application, are set out in paragraph 10 of BMS' notice of motion:

> (a) The NOA provides no facts whatsoever as to the level of education, training and experience of the alleged skilled person in the art, whose key perspective frames the invalidity analyses and defines the relevant content of the common general knowledge.
>
> (b) The NOA does not detail the relevant common general knowledge and it appears to be broader in scope than the prior art references including undisclosed information.
>
> (c) With respect to obviousness, the NOA alleges the inventive concept and differences from the state of the art for the '840 Patent claims; however, the NOA is completely silent on these key issues in relation to the claims of the '736 Patent.
>
> (d) Teva broadly asserts that it relies upon the entirety of the Schedule B and C [prior art] references (spanning a multitude of diverse journal publications, book chapters and patents). However, many of these references are not even discussed in the NOA. For those that are, the majority of their content is ignored, but Teva is supposedly relying on the entirety of this content in some undisclosed, hidden and yet-to-be-revealed manner.
>
> (e) Teva advances bald allegations that the claims of the 840 and 736 Patents are invalid for inutility, insufficiency, and anticipation, without describing how the patents lack utility

> as defined under section 2 of the *Patent Act*, how the patents are not fully described in accordance with section 27(3) of the *Patent Act*, and how the claimed inventions are disclosed and enabled under anticipation law.

BMS relies on the evidence of Drs. Mark Lautens and Stephen Byrn who state that they are unable to understand or anticipate what Teva will deliver in its responding evidence, or how Teva and its experts will rely on the prior art in Schedules B and C to support Teva's invalidity allegations.

Indeed, Dr. Lautens states in paragraph 12 of his affidavit that he was asked to review the 840 Patent, the Teva NOA and the references in Schedule B to the NOA and determine whether he is able to understand/appreciate/anticipate how Teva might use the Schedule B prior art to support the NOA allegations of obviousness and lack of utility regarding the 840 Patent. Dr. Byrn was given a similar mandate in respect of the 736 Patent and the references contained in Schedule C of the NOA. Both review in detail the NOA and the Schedules that relate to their respective mandates and note what in the Schedules are not discussed or referenced in the body of the NOA. Both also state that the absence in Teva's NOA of any statement as to the characteristics (ie. education, training and experience) and common general knowledge of the alleged person skilled in the art makes it difficult to anticipate what Teva might advance to support its allegations of invalidity (on any grounds).

Teva has filed the evidence of Drs. Lawrence Kruse and Harry Brittain who both state that they cannot comprehend how Drs. Lautens and Byrn could not understand the content and intent of the NOA. They also state that an ordinary person skilled in the art would be able to read and understand the NOA without difficulty and understand that the prior art cited in

Schedules B and C that is not specifically referenced or discussed in the body of the NOA clearly provides an overview of the common general knowledge at the relevant time.

What is not in dispute is that it is BMS's burden to establish that partial reversal will lead to efficiencies, that there are special circumstances and that a benefit (savings in time, expense and resources) will be realized by the partial reversal. A reversal/partial reversal is, even in the unique context of PMNOC proceedings, an exception to the ordinary course for the delivery of evidence that should only be ordered in the clearest of cases. As noted in *Biovail Corp. v. Canada (Minister of Health)* 2008 FC 1162, some basis must be established for the court to conclude that the proposed reversal will more likely than not:

(1) narrow the issues;

(2) lead to a more streamlined proceeding;

(3) reduce the need for judicial intervention;

(4) reduce the use of judicial resources (eg. further motions for leave to file reply evidence); and

(5) result in fairness to the parties.

As further noted in *Pfizer Canada Inc. v. ratiopharm Inc.* Court File No. T-1422-09 and *AstraZeneca Canada Inc. v. Teva Canada Limited* Court File No. T-1259-11, a reasonably accessible NOA (namely one that provides a "road map") will work against a reversal of the order of evidence. A large number of prior art references alone will also not create the special circumstances that support reversal/partial reversal.

With respect to the within motion, the issue is not whether BMS or Drs. Lautens and Byrn can anticipate what Teva and its experts will say. BMS should focus on what the NOA already says, which on the motion material filed it appears they readily can.

The NOA is 30 pages in length and includes 22 prior art references in Schedule B for the 840 Patent and 37 prior art references in Schedule C for the 736 Patent (4 of which are duplicates). The NOA (pp.15-22) alleges invalidity of the 840 Patent on the bases of obviousness; selection patent related issues (leading to invalidity for lack of utility, insufficiency, obviousness and anticipation), obviousness double patenting/improper selection (leading to invalidity for lack of utility, insufficiency obviousness and anticipation) and lack of utility (see also NOA refs at paras. 34-38 of Teva's written representations). Similarly the NOA (at pp. 22-30) alleges invalidity of the 736 Patent on the bases of obviousness, double patented/anticipated/lacks utility/insufficient in view of the 840 Patent, lack of utility and claims broader (see also NOA refs at paras.. 40-44 of Teva's written representations).

On cross-examination, Teva provided the NOA and the 840 Patent to Dr. Kruse and the NOA and the 736 Patent to Dr. Brittain – each confirmed that they were able to comprehend and appreciate the allegations made in the NOA related to the patent each was given. As noted by Teva, neither Dr. Kruse nor Dr. Brittain had any difficulty in understanding what was being alleged, what the arguments were that were being advanced and that it would be so for any ordinarily skilled reader.

Accordingly, I am not satisfied that BMS is unable or that it would be unfair for it to proceed in the usual way and as Applicant, deliver its evidence first. I am also not satisfied that any efficiency or cost-saving will be achieved by the partial reversal. The partial reversal

already requires the extra step of BMS delivering its fact evidence relating to the invention first – and there is but a dismal prospect at best, of there not being further motions for leave to file additional evidence.

THIS COURT ORDERS that:

1. The motion for a partial reversal of the order of evidence is dismissed.

2. Subject to any further order or direction of the Court, the timetable for the completion of the remaining steps in this application is as follows:

   a. The Applicants' evidence shall be served no later than November 19, 2014.

   b. Teva's evidence shall be served no later than March 30, 2015.

   c. The Applicants shall serve and file a requisition for hearing by April 28, 2015.

   d. The parties shall confirm whether a Rule 312 or s.6(5) motion pursuant to the PMNOC Regulations is anticipated and shall request a case management teleconference (if a motion or motions are to be brought) by April 20, 2015.

   e. Any motion referred to in para(d) shall be served and filed by May 4, 2015. Responding record(s) shall be filed by May 18, 2015.

   f. Cross-examinations if any shall be completed by August 14, 2015.

   g. The Applicants' Application Record shall be served and filed by September 25, 2015.

   h. Teva's responding Application Record shall be served and filed by November 13, 2015.

3. Leave is granted to the Applicants to file, with proof of service, the amended notice of application.

4. In the event the parties cannot agree on the costs of this motion, written submissions may be filed, no longer than three pages in length, within 15 days of the date of this Order.

"Martha Milczynski"
Prothonotary

I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the 19th day of September A.D. 20 14

Dated this 19th day of September 20 14

ABIGAIL GRIMES
REGISTRY OFFICER
AGENT DU GREFFE