Conseil d'examen du prix des médicaments brevetés

PMPRB-02-D1-REMICADE

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Schering Canada Inc. (the "Respondent") and the medicine "Remicade"

APPLICATION FOR LEAVE TO INTERVENE

The Board received an application from Cameron Smith to intervene in this proceeding. The application came in the form of a letter from Mr. Smith in which he noted the impact that Crohn's disease has on his life and the cost of the Remicade treatment he takes to ameliorate his symptoms. He stated that he wished to argue that the price of Remicade is "grossly excessive".

Schering Canada Inc. ("Schering") submitted detailed written submissions contending that Mr. Smith should not be granted intervenor status. In summary of Schering's submissions, it was argued that Mr. Smith would not provide evidence relevant to the matters in issue in this proceeding.

The Board was satisfied that, while the particulars of Mr. Smith's condition and the impact of the pricing of Remicade on him personally would be of little or no relevance to the application of the Board's pricing Guidelines to the pricing of Remicade, it was possible that Mr. Smith would provide relevant evidence on the reasonableness of the Guidelines. Accordingly, the Board determined that he should be granted intervenor status in this proceeding.

Schering, in its written submissions on Mr. Smith's intervention, had argued that if Mr. Smith was granted intervenor status, it should be a restricted status. The Board was inclined to agree with Schering on this point and considered that Mr. Smith's role as an intervenor should be limited to presenting his own evidence under oath, subject of course to cross-examination, if any. At the Pre-hearing Conference, the Board communicated this inclination to Schering and asked if Schering thought that this was an appropriate role for Mr. Smith to play as an intervenor.

Schering argued that Mr. Smith should have an even more restricted role. Schering argued that Mr. Smith should not be entitled to give evidence under oath, but only to provide his "perspective" by making a "statement" that would not constitute evidence. Schering's argument was that Mr. Smith had not, in his application for intervenor status, discussed any topic relevant to the issues in this proceeding and thus should not be allowed to give any evidence.

The Board is satisfied that Mr. Smith could present evidence relevant to the reasonableness of the Board's pricing Guidelines. If he presents other evidence that is not relevant to the issues in this proceeding, the Board will give that evidence no weight. The Board makes decisions based on evidence that is on the record in its proceedings and cannot have reference to a "statement" that is not evidence.

Accordingly, the Board has decided that Mr. Smith's role as an intervenor will be limited to presenting evidence under oath. He may do this by providing a summary of his evidence by way of a witness statement, to be filed on the date that Board Staff will be providing its witness statements (April 7, 2003), and then appear at the proceeding to give evidence. If Mr. Smith takes this route, his evidence would be presented after that of Board Staff and before that of Schering. Alternately, Mr. Smith may file a sworn affidavit on or before April 7, 2003, and if Schering elects not to cross-examine him, he will not be obliged to but may attend at the hearing to give *vive voce* evidence.

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Board Members: Robert G. Elgie

Réal Sureau

Thomas (Tim) Armstrong Anthony Boardman

Board Counsel: Gordon Cameron

Sylvie Dupont Secretary of the Board

February 17, 2003