PATENTED MEDICINE PRICES REVIEW BOARD

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

AND IN THE MATTER OF
Horizon Pharma (the "Respondent")
and the medicine Cysteamine Bitartrate sold by the Respondent under the trade name Procysbi

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BOOK OF AUTHORITIES OF BOARD STAFF

(Motion to Bifurcate, Strike Evidence, and for the Inspection and Production of Documents)

DATED October 24, 2019

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TAB 1

IN THE MATTER OF the *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3rd Supp.), and as further amended by S.C. 1993, c. 2

AND IN THE MATTER OF Canadian Patent Nos. 997,756, 1,028,264, 1,261,265, 1,297,057 and 1,297,058

AND IN THE MATTER OF ICN Canada Ltd. and ICN Pharmaceuticals Inc. (Respondents)

HEARING ON THE MERITS

DECISION/REASONS
PMPRB-95-D5/VIRAZOLE

INTRODUCTION

History of the Proceeding

On August 15, 1995, the Chairperson of the Patented Medicine Prices Review Board issued Notice of Hearing PMPRB-95-1 (the "Notice of Hearing"), pursuant to sections 83 and 86 of the *Patent Act* (the "*Act*"), in relation to Canadian Patents Nos. 997,756 (" '756") and 1,028,264 (" '264") granted to ICN Pharmaceuticals Inc. (U.S.A.) and expired respectively on September 28, 1993 and March 21, 1995. The Board named ICN Canada Ltd. and ICN Pharmaceuticals Inc. (hereafter the "Respondents") as Respondents in the Notice of Hearing.

The purpose of the proceeding commenced by the Notice of Hearing (the "Proceeding") was to consider whether the Respondents had, while patentees, sold the medicine known as Virazole in any market in Canada at a price that, in the Board's opinion, was excessive and, if so, what order, if any, should be made.

As in all proceedings held pursuant to sections 83 and 86 of the *Act*, the case against the Respondents was presented to the Board by a team drawn from the staff of the Board, separated from the Board members, and represented by its

own separate legal counsel ("Board Staff"). The parties to the Proceeding were thus Board Staff and the Respondents.

The Notice of Hearing scheduled a pre-hearing conference for November 7, 1995 and a hearing on the merits for December 11, 1995. By letter dated August 15, 1995 accompanying the Notice of Hearing, the Board also scheduled a hearing in respect of any preliminary matters for September 26, 1995 (subsequently postponed to September 27, 1995 at the request of the Respondents).

On September 8, 1995, the Respondents filed a Notice of Motion with the Board seeking an order that the Board is without jurisdiction to investigate, hold hearings or make any order in relation to the medicine Virazole. The Notice of Motion also sought an order providing for the confidentiality and non-disclosure of certain documents and an order amending a form relating to Virazole previously filed with the Board by ICN Canada Ltd. pursuant to the *Patented Medicines Regulations* ("*Regulations*").

On September 27, 1995, Board Staff filed a Notice of Motion for an order to amend the Notice of Hearing by adding thereto further patents pertaining to Virazole.

These patents were Canadian Patent Nos. 1,261,265 (" '265"), 1,297,057 (" '057") and 1,297,058 (" '058"), copies of which were obtained by Board Staff on September 26, 1995. The Respondents consented to the amendment of the Notice of Hearing as requested by Board Staff and the Board postponed the hearing on preliminary matters scheduled for September 27, 1995 to November 2 and 3, 1995.

On September 28, 1995, the Board issued an Amended Notice of Hearing reflecting the addition of the '265, '057 and '058 Patents as patents pertaining to Virazole.

On October 20, 1995, the Respondents filed an Amended Notice of Motion, revised to be responsive to the Amended Notice of Hearing.

The Parties pre-filed with the Board the affidavit evidence of their witnesses together with copies of the documents to be relied on by each such witness.

On November 2 and 3, the Board heard the cross-examination of the evidence of several of the witnesses and argument on its jurisdiction with respect to the matters described in the Amended Notice of Hearing.

On November 30, 1995, the Board issued its decision with respect to its jurisdiction in this case. In summary, the Board concluded that with respect to both the '264 and '265 Patents, the Respondents are patentees of patents for inventions which pertain to the medicine Virazole. Accordingly, the Board has jurisdiction over the actions of the Respondents with respect to the price at which they have sold Virazole in any market in Canada at all times material to the issues raised by the Amended Notice of Hearing. The '756 Patent pertained and expired on September 28, 1993. With respect to the '057 and '058 Patents, Board Staff accepted that the Respondents had no rights in relation to the said patents and thus they were not relevant to the Proceeding.

It remained to be determined whether the Respondents have sold Virazole at a price that, in the Board's opinion, is or was excessive and whether the Respondents have engaged in a policy of selling Virazole at an excessive price.

On December 1, 1995, the Respondents filed a Motion with the Federal Court of Canada for judicial review of the Board's decision. On December 6, the Federal Court denied the Respondents' application to stay the Board's proceeding. The application for judicial review was heard on January 29, 1996.

The Board's hearing had been scheduled to commence on January 22, 1996 but was delayed for the imminent hearing of the application for judicial review.

On December 1, 1995, ICN Canada Ltd. disclaimed, under the *Act*, certain parts of the '265 Patent.

On February 15, 1996, the Federal Court issued its decision denying the injunctive relief sought by the Respondents and upholding the Board's decision. In addition, the Court concluded that the disclaimer by ICN Canada Ltd. with respect to the '265 Patent was invalid and did not affect the jurisdiction of the Board.

On February 21, 1996, the Respondents appealed to the Federal Court of Appeal and the appeal was heard on May 21, 1996. The decision was reserved. As of this date, the Federal Court of Appeal has not issued its decision on the appeal.

On March 22, 1996, Board Staff filed a Motion for the Board to issue an order requiring the Respondents to provide various items of information and documentation.

The Board heard the parties on March 26, 1996 and concluded on March 28 that in order to address properly the issues raised in the Amended Notice of Hearing

in this matter, and in order to determine the correctness and reasonableness of the position taken by the Respondents in their Response and in the outlines of evidence they provided, it was necessary to obtain the information and documentation requested by Board Staff in its Motion.

The hearing on the alleged excessive pricing of Virazole commenced on April 9, 1996 and concluded on July 4, 1996.

The evidence established that ICN Canada Ltd. has been selling Virazole in Canada since 1986. For the period up to September 28, 1993, the Respondents acknowledged that the Board had jurisdiction to regulate the price of Virazole in Canada. On February 1, 1994, ICN Canada Ltd. took the position that on the expiry of the '756 Patent, that is on September 28, 1993, it was no longer subject to the Board's jurisdiction. Effective January 1, 1994, the Respondents increased the price of Virazole to $750 per vial from $409 per vial, and subsequently, in late 1994, to $1,540 per vial.

THE ISSUES BEFORE THE BOARD IN THIS PROCEEDING ARE AS FOLLOWS:

1. Whether either Respondent has sold Virazole in any market in Canada at an excessive price within the meaning of section 83 of the *Act*;

2. Whether either Respondent has engaged in a policy of selling Virazole at an excessive price within the meaning of section 83 of the *Act*;

3. If the Board finds that either Respondent has sold or engaged in a policy of selling Virazole at an excessive price, the Board must consider what order, if any, is appropriate pursuant to section 83 of the *Act*.

ISSUE 1: Whether either Respondent has sold Virazole in any market in Canada at an excessive price within the meaning of section 83 of the *Act*.

(i) The Board's Guidelines

Subsection 96(4) of the *Act* allows the Board to issue guidelines with respect to any matter within its jurisdiction. The Board issued its Excessive Price Guidelines in July 1988 and has revised them from time to time. The most recent version of the Guidelines was consolidated and

issued in April, 1994, and is contained in the Board's *Compendium of Guidelines, Policies and Procedures*.

The Guidelines were established to assist patentees and Board Staff in understanding the analysis and considerations that are relevant to the Board in determining whether or not the price of a patented medicine is or will be excessive, but the Guidelines are not binding on the Board or any patentee.
The language and logic of the Guidelines is to illustrate the manner in which the Board will determine a "maximum non-excessive price" ("MNE") for a medicine. The Guidelines were established as a way to implement the criteria for determination of excess prices as set out in section 85 of the *Act*. As discussed in greater detail below, the Guidelines describe various tests which might apply depending on the circumstances of a particular medicine, but in all cases the application of the Guidelines will result in the determination of a price (the MNE) that may be presumed by the patentee not to be excessive. Conversely, sales by the patentee at a price above the MNE (on an annual average basis) can be expected to be of concern to the Board and can be expected to invoke a review by Board Staff as to whether or not the medicine is being sold at an excessive price.

If Board Staff come to a conclusion that, in their view, a patentee is selling a medicine at an excessive price, and if efforts at resolution of the matter on a voluntary compliance basis are not successful, Board Staff can request the Board to hold a hearing at which the matter will be determined.

Though Board Staff's decision to bring the matter before the Board will likely be informed by the price of the medicine relative to the MNE set in accordance with the Guidelines, the Board itself looks at the issue afresh to determine whether or not the medicine is being sold at an excessive price. Nevertheless, the Guidelines have been issued by the Board after considerable deliberation and consultation by the Board with interested parties. Accordingly the Guidelines will be given due consideration in the course of the Board's review of the matter.

The onus is on Board Staff to establish that the price at which a medicine is or has been sold is or was excessive. This is not simply a matter of Board Staff demonstrating that the price has exceeded the MNE as derived by the application of the Guidelines. The Board is examining the issue in accordance with the criteria for determination of excessive prices as set out in section 85 of the *Act*, and if the Board Staff's case is

premised on pricing which exceeds the MNE price as established by the Guidelines, it is for Board Staff to satisfy the Board that the Guidelines do and should apply with respect to the medicine in question. There is no onus on the patentee to satisfy the Board that the Guidelines should not apply.

(ii) ICN Canada Ltd.

ICN Canada Ltd. plainly has sold and does sell Virazole in Canada. Accordingly the Board must consider whether those sales are or have been at excessive prices.

(a) The Relevant Criteria

Subsection 85(1) of the *Act* provides as follows:

> 85(1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
>
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

(d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.

It was agreed by the parties that at this time there is no other medicine in the same therapeutic class as Virazole. There have been no regulations passed for the purposes of this subsection. Accordingly the only relevant criteria are those in clauses 85(1)(a), (c) and (d).

(b) The position of the Respondents regarding the interpretation of subsection 85(1)

Counsel for the Respondents argued that subsection 85(1) of the *Act* is not restrictive, and that the Board, in coming to its conclusion on whether or not Virazole is or has been sold at an excessive price, is permitted to examine factors other than those enumerated in that subsection. In particular, the Respondents argue that the Board should, in making its determination on this matter pursuant to subsection 85(1), have regard to the costs that ICN Canada Ltd. incurs in making and marketing (which the Board takes to include "acquiring" where appropriate, as in this case) Virazole. In order to assess this argument it is necessary to examine the language of section 85 of the *Act*.

Subsection 85(1) provides that the Board "shall" determine the matter on the basis of the factors set out in that subsection, the last of which is:

> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.

Subsection 85(2) of the *Act* provides as follows:

> 85(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:

(a) the costs of making and marketing the medicine; and

(b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

It seems apparent to the Board, then, that it is instructed by the *Act* to first attempt to determine the matter by reference to criteria established by Parliament in subsection 85(1) of the *Act* or by regulations pursuant to that subsection, and only if that exercise is not successful should the Board consider factors such as the costs of making and marketing the medicine or other factors the Board considers appropriate pursuant to clause 85(2)(b). Accordingly the Board concludes that its deliberations pursuant to subsection 85(1) are indeed restricted to the factors set out in that subsection or in regulations passed pursuant to that subsection.

It is not appropriate for the Board, in its deliberations pursuant to subsection 85(1), to consider the costs to ICN Canada Ltd. of making and marketing Virazole.

(c) Clause 85(1)(a): The Virazole Pricing History

As noted above, the Board was established by amendments to the *Act* in December 1987. Virazole was sold in Canada by ICN Canada Ltd. before 1987, and during that period the price at which Virazole was sold was not regulated by any government authority. At that time ICN Canada Ltd. had the benefit of patents (the '756 and '264 Patents) for two processes for the production of Virazole and ICN Canada Ltd. was the only source in Canada of Virazole or any comparable antiviral medicine. Accordingly, before the establishment of the Board, Virazole was sold in Canada by ICN Canada Ltd. at a price established by ICN Canada Ltd.

The Board's Guidelines provide that the prices of medicines being sold in Canada at the time of the Board's inception will be presumed not to be excessive. This appears to be a reasonable conclusion in this case, and certainly one which is eminently fair to the Respondents.

(d) Clause 85(1)(d): Changes in the Consumer Price Index

The Guidelines provide that the initially-established non-excessive price of a medicine (in the case of Virazole, its average price in 1987) is the "benchmark price", and the MNE is the benchmark price as adjusted

(typically increased) in accordance with the Consumer Price Index ("CPI") from year to year.

Again, while the Board is not bound by its Guidelines, the Board is satisfied that in this case the Guidelines are entirely consistent with the *Act* and the Board accepts that the use of the CPI to adjust the MNE of Virazole from the benchmark price from year to year is appropriate.

Furthermore, the Board notes that ICN Canada Ltd. did not raise any objection to the establishment of its pre-regulation market price as the initial MNE and thus the benchmark price, nor to the use of the CPI to adjust that price from year to year from 1988 until these proceedings. Indeed, in June, 1990, the Board wrote to ICN Canada Ltd. to inquire as to whether ICN Canada Ltd. accepted the initial benchmark price and the use of the proposed CPI methodology. ICN Canada Ltd. responded confirming the benchmark price and indicating that the CPI methodology would be used to adjust the benchmark price.

A secondary issue arose in the hearing as a result of amendments effective January 1994, which altered the methodology by which the CPI was applied to determine the MNE from year to year. Given the change that these amendments introduced in the reference period for application of the CPI, it was possible for the amendments to have the effect of actually reducing the MNE of a medicine. This effect was not intended and so the Board applied a transitional measure stipulating that a patentee who faced a price reduction "solely" as a result of the application of the new methodology would not have to reduce its price below the pre-amendment MNE. Board Staff argued that, since ICN Canada Ltd. faced a reduction in the price of Virazole both because of the new methodology and because of its decision to increase the price of Virazole beyond the MNE, ICN Canada Ltd. should not have the benefit of the transitional measure.

The Board is satisfied that the wording of the transitional measure was not intended to deny ICN Canada Ltd. the benefit of that measure in the circumstances of this case. Accordingly the Board concludes on this issue that the MNE for Virazole should be calculated by application of the transitional measure.

(e) Clause 85(1)(c): The Price of Virazole in Other Countries

The price at which a medicine is sold in other countries will not usually be a determining factor where a benchmark price has been established

based on a history of sales in Canada. Though the Board's Guidelines do provide that the price of a medicine will be considered excessive if it is higher in Canada than in any other of the countries listed in the *Regulations* (Germany, France, Italy, Sweden, Switzerland, the United Kingdom and the United States), Virazole is not so priced and thus that factor is not material to the Board's consideration in this case.

While large and consistent deviations in the price of a medicine in other countries relative to the Canadian price could be significant to the Board, the multitude of factors that could be influencing the foreign prices, but that are not relevant to the Canadian market, makes it preferable to the Board to use the Canadian pricing history where it is available.

Nonetheless, the Board did receive evidence on the prices of Virazole in the countries listed in the *Regulations*. The evidence was not entirely satisfactory because the comparison was to the "list" prices of Virazole abroad. The Board's Guidelines do suggest reference to list prices where the foreign prices are material to the Board's deliberations because it is difficult to obtain information on actual selling prices. The list prices in Canada and abroad are often discounted and so the comparison may not be reliable.

In any event, having considered such evidence on the foreign prices as was available, the Board concludes that those prices did not differ sufficiently from the actual prices in Canada to alter the Board's conclusions based on the Canadian pricing history and the CPI.

(f) Conclusion

The Board is able to determine a MNE by the application of the criteria set out in subsection 85(1). That price is the price that the Board has established from year to year as the MNE for Virazole by the use of the benchmark price of Virazole (the average price during 1987) as adjusted by the CPI.

While this conclusion has necessarily only been reached with reference to the years 1988 to 1996, the Board cannot at this time foresee any reason why the MNE for Virazole would be determined in any other way from 1997 to 2006, at which time the '265 Patent expires.

(g) Subsection 85(2)

Having been able to determine, through the application of the criteria set out in subsection 85(1), that the price at which Virazole was sold in Canada since January 1994 was excessive, there remains the issue of the relevance, if any, of the criteria in subsection 85(2) of the *Act*. As can be seen in the sections of the *Act* set out above, unlike the mandatory "shall" of subsection 85(1), subsection 85(2) provides that the Board "may" consider the criteria set out in that subsection where the Board is unable to determine the matter on the basis of the criteria set out in subsection 85(1).

The Board has been able to make its determination on the basis of the criteria set out in subsection 85(1) and it was therefore not necessary to evaluate the evidence of ICN Canada Ltd. concerning the costs it incurs in making and marketing Virazole in Canada, nor the responding evidence of Board Staff on this issue.

However, for the benefit of patentees who are, or might in the future be, subject to the Board's jurisdiction, the Board would like to comment on the position of the Respondents that the price of Virazole could not possibly be said to be excessive if the costs of making and marketing the medicine exceeded the revenue from sales.

There would have to be compelling reasons for the Board to determine the MNE on the basis of a patentee's costs of making and marketing a medicine and it seems likely that the instances in which that analysis will be appropriate will be rare. However, it is not inconceivable that, where the criteria in subsection 85(2) were properly being considered by the Board, a patentee could present evidence which would satisfy the Board that the MNE for a medicine could be established by reference to the costs of making and marketing the medicine.

Nonetheless, even where the Board is instructed by the *Act* that it may consider such evidence, it is not axiomatic that in each case the costs of making and marketing the medicine will establish a floor for the MNE of the medicine. While each case would have to be considered on its merits, it seems probable that the Board would, pursuant to clause 85(2)(b), examine the broader context in which the situation arose before coming to a conclusion on the point. Also, it will always be for the Board itself, after consideration of the relevant evidence, to make its own determination on the identification, characterization and relevance of

each element of costs alleged by a patentee to comprise part of the costs of making and marketing the medicine.

Finally, it should be noted that, given the potentially complex and contentious nature of the financial and accounting evidence on this issue, the Board expects that the determination of a MNE by reference to the costs of making and marketing the medicine would only be possible where the Board received clear and reliable evidence on the point.

(iii) The prices at which Virazole has been sold in Canada

The history of the price of Virazole has been outlined in the comments that introduced this decision. Attached as Appendix A to this decision is a table prepared by Board Staff detailing this pricing history.

It is plain that these prices exceed the maximum non-excessive price determined in this decision, and accordingly in its finding on the first issue, the Board concludes that ICN Canada Ltd. has sold Virazole in Canada at an excessive price from January 1994 to the present time.

(iv) ICN Pharmaceuticals Inc.

For the reasons set out below regarding the policy of excessive pricing, the Board concludes that ICN Pharmaceuticals Inc. has sold Virazole in Canada at an excessive price from January 1994 to the present time.

ISSUE 2: Whether either Respondent has engaged in a policy of selling Virazole at an excessive price within the meaning of section 83 of the *Act*.

(i) ICN Canada Ltd.

Subsection 83(4) of the *Act* provides as follows:

> 83(4) Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will in the Board's opinion offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price.

The "extent" of the increases in the price of Virazole beyond its MNE was considerable, representing an approximate doubling and then redoubling of the price from 1993 to 1994. Counsel for the Respondents himself referred to these price increases as "enormous". The "duration" of the price increases has been substantial and permanent: the price increases were instituted in 1994 and have endured to the most recent period for which ICN Canada Ltd. has filed pricing information with the Board, that is to December 31, 1995.

Also, the price increases were intentional and undertaken with knowledge that the resulting price of Virazole would exceed significantly the MNE for Virazole.

The Respondents argued that, despite these factors, the price increases should not be characterized as a policy of excessive pricing because ICN Canada Ltd. believed that as of September 1993 it was no longer subject to the jurisdiction of the Board.

The evidence on this point did not satisfy the Board. ICN Canada Ltd. alleged that it obtained legal opinions in late 1993 (as regards the '265 Patent) and early 1994 (as regards the '264 Patent) to the effect that the patents did not pertain to Virazole. However, these opinions were not put on the record during the hearing and the Board does not know the wording of the opinions. It is apparent from the Securities Exchange Commission 10K filing of ICN Pharmaceuticals Inc. that the company considered itself to have the benefit of two Canadian patents which were to expire respectively in 1994 and 2006 and that these patents would provide it with material patent protection for its sales of Virazole. These two Canadian patents are undoubtedly the '264 and '265 Patents. Yet the evidence of the Respondents was that on the strength of a legal opinion obtained by ICN Canada Ltd., the decision was made not to disclose the existence of the '265 Patent to the Board, even in the face of the specific question from Board Staff as to whether or not any patents other than the '264 Patent pertained to Virazole.

It was the position of Board Staff that ICN Canada Ltd. "took a chance" by increasing the price of Virazole without waiting for a ruling by the Board or the Federal Court confirming its position that the Board did not have jurisdiction in the matter. Board Staff argued that ICN Canada Ltd. knew that there was a possibility that the Board and the courts would determine that the Board had jurisdiction and that the price increases would attract the sanctions of the *Act*.

While the Board agrees with these submissions of Board Staff, it would not be necessary for the Board to find that ICN Canada Ltd. had knowledge of the uncertainty of its position and the risks it was taking in increasing its prices. It is

the Board's view that a patentee's mistaken understanding of the law does not insulate the patentee from a finding by the Board that the patentee has engaged in a policy of excessive pricing.

Accordingly the Board concludes that ICN Canada Ltd. has engaged in a policy of excessive pricing since January 1994.

(ii) ICN Pharmaceuticals Inc.

The evidence before the Board established that ICN Canada Ltd. is the wholly owned subsidiary of ICN Pharmaceuticals Inc., and that the increases in the price of Virazole from 1994 to the present were at the direction of ICN Pharmaceuticals Inc. Indeed, the evidence of the Respondents was that the price increases were at least in part implemented in order to protect ICN Pharmaceuticals Inc.'s American market for Virazole, which, it was alleged (though without support from the evidence), might otherwise be imperiled by the "grey marketing" in the United States of Virazole purchased in Canada.

Though the wording of the *Act* does not expressly describe aiding, abetting or assisting in a policy of excessive pricing, this Board is not blinded by a corporate veil to the reality of this situation. The actions of ICN Canada Ltd. were in all relevant senses the actions of ICN Pharmaceuticals Inc. Also, through its sole ownership of ICN Canada Ltd. and as beneficiary of the Canadian price increases (as ICN Pharmaceuticals Inc. saw it) in protecting its sales of Virazole in the United States, the actions of ICN Canada Ltd. were for the exclusive benefit of ICN Pharmaceuticals Inc. ICN Pharmaceuticals Inc. was the directing mind of ICN Canada Ltd. and the Board could not effectively carry out its mandate if it could not address the actions of a parent company acting in this manner through its wholly owned subsidiary.

Accordingly, for the reasons given above with respect to ICN Canada Ltd., the Board concludes that ICN Pharmaceuticals Inc. has engaged in a policy of excessive pricing since January 1994.

The Respondents argued that they were prejudiced by what they submitted was the slow pace at which the Board dealt with the issue of whether the '264 Patent pertained to Virazole. On the evidence before the Board it is apparent that the Respondents did not suffer any such prejudice and acted throughout these events independently of any position taken by Board Staff.

ISSUE 3: What order, if any, is appropriate pursuant to section 83 of the *Act*.

Section 83 of the *Act* provides as follows:

83 (1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

(2) Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:

(a) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

(b) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or

(c) pay to Her Majesty in right of Canada an amount specified in the order.

(4) Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price, the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will, in the Board's opinion, offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price.

For the reasons set out above with respect to the first issue, the Board orders that the maximum non-excessive price for Virazole for the years 1994 to 1996 was and is the price calculated by Board Staff by application of the Guidelines, except that ICN Canada Ltd. shall be given the benefit of the transitional

measures with respect to the introduction in 1994 of the new methodology for the calculation of CPI adjustments.

With respect to the Board's finding that the Respondents engaged in a policy of excessive pricing, the Board concludes that the actions of the Respondents warrant the exercise of the Board's remedial power to the full extent permitted by the *Act*, that is an order which will recover twice the cumulative excess revenues received by ICN Canada Ltd. to date. Accordingly, pursuant to the provisions of subsection 83(4) of the *Act*, the Board makes the following order in lieu of an order under subsection 83(1) or (2) of the *Act*:

i) ICN Canada Ltd. shall, no later than August 5, 1996, report to the Board with respect to the volume and prices of sales of Virazole in Canada from January 1, 1996 to July 31, 1996. Within ten days of the receipt of this information, Board Staff shall calculate the total excess revenues received by ICN Canada Ltd. from January 1, 1994 to July 31, 1996, and this information shall be provided to the Board and ICN Canada Ltd.;

ii) ICN Canada Ltd. and/or ICN Pharmaceuticals Inc. shall, no later than August 26, 1996, make a payment or payments to Her Majesty in right of Canada in the total amount of $1,200,000. The obligation to make payment in this amount shall be that of ICN Canada Ltd. and ICN Pharmaceuticals Inc. jointly and severally;

iii) From and after August 1, 1996, the average price (on an annual basis) at which Virazole is sold in Canada shall be reduced to an amount that is $200 per 6 gram vial less than the MNE for Virazole in each year. For the purposes of calculating the future MNE for Virazole, sales of Virazole at prices reduced in accordance with this order shall be deemed to have been made at the applicable MNE for Virazole;

iv) The price reduction described in paragraph (iii) shall remain in effect until the earlier of December 31, 1999, or the date on which an amount equal to twice the cumulative excess revenues (as calculated pursuant to paragraph (i) above) has been offset by the sum of the amount paid pursuant to paragraph (ii) above and the cumulative price reductions pursuant to paragraph (iii) above;

v) In the event that the cumulative excess revenues have not been offset by December 31, 1999, ICN Canada Ltd. and/or ICN Pharmaceuticals Inc. shall, no later than January 31, 2000, make a payment or payments to Her Majesty in right of Canada equal to the balance of excess revenues

outstanding as at December 31, 1999. The obligation to make any payment required by this paragraph shall be that of ICN Canada Ltd. and ICN Pharmaceuticals Inc. jointly and severally;

vi) If at any time before December 31, 1999, Virazole is not reasonably available for purchase in Canada, ICN Canada Ltd. and/or ICN Pharmaceuticals Inc. shall make a payment or payments to Her Majesty in right of Canada equal to the balance of excess revenues outstanding as at the first date on which Virazole is not reasonably available for purchase in Canada. The obligation to make any payment required by this paragraph shall be that of ICN Canada Ltd. and ICN Pharmaceuticals Inc. jointly and severally.

In the event that the manner of implementing or complying with these orders requires further directions from the Board, either Board Staff or the Respondents may apply in writing for such directions.

Sylvie Dupont-Kirby
Secretary to the Board

July 26, 1996

TAB 2

May 27, 2011

Decision: PMPRB-08-D3-ratio-Salbutamol HFA - Merits

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

AND IN THE MATTER OF ratiopharm Inc. (the "Respondent") and the medicine "ratio-Salbutamol HFA"

DECISION

Introduction

1. These reasons pertain to a decision of the Patented Medicine Prices Review Board ("the Board") following a hearing into whether ratiopharm Inc. ("ratiopharm"), under sections 83 and 85 of the *Patent Act* (the "*Act*"), is selling or has sold the medicine known as ratio-Salbutamol HFA ("ratio HFA") in any market in Canada at a price that, in the opinion of the Board is, or was, excessive and, if so, what order, if any, should be made (the "Proceeding").

The Medicine

2. ratio HFA is an authorized generic version of the medicine manufactured, marketed and sold in Canada by GlaxoSmithKline Inc. ("GSK") under the brand name Ventolin HFA. Ventolin HFA and ratio HFA are taken to relieve asthma, chronic bronchitis and related symptoms. ratio HFA is essentially Ventolin HFA with the same chemical composition, strength, dosage form and delivery mechanism. It differs only in labeling, packaging, and product monograph. Ventolin HFA and ratio HFA are bronchodilators whereby approximately 200 doses of the active ingredient salbutamol sulphate is delivered through a pressurized canister referred to as a metered dose (aerosol) inhaler ("MDI") in doses of 100 micrograms.

3. Both Ventolin HFA and ratio HFA are manufactured, packaged, and labeled by GSK. ratio HFA was sold by GSK to ratiopharm, an arm's length company, in final packaged and labeled form for sale in Canada by ratiopharm, from the latter half of 2002 until the end of 2009, pursuant to a series of licensing/supply agreements (the "Agreements") between GSK and ratiopharm. The Agreements were not renewed at their expiry at the end of 2009 and ratio HFA was no longer sold by ratiopharm in Canada by the end of January 2010.

The Proceeding

4. The Proceeding before a panel of the Board (the "Panel") was commenced by the issuance of a Notice of Hearing by the Chairman of the Board on July 18, 2008, after his review of a Statement of Allegations dated July 8, 2008 prepared by the staff of the Board ("Board Staff") alleging that ratiopharm was selling and had sold ratio HFA in Canada at excessive prices, contrary to sections 83 and 85 of the *Act*.

5. Before hearing Board Staff and ratiopharm (collectively the "Parties") on the merits in the Proceeding, the Panel heard the Parties on preliminary matters at a pre-hearing conference on October 27, 2008. The Panel also heard the Parties and GSK on July 8, 9 and 10, 2009 on two preliminary motions brought by Board Staff (the "Preliminary Motions") and at a further pre-hearing session on November 2, 2009.

6. In the first Preliminary Motion, Board Staff sought an order from the Panel to add GSK as a party to the Proceeding, to require GSK to file with the Board the price at which GSK has sold or is selling ratio HFA to ratiopharm, and to provide to the Board certain information with respect to the sale of ratio HFA to ratiopharm since 2001.

7. In the second Preliminary Motion, Board Staff sought an order requiring ratiopharm to permit Welch LLP ("Welch"), an accounting and consulting firm, to inspect ratiopharm's books and accounts in respect of the purchase and sale of ratio HFA and to provide to the Board certain information and documents related to such purchase and sale.

8. On August 14, 2009, the Panel denied the motion to add GSK as a party to the Proceeding but issued a *subpoena* to GSK requiring the production of information to the Board in respect of all sales of ratio HFA to ratiopharm since 2001, including quantities and prices charged with respect to such sales.

9. With regard to the second Preliminary Motion, the Panel issued on August 14, 2009: (i) an order requiring ratiopharm to provide certain information and documents to the Board; and (ii) an inspection order (the "Inspection Order") permitting Welch, on behalf of Board Staff, to conduct an on-site inspection at ratiopharm's offices and to perform an audit of ratiopharm's transactions in respect of the purchase and sale of ratio HFA in Canada for certain sample periods. The Inspection Order required ratiopharm to provide access to Welch to all books, records, documents, accounts and other forms of records necessary to

verify the amounts claimed by ratiopharm in respect of benefits given or other costs of selling ratio HFA in the sample periods and to take all reasonable steps to direct Welch to any document, record or information from which Welch could ascertain the benefits given and other costs incurred by ratiopharm in respect of its sales of ratio HFA in the sample periods. In issuing the Inspection Order, the Panel relied in part on the sworn evidence of Ms. Shari Saracino, Vice-President of Sales and Marketing at ratiopharm, that the benefits and costs of selling products, including rebates related thereto, are tracked and recorded by ratiopharm by product and by customer.

10. On January 25 and 26, 2010 and April 12 to 15, 2010, the Panel heard the evidence and arguments of the Parties on the merits in the Proceeding. Parties filed extensive and detailed written final arguments and replies thereto on April 30, 2010 and May 14, 2010 respectively.

The Issues

11. Based on the submissions of the Parties and the Panel's review of the record, the Panel has identified the following issues to be determined:

    I. Whether sections 79 to 103 of the *Act* are constitutional;

    II. Whether ratiopharm is a patentee, under sections 79 to 85 of the *Act*, with respect to the sale of ratio HFA in any market in Canada between 2002 and 2010;

    III. Whether ratiopharm, to the extent that it is a patentee, is selling or has sold ratio HFA in any market in Canada at an excessive price, contrary to sections 83 and 85 of the *Act*;

    IV. Whether, in determining the price at which ratiopharm is selling or has sold ratio HFA in any market in Canada, the Panel can take into account any rebates or discounts given by ratiopharm in respect of such sales and reported to the Board pursuant to section 4 of the *Patented Medicines Regulations* (the *"Regulations"*); and

    V. What order, if any, should be made by the Panel with respect to the sale of ratio HFA by ratiopharm in Canada.

Discussion and Determinations

I. Whether Sections 79 to 103 of the *Act* are Constitutional

a. The Argument

12. ratiopharm submits that sections 79 to 103 of the *Act*, which establish the Board and grant it certain powers with respect to the excessive pricing of patented medicines, are not supported by any federal head of power in the *Constitution Act, 1867* (the *"Constitution"*) and are *ultra vires* the power of Parliament. Specifically, ratiopharm argues that the Board's mandate under the *Act* consists of pure price regulation, a matter of provincial jurisdiction, property and civil rights, pursuant to subsection 92(13), and not a matter of federal jurisdiction, patents of invention and discovery, pursuant to subsection 91(22).

b. Conclusion

13. The Board's mandate and purpose in the *Act* is the monitoring of the price of patented medicines to ensure that prices charged by pharmaceutical companies for such medicines do not rise to unacceptable levels and the protection of Canadian consumers from the excessive pricing of such medicines. The Panel is satisfied that case law has affirmed that this mandate and purpose are consistent with subsection 91(22) of the Constitution: see for example, *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 F.C. 32 ("*ICN*") approving *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485 (Man. Q. B.); affd. (1992), 96 D.L.R. (4th) 606 (Man. C.A.) ("*Manitoba Seniors*"). In *Manitoba Seniors*, the Manitoba Court of Appeal affirmed the decision of Dureault, J. of the Manitoba Queen Bench that the fact that sections of the *Act* may have an effect upon matters within provincial jurisdiction, in this case property and civil rights, is of no consequence.

14. Hughes, J. of the Federal Court in *Teva Neuroscience G.P. – S.E.N.C. v. Attorney General of Canada*, 2009 F.C. 1155 noted, at paragraph 71:

71. The constitutional jurisdiction of the Board has not been the subject of judicial consideration since the Manitoba decision. I do note that the late Justice Cullen of this Court did incorporate the entirety of Justice Dureault's reasons reflecting the historic review of the *Patent Act* and the Board in his reasons in *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)* (1996), 66 C.P.R. (3rd) 46.

II. Whether ratiopharm is a patentee under sections 79 to 85 of the *Act* with respect to the sale of ratio HFA in any market in Canada between 2002 and 2010.

a. The relevant legislative provisions

15. For the purposes of sections 80 to 103 of the *Act*, a patentee is defined in subsection 79(1) as follows:

> 79.(1) "patentee", in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act*, 1992, that other person in respect of those rights.

16. Subsection 79(2) of the *Act* provides that, for the purposes of subsection (1) and sections 80 to 103, "an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine."

17. Sections 80 and 81 of the *Act* require a patentee or former patentee of an invention pertaining to a medicine, as required by and in accordance with the *Regulations*, or in accordance with a Board order, to provide to the Board certain information and documents respecting the medicine, including the price at which the medicine is being sold or has been sold in any market in Canada.

18. The powers of the Board to make findings of excessive pricing under section 83 of the *Act* are also granted with respect to a patentee of an invention pertaining to a medicine.

19. Reviewing the provisions relating to the Board's jurisdiction under the *Act* in *ICN*, the Federal Court of Appeal, at paragraph 47, established three conditions precedent for the Board to acquire jurisdiction under section 83 of the *Act*: (i) the party before it must be a patentee of an invention; (ii) the patentee's invention must pertain to a medicine; and (iii) the patentee must be selling the medicine in any market in Canada.

20. There is no dispute between the Parties that ratio HFA is a medicine, and would be, if the Board had jurisdiction in relation to the sale of ratio HFA by ratiopharm, a Category 1 drug product within the Board's Compendium of Guidelines, Policies and Procedures-pre-2010 (the "Guidelines"). As described in the Guidelines, it is a new Drug Identification Number ("DIN") of an existing or comparable dosage form of an existing medicine, Ventolin HFA. A new DIN was assigned to ratio HFA in 2001 by Health Canada under the *Food and Drug Regulations*. There is also no dispute between the Parties that ratio HFA was sold in Canada by ratiopharm under a Notice of Compliance ("NOC") issued by Health Canada to ratiopharm on July 16, 2002, pursuant to those *Regulations*.

21. Neither do the Parties dispute that two Canadian patents, Nos. 2,125,665 and 2,125,667 (the "Patents"), granted to Glaxo Group Ltd., UK and licensed to GSK, pertain to an invention for the production of Ventolin HFA and ratio HFA within the meaning of subsection 79(2) of the *Act*. The Patents cover formulations of salbutamol sulfate with a hydrofluoroalkane propellant used to form an aerosol for inhalation.

22. ratiopharm's witness, Mr. Kent Major, Vice-President of Research and Development and Regulatory Affairs at ratiopharm, acknowledged during his sworn testimony that, in September 2001, in order to obtain an NOC from Health Canada for the sale of ratio HFA by ratiopharm, he had listed on the relevant Health Canada form signed by him (Form V: Declaration Re: Patent List) one of the Patents, with its expiry date of 2012, as applicable to ratio HFA, and had indicated on that Form that ratiopharm had obtained consent from the Patent owner "to the making, constructing using or selling of [ratio HFA] in Canada".

23. Mr. Major's testimony was that ratiopharm had introduced ratio HFA in Canada in 2002 and sold it in markets in Canada from September 2002 until the end of January 2010.

24. ratiopharm argues, however, that it is not a patentee within the meaning of section 79 of the *Act* with regard to the sale of ratio HFA because any patent that pertains to ratio HFA is owned exclusively by GSK and all rights, interest and title in and to the Patents and the invention they document and protect are the exclusive rights, interests and title of GSK, to the complete exclusion of ratiopharm. ratiopharm emphasizes that it has never held any patent for ratio HFA.

b. The Agreements

25. As part of the arrangement under which ratiopharm sold ratio HFA, ratiopharm took title to ratio HFA from GSK for resale in Canada at a price per MDI agreed to by the parties pursuant to the Agreements which were amended and restated over time. In essence, the Agreements grant to ratiopharm an exclusive licence to promote, market, and sell ratio HFA in Canada. Under the Agreements, ratiopharm assumed the responsibility for all activities related to the resale of ratio HFA, including pricing. The Agreements expressly prohibit ratiopharm from sub-licensing the rights granted in the Agreements and expressly reserve to GSK ownership in its intellectual property, including the Patents.

26. In ratiopharm's submission, since GSK did not transfer, assign or license any rights of use or exploitation or any interest in patent rights or any licence in patents owned exclusively by GSK, ratiopharm has no entitlement to any right or interest in the Patents, express or implied, and is not entitled to the benefit of the Patents pertaining to GSK's ratio HFA invention other than the right to market and sell ratio HFA. Therefore, ratiopharm argues, the Board has no jurisdiction under the *Act* in relation to the sale of ratio HFA in Canada by ratiopharm.

27. Board Staff takes the position that:

    (a) under section 42 of the *Act*, the exclusive rights associated with the grant of a patent include the right to use the invention or to sell the invention to be used;
    (b) by permitting ratiopharm to market and sell ratio HFA in Canada under its own brand name, GSK granted ratiopharm a right the exercise of which, absent such permission, would have infringed the Patents; and
    (c) this results in ratiopharm exercising a right in relation to a patent pertaining to ratio HFA within the meaning of subsection 79(1) of the *Act* and, accordingly, qualifies ratiopharm as a patentee in respect of the sale of ratio HFA.

28. Section 42 of the *Act* provides as follows:

> 42. Every patent granted under this *Act* shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this *Act*, grant to the patentee's legal representative for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.

c. The "ex-factory price" Issue

29. ratiopharm argued that the Board might have jurisdiction over GSK, the manufacturer of ratio HFA, with regard to GSK's ex-factory sales of ratio HFA to ratiopharm, but not over ratiopharm's resale of ratio HFA pursuant to the Agreements. In ratiopharm's view, there cannot be two patentees, each with a different ex-factory, or factory gate price, or manufacturer's price of a medicine for the same unit in the same sales and distribution chain. ratiopharm relies on *Pfizer Canada Inc. v. Attorney General of Canada* 2009 FC 719 ("*Pfizer*") to conclude that the Board's jurisdiction is limited to the first sale in the supply or distribution chain, in this case the sale of ratio HFA by GSK to ratiopharm for resale by ratiopharm to wholesalers, pharmacies, hospitals, or others.

30. Subparagraph 4(1)(*f*)(ii) of the *Regulations* requires patentees to file, as part of the information related to a patented medicine required to be filed by paragraph 80(1)(*b*) of the *Act*, the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold by a patentee to each class of customer in each province and territory. "Ex-factory price" is not defined in the *Regulations*.

31. In the Board's Patentee's Guide to Reporting (the "Guide"), "ex-factory price" is defined in part as follows:

> Ex-factory price: The price established for the first sale ... of the product "at arm's length" to distributors, wholesalers, hospitals, pharmacies, etc... The ex-factory price is generally the "list price" for medicines ...

32. The Board thus identified in the Guide as the "ex-factory price" the point at which patented medicines are sold to distributors, wholesalers, hospitals or pharmacies, as distinct from retail sales. If the Board is to carry out its statutory mandate as determined in *ICN* with consistency, it must be responsive, in establishing the price over which it has jurisdiction, to different sales, distribution, commercial and marketing arrangements, such as those applicable to ratiopharm where ratiopharm purchases ratio HFA from GSK, the manufacturer, and resells it at a price that it determines to distributors and pharmacies for sale to customers.

33. Moreover, the Panel notes that *Pfizer* did not address or determine who, in any specific circumstances such as those in the case before the Panel, can be considered to be the patentee for the purposes of sections 83 and 85 of the *Act*. Neither did *Pfizer* address or determine therefore what is, under such specific circumstances, the "publicly available ex-factory price" for the purpose of subparagraph 4(1)(*f*)(ii) of the *Regulations* or the "first" or "list" price of the medicine at issue.

d. The meaning of "patentee" for the purposes of sections 80 to 85 of the *Act*

34. The issue of whether ratiopharm is a patentee with respect to the sale of ratio HFA requires the Panel to determine whether ratiopharm can be characterized as "any other person entitled to exercise any rights" in relation to a patent pertaining to ratio HFA within subsection 79(1) of the *Act* at the time of the sale of ratio HFA in Canada by that other person.

35. It is a well established principle of statutory interpretation that "the words of an *Act* are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the *Act*, the object of the *Act*, and the intention of Parliament." The Supreme Court agreed in *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27 ("*Rizzo*") with this basic principle enunciated by Elmer Driedger in *Construction of Statutes* (2nd ed. 1983) and it has been generally applied by the courts since.

36. In *Shire Biochem Inc. v Attorney General of Canada*, 2007 FC 1316, Russell, J., relying on *Rizzo* and on the provisions of the *Interpretation Act*, considered that the interpretation of the jurisdiction conferred on the Board by statute requires a purposive analysis and as fair, large and liberal a construction of the words of the statute as will best ensure the attainment of the objective of the statute, in accordance with the relevant jurisprudence.

37. In *Celgene Corp. v. Canada (Attorney General)*, 2011 SCCI ("*Celgene*"), the Supreme Court agreed with the Board and the Federal Court of Appeal that, in interpreting disputed words in the *Act*, the legislative context and the purpose of the statute must be considered. It agreed with the Court below that the meaning of the words "sold in any market in Canada" in sections 80(1)(*b*), 83(1) and 85 of the *Act* cannot be given a meaning strictly in accordance with commercial law principles. The words must yield to an interpretation that best meets the overriding purpose of the statute.

38. Abella, J., speaking for the full Court in *Celgene*, agreed that the purpose of the *Act* was, as affirmed in *ICN*, consumer protection, and that the mandate of the Board was to ensure that Canadians have access to patented medicines that are reasonably priced. An interpretation by the Board of its mandate under disputed provisions of the *Act* consistent with its consumer protection purpose should not be disturbed and therefore, the Supreme Court held in *Celgene*, the Board's jurisdiction extends to a patented medicine shipped from the United States to doctors in Canada and paid in the United States in U.S. dollars as a medicine "sold in any market in Canada".

39. In addressing the meaning of "patentee" in section 79 of the *Act*, both the Board and the Federal Court have taken a purposive approach. In PMPRB-99-D6-NICODERM (August 8, 2000), a panel of the Board considered whether Hoechst Marion Roussel Canada Inc. ("HMRC"), selling Nicoderm in Canada pursuant to a Licensing Agreement between its parent and the holder of the relevant Canadian patents, was itself a patentee for the purpose of section 83 of the *Act.* The panel concluded as follows:

> The definition of "patentee" for the purposes of the Board's jurisdiction is expressly broadened by section 79(1) of the *Act* to include not only the person entitled for the time being to the benefit of the patent but also any person entitled to exercise rights in relation to the patent. Needless to say, this expansion of the definition of patentee is necessary for the Board to fulfil its mandate. The Board must be able to prevent excessive pricing of medicines by persons taking advantage of the patent regime established by the *Act*, whether or not they are actually the holder of a patent or patents pertaining to the medicine.

40. In *Hoechst Marion Roussel Canada Inc. v. Canada*, [2005] F.C.J. No. 1928, at paragraph 128, Heneghan, J. agreed that, while the patents at issue were actually held by a party other than HMRC under a License Agreement between the patent holder and HMRC's parent, HMRC was authorized to exercise in Canada the rights held by its parent under that Agreement and HMRC thus was within section 79 of the *Act* with respect to those patents.

41. Turning to the situation before us and considering the words of the *Act* and the mandate and purpose of the Board, the Panel notes that subsection 79(1) of the *Act* does not, on its face, encompass only a person who owns a patent in respect of an invention pertaining to a medicine and does not require that a person be entitled to exercise all rights in relation to a patent in order to fall within the definition of patentee for the purposes of sections 80 to 103 of the *Act*. Since subsection 79(1) expressly includes as a patentee any other person entitled to exercise any rights in relation to a patent, it is incumbent on the Panel to assign a meaning to those words that is consonant with the discharge of the Board's statutory mandate.

42. The Agreements gave ratiopharm the exclusive right to set the price of and to sell ratio HFA and to obtain the necessary regulatory approvals to do so. Absent the licence granted, these acts would have violated rights held exclusively by GSK pursuant to section 42 of the *Act*. There can be no doubt that these rights are "in relation to" the patent held by GSK.

43. In the Panel's view, were it to accept ratiopharm's position that the jurisdiction of the Board could be avoided through the supply under contract of a patented medicine at one negotiated price to another party for resale in any market in Canada at a different price set by that second party, while the first party retains ownership in its intellectual property apart from the right to market and sell, the Board's jurisdiction would be severely undermined and the attainment of the objective of the *Act* enunciated in *ICN* in effect rendered nugatory with regard to the patented medicine involved. This would allow the simple insertion of a commercial entity such as ratiopharm in the distribution chain in a manner that would cause the Board to lose the ability to review the pricing of the medicine, without any rationale for this result. Provided that the sale by the patent holder was at a non-excessive price, the distributor who is given the right to resell the patented medicine would be able to sell to pharmacies or other consumers at an unregulated price, thereby completely defeating the Board's mandate.

44. For these reasons the Panel believes that there is a sound basis for the interpretation of section 79 of the *Act* in a manner that captures entities in the position of ratiopharm: not only does the plain meaning of the words in section 79 capture ratiopharm selling ratio HFA under an agreement with GSK as a person entitled to exercise rights in relation to the Patents, but the purposive interpretation of the *Act* requires such a conclusion in order for the Board to carry out its statutory mandate.

e. Conclusion

45. The Panel concludes that, for the reasons enunciated, ratiopharm is a patentee under sections 79 to 85 of the *Act* with respect to the sale of ratio HFA in any market in Canada, and that, as a patentee, it had the sole responsibility to ensure that the price at which it sold ratio HFA in any market in Canada was not excessive under sections 83 and 85 of the *Act*.

46. The Panel is of the view that, although GSK may hold title to the Patents related to ratio HFA, in the circumstances of this case, and in accord with the purposive construction of the words "selling [a] medicine in any market in Canada" in section 83 of the *Act*, GSK is not the patentee of ratio HFA for the purpose of that section. GSK is not, in the Panel's view, in the circumstances of the case before it, the party responsible for ensuring that the price paid by Canadian consumers for ratio HFA is set at a non-excessive level, as required by the *Act.* ratiopharm is.

47. The Panel notes further that, by virtue of subsection 4(5) of the *Regulations*, as a patentee who sells a patented medicine to another patentee, GSK is exempt from filing the price and sales information for ratio HFA required by section 80 of the *Act*, and section 4 of the *Regulations*, including the publicly available ex-factory price at which ratio HFA was sold.

III. Whether ratiopharm has sold ratio HFA in any market in Canada at an excessive price, contrary to sections 83 and 85 of the *Act*.

a. The Board's jurisdiction over excessive pricing

48. Section 83 of the *Act* confers on the Board the power to find that a patentee of an invention pertaining to a medicine is selling or has sold the medicine in a market in Canada at a price that, in its opinion, is excessive and, upon such a finding, to issue remedial orders to offset the amount of excess revenues estimated by the Board to have been derived by the patentee from such sale. The Board can

make an order, *inter alia*, that a payment be made to Her Majesty in right of Canada of an amount specified in the order.

49. Subsections 85(1) and (2) of the *Act* set out the factors to be taken into consideration by the Board in making a determination under section 83, to the extent that information on these factors is available to the Board. They are as follows:

> 85.(1) (*a*) the prices at which the medicine has been sold in the relevant market;
> (*b*) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
> (*c*) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
> (*d*) changes in the Consumer Price Index; and
> (*e*) such other factors as may be specified in any regulations made for the purposes of this subsection.
>
> 85.(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:
> (*a*) the costs of making and marketing the medicine; and
> (*b*) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

50. The Panel must therefore determine whether or not the price of a patented medicine sold in Canada is, or was, excessive, by comparing the price of the medicine in Canada to the price at which comparable medicines are sold in Canada, by comparing the price at which the medicine is sold in other countries specified in the *Regulations* and the price at which comparable medicines are sold in those countries, and by taking into account changes in the Consumer Price Index ("CPI").

b. Filing requirements under the *Act*

51. The Board's ability to fulfil its mandate under sections 83 and 85 of the *Act* to monitor the prices of patented medicines and make remedial orders in response to incidences of excessive pricing is dependent on a system of self-reporting. Under paragraph 80(1)(*b*), of the *Act*, patentees must, as required by and in accordance with the *Regulations,* provide to the Board for stated periods, *inter alia*, price and sales data for the patented medicines they sell in Canada.

52. Subparagraphs 4(1)(*f*)(i) and (ii) of the *Regulations* provide in part as follows:

> 4(1)(*f*) For the purposes of paragraphs 80(1)(*b*) and (2)(*b*) of the *Act*, information identifying the medicine and concerning the price of the medicine shall indicate:
>
> (i) the quantity of the medicine sold in final dosage form and either the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory,
>
> (ii) the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory.

53. For the purposes of subparagraph 4(1)(*f*)(i) of the *Regulations*, subsection 4(4) provides that:

> 4(4)(*a*) in calculating the average price per package of medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after any deduction of the federal sales tax shall be used; and
>
> 4(4)(*b*) in calculating the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of federal sales taxes shall be used.

This information is included in Form 2 Filing implementing section 4 of the *Regulations*. Form 2 Filings allow the Board to calculate the net average transaction price ("ATP") per dose of a patented medicine sold by a patentee during six-months periods, on the basis of net revenues and total units sold, as required by section 4 of the *Regulations*.

c. ratiopharm's Form 2 Filings for ratio HFA

54. Although ratiopharm sold ratio HFA in Canada beginning in September 2002, it did not file any information in respect of the sale of ratio HFA until requested to do so by Board Staff. On September 29, 2006, ratiopharm filed Form 2 Filing information for ratio HFA for the period July 2, 2002 to June 30, 2006 and continued to file such information for subsequent periods (the "Initial Form 2 Filings"). In the Initial Form 2 Filings, the net revenues derived from the sale of ratio HFA were calculated by deducting from gross revenues amounts paid as (i) fees for product distribution; (ii) prompt pay discounts; and (iii) product returns.

55. On March 30, 2009, approximately eight months after the issuance of the Notice of Hearing regarding ratio HFA, ratiopharm filed revisions to its Initial Form 2 Filings for the period July 2, 2002 to December 31, 2008 (the "Revised Form 2 Filings"). ratiopharm stated that these revisions were due to an oversight in the calculation of average prices in the Initial Form 2 Filings. In recalculating the net revenues derived from the sale of ratio HFA, ratiopharm made further deductions: it deducted from gross revenues, as rebates: (i) amounts paid to pharmacies referred to as continuing education ("CE") payments; (ii) performance enhancement program ("PEP") payments – collectively "Professional Allowances"; (iii) prompt pay discounts; and (iv) amounts related to product returns. ratiopharm removed as rebates the fees for product distribution previously included. The result of the revisions is a significant reduction in ratiopharm's ATP for ratio HFA during these periods, amounting to tens of millions of dollars. The revised ATPs for ratio HFA in the 2003-2007 period range from 11% to 26% lower than the ATPs based on the Initial Form 2 Filings for those years.

d. The role of the Board's Guidelines in determinations of excessive pricing

56. A decision of the Board under subsection 83(1) of the *Act* is discretionary in that the Board is required to formulate an opinion whether a medicine is sold or has been sold in any market in Canada at an excessive price. In formulating such an opinion, the Board is required to take into consideration the factors enumerated

in subsection 85(1) and no others, unless the Board is unable to make a decision on those factors and thus needs to consider the factors set out in subsection 85(2) of the *Act*. Subsection 85(1), however, provides only basic factors and limited guidance to the Board in determining excessive pricing.

57. The Board's Guidelines are intended to implement subsection 85(1) of the *Act* by providing parameters and information on how the Board, in the normal course, will assess the factors in subsection 85(1) to make a determination of excessive pricing. The Guidelines were issued by the Board after consultation with its stakeholders and are periodically updated after further consultations. Pursuant to subsection 96(4) of the *Act*, the Guidelines are not binding on the Board or on any patentee. However, they provide detailed and comprehensive guidance and predictability to patentees, as well as transparency and consistency in the discharge of the Board's mandate.

58. As recently as December 21, 2009, in PMPRB-07-D5 Quadracel and Pentacel ("*Quadracel*"), a panel of the Board emphasized that it has been recognized by all prior panels of the Board, and by the Federal Court, that a panel, when considering whether a medicine is being sold or has been sold at an excessive price, can give due consideration to the Board's Guidelines.

59. In *ICN Pharmaceuticals, Inc. v. Canada* (*Patented Medicine Prices Review Board)*, [1996] F.C.J. No. 1112 (FC-TD), Rothstein, J., then a Federal Court Justice, considered whether the Board acted without jurisdiction in taking into consideration its Guidelines in deciding whether Virazole had been sold at an excessive price, given that such Guidelines are not an enumerated factor in subsection 85(1) of the *Act*. He stated, at paragraph 6:

> 6. The applicants say the Board could not have regard to its Guidelines under subsection 85(1) as the Guidelines are not an enumerated factor in the subsection. However, each factor listed in subsection 85(1) is not an abstract concept that would be useful in a vacuum. The Board is obviously required to consider the factors in subsection 85(1) according to some rationale, approach or methodology. The rationale, approach or methodology may be ad hoc or may be derived from the Board's Guidelines. That it had regard to the Guidelines for rationale, approach or methodology did not take the Board outside of the scope of subsection 85(1)[2].

Rothstein, J. specified in note 2 of paragraph 6 of his judgment that, had the Board treated the Guidelines as binding, it may well have erred, in light of subsection 96(4) of the *Act*.

60. A Board panel must thus be satisfied that the Guidelines provide for an appropriate implementation of subsection 85(1) of the *Act* in a case before it. The panel's conclusions in that regard will be informed by the evidence and argument of the parties, with the initial onus resting on the staff of the Board to satisfy the panel, in light of the factors set out in subsection 85(1), of the appropriateness of applying the Guidelines, and to convince the panel that the price of a medicine is excessive, on a balance of probabilities: see, for example, *Leo Pharma Inc. v. Canada (Attorney General)* 2007 FC 306, at paragraph 27 ("*Leo Pharma*").

61. It was made equally clear in *Quadracel* that a panel can depart from the Board's Guidelines when it is satisfied that it is appropriate to do so, based on the evidence, in reaching a conclusion on excessive pricing. The panel's determinations must be based on a balanced consideration of the factors in the *Act* taken together and after due consideration of the appropriateness of the Board's reliance on the pricing tests set out in the Guidelines and on the presumption of excessive pricing flowing from them in the case before it.

62. It was the testimony of Ms. Ginette Tognet, Director of Regulatory Affairs and Outreach Branch of the Board and responsible for conducting the price review of patented medicines, that the allegations of excessive pricing by Board Staff with regard to the sale of ratio HFA by ratiopharm are based on analyses that are consistent with the pricing and other tests set out in the Board's Guidelines. However, despite the presumptive effect of the analysis conducted in accordance with the Guidelines, Board Staff presented evidence and arguments for the Panel's consideration during the Proceeding concerning: the appropriateness of applying the Guidelines in the circumstances of this case; the weight to be given to any particular factor in subsection 85(1); and the appropriateness of a departure from the applicability of the Guidelines as advocated by ratiopharm. Board Staff did not simply rely on the existence of the Guidelines, but adduced evidence and made argument to the effect that the Guidelines provided an appropriate implementation of subsection 85(1) of the *Act* in the particular circumstances of the case before the Panel.

e. The pricing of ratio HFA by ratiopharm

63. When ratiopharm began to sell ratio HFA in Canada in September 2002, there were four salbutamol MDIs containing a chlorofluorocarbon ("CFC") propellant available:

i. Ventolin CFC, at a list price of $12.27 per MDI, in the market in Canada since 1972, well before the establishment of the Board in 1987;

ii. ratio-Salbutamol;

iii. Apo-Salvent; and

iv. Novo-Salmol, at list prices of $4.64 per MDI.

Airomir, a salbutamol CFC-free MDI introduced in Canada in 1998, was also available at a list price of $4.65 per MDI.

64. As a result of a Canadian government ban of the use of CFC in MDIs, CFC-containing MDIs were no longer sold in Canada after December 31, 2002. Apo-Salvent, an authorized generic version of Airomir, was an additional CFC-free MDI made available in 2002. The list price of ratio HFA and CFC-free Apo-Salvent was set at $4.64 per MDI and Airomir soon reduced its list price from $4.65 to $4.64 per MDI. Ventolin HFA was also introduced in Canada by GSK in 2002, at the same list price per MDI as Ventolin CFC.

65. The list price of ratio HFA, Airomir, and CFC-free Apo-Salvent remained the same until November 2004 when ratiopharm, then holding approximately 75% of the Canadian market for salbutamol MDIs, raised the list price of ratio HFA by 67% to $7.73 per MDI. There had been no increase in Canadian prices of comparable medicines prior to this price increase. International prices had generally declined or been stable since 2002. In the weeks following the increase in the price of ratio HFA, the list prices of Airomir and CFC-free Apo-Salvent were also raised to $7.73 per MDI. In October 2009, GSK advised the Board of the expiry of the Agreements and of the reduction of the list price of Ventolin HFA to $6.50 per MDI to obtain provincial formulary listings. ratio HFA's list price was reduced to $6.50 per MDI in November 2009 until ratiopharm's stock of ratio HFA was liquidated by the end of January 2010. The list price of Airomir was substantially reduced following a voluntary compliance undertaking ("VCU") with the Board in April 2007. CFC-free Apo-Salvent is currently the subject of an excessive price proceeding before the Board.

f. Board Staff's application of the Guidelines pricing tests

66. When a patented medicine is introduced to the market in Canada, the maximum non-excessive price ("MNE") of the medicine is determined by the staff of the Board based on either the price of comparable medicines, i.e. medicines in the same therapeutic class, or on the international prices of the medicine – median or

the highest – as sold in the seven countries specified in the *Regulations*. The price of the new medicine at introduction will be presumed by the staff of the Board not to be excessive under the Board's Guidelines if it is sold at or below the MNE thus established. In subsequent years, the yearly MNE is determined by the ATP of a previous year, grown by the CPI factors (if the patentee elects to so increase the price of the medicine) according to the Board's CPI-Adjustment Methodology, subject always to the price of the medicine not being the highest price of the medicine in the seven stipulated countries. The ATP of the medicine for a given year will be presumed not to be excessive if it is at or below its MNE for that year.

67. Under the Board's Guidelines, no further pricing test is required to make a determination of excessive pricing once the MNE of a medicine at introduction is established. However, in light of the position of ratiopharm on the appropriateness of relying on this test in the case of its sale of ratio HFA, Board Staff conducted further pricing tests in preparation for this Proceeding. Tests were conducted for the post-introductory period and until 2009, based on the price of comparable medicines sold in Canada and in the countries specified in the *Regulations*. The calculations of net revenues for ratio HFA, with CE and PEP rebates, could only cover to the end of the 2008 reporting periods in light of the Form 2 Filing information provided by ratiopharm at that time. Some information was updated during the Proceeding.

i) Determining comparability

68. As suggested by the Board's Guidelines, the comparable medicines used by Board Staff to establish the introductory MNE of a Category 1 medicine and to conduct price tests under subsection 85(1) of the *Act* are determined pursuant to a scientific review designed to identify medicines that are clinically equivalent in addressing the approved condition for which they are used, and having comparable dosage form and strength. These criteria establish the therapeutic class of the medicine for the purposes of paragraphs 85(1)(*b*) and (*c*) of the *Act*. The Human Drug Advisory Panel ("HDAP"), an independent panel of scientists who advise Board Staff on these matters, recommended that the therapeutic class of ratio HFA include Airomir and the CFC versions of Ventolin, Apo-Salvent, ratio-Salbutamol, and Novo-Salmol. Board Staff used these medicines for the pricing tests at the introduction of ratio HFA in 2002. Board Staff noted that Ventolin was not used for the price test that established the benchmark MNE of ratio HFA because it was subject to investigation for excessive pricing at the time, although it was later found to be non-excessive as of 2003. The Board's practice is not to use a medicine under investigation as a price comparator since it is neither consistent nor logical to establish the MNE of a medicine by reference

to the price of a medicine that may, itself, be excessively priced. (See PMPRB-99-D10-Nicoderm-Merits (April 9, 2010)).

69. The appropriate comparators to ratio HFA sold in Canada and in the countries specified in the *Regulations* for assessing the price of ratio HFA after the introductory period were found by Board Staff to be Ventolin HFA after 2003, Airomir, and CFC-free Apo-Salvent and, in six of the seven countries specified in the *Regulations* Ventolin HFA, and in Germany, Ventolin HFA and ratio HFA.

70. ratiopharm sought to expand the therapeutic class of comparators of ratio HFA used for these pricing comparisons. Ms. Joan McCormick, a consultant at Brogan Inc., now IMS Brogan, but not a medical expert, pharmacist or scientist, gave evidence to that effect. Her evidence was contrary to that given on behalf of Board Staff by Dr. Adil S. Virani, Assistant Professor of Pharmaceutical Sciences at the University of British Columbia, Director of Pharmacy Sciences at the Fraser Health Authority and a member of the HDAP. Dr. Virani testified that it is not necessary to compare ratio HFA to further medicines, given the existence of the drug products with the same dosage form of the same active ingredient as those of ratio HFA. Dr. Virani's evidence was that salbutamol MDIs constitute the appropriate class of comparators for ratio HFA, "the best apples to apples comparison". The evidence of Dr. Tom Kovesi, a pediatric respirologist, was that the additional medicines that Ms. McCormick sought to add as comparators to ratio HFA for pricing comparisons are not, in fact, clinically equivalent to ratio HFA.

71. The Panel is satisfied, on the basis of the evidence, that the correct comparators were used by Board Staff to establish the non-excessive price of ratio HFA at introduction and in the period 2002 to 2009.

ii) The introductory price of ratio HFA and paragraphs 85(1)(a) and (b) of the Act

72. By reference to publicly available prices of the comparators to ratio HFA in Canada, Board Staff found the price of ratio HFA during the introductory period to have been non-excessive when assessed according to the test set out in the Board's Guidelines. The Therapeutic Class Comparison Test in the Guidelines provides that the price of the medicine at introduction will be presumed not to be excessive by Board Staff if it is no higher than the price of its highest comparator. The introductory price of ratio HFA was lower than the highest price of comparable drugs sold in Canada.

73. The ATP of ratio HFA in the period after introduction was calculated by Board Staff with the deduction of only the prompt pay discounts and returns filed by ratiopharm in its Initial Form 2 Filings and then, when ratiopharm filed the Revised Form 2 Filings, with the added deduction of the CE and PEP rebates recorded in the Revised Form 2 Filings. Board Staff found ratio HFA's ATP to be non-excessive in both cases until after the list price of ratio HFA was raised to $7.73 per MDI in November 2004. It is common ground between the Parties that, absent a departure by the Panel from the Board Guidelines' pricing methodology, the price of ratio HFA, on the basis of both the original and revised Form 2 information, is excessive after 2004. The only issue is the quantum of the excess revenues. These are essentially cut in half if all rebates that ratiopharm claims in the Revised Form 2 Filings, rather than only prompt pay discount and returns in the Initial Form 2 Filings, are taken into account.

74. Since 2005, the public price of ratio HFA and its ATP, without the deduction of CE and PEP rebates, were higher than the Canadian public prices of comparable medicines not considered to be excessive, including the public price of Ventolin HFA which trended downward after 2002. The public price of ratio HFA, without the deduction of CE and PEP rebates, was also higher than the CPI-adjusted VCU price of Airomir. With the full deduction of CE and PEP, ratio HFA's ATP remained below the price of Ventolin HFA. The public price of Apo-Salvent was not relied upon as a comparator for the price tests however as it is the subject of an investigation for excessive pricing.

75. ratiopharm objected to the fact that Board Staff used, as the list price of Ventolin HFA for the price tests conducted for the period 2003 to 2009, the average price of sales of Ventolin HFA by GSK to hospitals and to community pharmacies. ratiopharm referred to this average price as a "mixed market price" which, in its view, is a variable or shifting price at which Ventolin HFA is not in effect sold in any market. ratiopharm indicated that the proportion of sales of Ventolin HFA by GSK to hospitals at one price and to community pharmacies at another price varies over time and the price of Ventolin HFA to hospitals can be as low as 25% of the price of Ventolin HFA to community pharmacies. Therefore, in its view, using an average for the price of Ventolin HFA has the effect of keeping the price of Ventolin HFA to pharmacies lower than it should be for the purpose of a comparison with the list price of ratio HFA, to ratiopharm's detriment. ratiopharm argued that the price of ratio HFA should be compared only to the IMS Health Inc., now IMS Brogan ("IMS") price of Ventolin HFA to pharmacies which, it claims, contrary to Board Staff's tests, has remained above the price of ratio HFA.

76. Ms. Tognet referred to the public price used for Ventolin HFA as an average public price as collected by IMS in the ordinary course on the basis of total sales and total number of units sold, rather than the 'constructed' price claimed by ratiopharm. She emphasized that this approach for determining average price is consistently applied by the Board, most recently in its investigation of the comparable medicine, Airomir.

iii) Paragraph 85(1)(c) of the Act

77. An International Price Comparison Test ("IPC") and an International Therapeutic Class Comparison Test ("ITCC") were also conducted by Board Staff in preparation for the Proceeding, in the manner described in (though not in these circumstances required by) the Board's Guidelines and using publicly available ex-factory prices of ratio HFA and of comparable medicines in the seven countries specified in the *Regulations*. In accordance with the Guidelines, under the IPC test, the price of a patented medicine sold in Canada will be presumed by Board Staff not to be excessive if it is not the highest of the international prices of the medicine in the comparator countries identified in the *Regulations.* Under the ITCC test, primary weight is given to the median of the international prices. At introduction, the price of ratio HFA in Canada was less than the highest ex-factory price of Ventolin HFA and of ratio HFA in the seven countries listed in the *Regulations.* Neither did ratio HFA's introductory price exceed the international median of the ITCC test.

78. However, since 2004, allowing the deduction of the CE and PEP amounts claimed by ratiopharm, the ATP of ratio HFA exceeded the median international price ("MIP") of ratio HFA in 2005, 2007 and 2008. Without such deduction, ratio HFA's ATP was higher than the MIP of ratio HFA in each year from since 2004, although ratio HFA's price was not the highest price in the comparator countries.

iv) Paragraph 85(1)(e) of the Act

79. Board Staff found that, in each year since 2005, the price of ratio HFA has exceeded substantially its MNE adjusted for CPI in accordance with the three-year banking methodology set out in the Board's Guidelines, even if its ATP is calculated with the deduction of the CE and PEP amounts claimed by ratiopharm.

80. ratiopharm objected to the application by Board Staff of the methodology established in the Board's Guidelines for CPI adjustments in assessing the price of ratio HFA after introduction. Its objection was based in large part on the argument that, in 2002, when the benchmark MNE of ratio HFA was set, ratiopharm could have, within the pricing tests in the Board's Guidelines, introduced ratio HFA to the market at the $9.02 per MDI public price of Ventolin HFA, based on IMS data, rather than at the "arbitrarily low" price of $4.64 per MDI.

81. ratiopharm argued that it introduced ratio HFA in 2002 at an artificially low price that did not reflect its costs of acquisition from GSK, in response to the government's expectation, when the use of the CFC propellant in MDIs was banned, that the use of another propellant not be the cause of price increases for MDIs. Dr. Richard Schwindt, an expert economist, testified on behalf of Board Staff regarding the appropriateness of using ratio HFA's introductory price as the benchmark to calculate subsequent price increases. He was of the view that the evidence indicates that the price constraint on ratiopharm for ratio HFA at introduction was likely the presence of CFC-free Airomir in the market at a list price of $4.65 per MDI, at parity with the competing CFC MDIs, and of CFC-free Apo-Salvent at $4.64 per MDI and that, effectively, ratio HFA was introduced in a price competitive market in 2002 that informed its pricing strategy at the time. The introductory price of ratio HFA thus was not arbitrarily or artificially low, but rather calculated on the basis of the market conditions prevailing at the time of introduction.

82. Dr. Schwindt's expert opinion was that the Board's CPI-adjustment methodology in the Board's Guidelines, which permits a limit of a three-year "bank" of price increases, reflects the desirability of avoiding excessive changes in the price of a medicine in a given period, changes which would be at the expense of price stability and predictability for consumers and contrary to the *Act's* objective. Dr. Ronald J. Corvari, Director of the Policy and Economic Branch of the Board until 2008, testified that sudden and significant price increases was one of the major concerns of the Board during the extensive stakeholder consultations that led to the 1994 changes in the CPI-adjustment methodology in the Board's Guidelines. The Guidelines allow a patentee to increase the price of its medicine in line with increases in CPI, and provide some flexibility in that regard by allowing a patentee to "bank" increases for a limited period, but prevent sudden significant price increases by limiting that banking of price increases to the three most recent years of CPI.

83. Board Staff submitted in argument that, given its submissions on the application of the Board's Guidelines to the evidence before the Panel, the Panel should find that the price of ratio HFA has been excessive since 2004. It argued however that, in light of the very magnitude of the price increase of 67% effected by ratiopharm for ratio HFA in 2004, at a time when there was no change in the price of Airomir or CFC-free Apo-Salvent, the price of Ventolin HFA was decreasing and prices for comparable medicines in foreign countries were stable or decreasing, the Panel should, in its discretion, give greater weight to the CPI factor in this case.

84. The Panel considers that the Board's CPI-adjustment methodology constitutes an important protection from sudden and significant price increases. It is intended to moderate the extent to which a patentee may increase the price of a medicine from year to year. The Panel concludes that it should be given considerable weight in this case, where the price of a widely-used patented medicine was increased suddenly and significantly in 2004 in circumstances that, in the Panel's view, did not warrant such an increase. The Panel accepts the appropriateness of applying the CPI-adjustment methodology in the manner contemplated by the Board's Guidelines and in line with ratio HFA's MNE at introduction.

v) Paragraph 85(1)(e) of the Act

85. No other factor to be taken into consideration by the Panel for the purposes of subsection 85(1) determinations has been specified in the *Regulations*.

vi) Subsection 85(2) of the Act

86. In accordance with subsection 85(2) of the *Act*, the Panel need only take into consideration the factors set out therein if it is unable to determine whether the medicine under review is being or has been sold at an excessive price after taking into consideration the factors referred to in subsection 85(1).

87. ratiopharm introduced evidence with regard to the costs of acquisition of ratio HFA and with regard to the costs of making and marketing ratio HFA prepared by Cole Valuation Partners Limited ("Cole Partners"). Board Staff, for its part, submitted that it is neither necessary nor appropriate for the Panel to consider subsection 85(2) factors in the circumstances of this case since its evidence was that, since 2004, under all the factors identified in subsection 85(1) of the *Act*, implemented in accordance with the Board's Guidelines, only when the full amounts of the CE and PEP claimed by ratiopharm are deducted to determine the ATP of ratio HFA is the price of ratio HFA lower than the price of Ventolin

HFA. If the price of ratio HFA is compared to the CPI-adjusted VCU price of Airomir, to international prices and to the price resulting from the application of the Guidelines' CPI methodology, even with the full amounts of the CE and PEP claimed by ratiopharm, the price of ratio HFA has been excessive since 2004.

88. The Panel considers that it is in a position to reach a decision in this case on the basis of the subsection 85(1) factors. Moreover, ratiopharm, as the reseller of ratio HFA, has no evidence of the material costs of making ratio HFA nor has it such information within its knowledge or control.

vii) The existence of market power

89. ratiopharm also argued that its price for ratio HFA could not be considered excessive since it did not enjoy monopoly power or even market power in the sale of ratio HFA in any market in Canada. The Panel notes that it was made clear by the Federal Court of Appeal in *ICN* that the existence of market power is not a pre-condition to the Board's exercise of its jurisdiction, nor is it relevant to that exercise.

g. Conclusion

90. Based on Board Staff evidence, the Panel has determined that it is appropriate to apply the tests set out in the Board's Guidelines in this case. It is also satisfied that the price tests conducted by Board Staff allow it to weigh all the factors to be considered under subsection 85(1) of the *Act* in the case before it. However, the Panel's final conclusions on the issue of excessive pricing under section 83 of the *Act* require it to determine first whether and, if so, which rebates claimed by ratiopharm can be taken into account in establishing whether ratiopharm has sold ratio HFA at an excessive price contrary to the *Act*.

IV. Whether, in determining the price at which ratiopharm is selling or has sold ratio HFA in any market in Canada, the Panel can take into account any rebate or discount given by ratiopharm in respect of such sale and reported to the Board pursuant to section 4 of the *Regulations*.

a. The indirect sales and distribution of ratio HFA

91. During the Proceeding, Ms. Saracino described what ratiopharm refers to as an indirect distribution model of ratio HFA almost exclusively to pharmacies for eventual resale to consumers. Under this model, ratiopharm sells ratio HFA, with few exceptions, to what she characterized as 'distributors', consisting of

wholesalers and 'distribution centres', for resale to pharmacies. Distribution centres include the distribution arms of large pharmacy groups and buying groups of a number of unaffiliated pharmacies and potentially hospitals who have banded together for purchasing. Wholesalers and distribution centres make up ratiopharm's corporate accounts, a few individual pharmacies its retail accounts. Witnesses for ratiopharm estimated the number of ratiopharm's corporate accounts for the sale of ratio HFA to be in the range of ten to twelve.

92. Ms. Saracino's testimony was that wholesalers and distribution centres purchase ratio HFA from ratiopharm at the list price and sell ratio HFA to pharmacies at that same list price and on terms of payment they negotiate and enforce independently of ratiopharm. Wholesalers and distribution centres are paid a fee by ratiopharm for what Ms. Saracino characterized as their distribution services. They also generally benefit from prompt pay discounts and handle the return to ratiopharm of ratio HFA product recalled, damaged or beyond expiry date and for which they issue a credit to retailers and then receive an associated credit from ratiopharm. Distributors distribute ratio HFA at the price they paid ratiopharm for the product, with no mark-up. This model avoids the need for ratiopharm to own and operate its own system of distribution to retailers or to follow up with delinquent accounts.

93. It was Ms. Saracino's view that in this indirect business model, distributors do not sell ratio HFA or market it but that it is their distribution services they sell.

94. Ms. Saracino explained that the quantities of ratio HFA that individual pharmacies are forecast to purchase through wholesalers and distribution centres are estimates made by those pharmacies for varying forward-looking periods. These estimates generate the supply need. The percentages to be applied to the total sales of ratio HFA by pharmacies to determine Professional Allowances, CE payments in the case of corporate accounts and PEP payments in the case of retail accounts, are also agreed upon on a going-forward basis. CE and PEP payments are made by ratiopharm directly to individual pharmacies or the regional corporate head offices of banner pharmacies, not to the latter's distribution arm, according to the level of sales anticipated and the rebate percentage agreed to. Those payments are later validated and reconciled by ratiopharm with the help of data purchased from IMS. The payments made are adjusted in the next sales period, as and when required. Ms. Saracino therefore identified the pharmacy as ratiopharm's "ultimate customer" in the sales and distribution chain since it is the pharmacy that really creates demand.

b. ratiopharm's Revised Form 2 Filings

95. The deductions claimed for the sale of ratio HFA by ratiopharm in its Revised Form 2 Filings, whether for prompt pay discounts, returns or CE and PEP rebates, consist largely of estimates. All deductions are attributed to ratio HFA sales *pro rata* on the basis of the sales volume of ratio HFA as a percentage of total company sales reported in ratiopharm's accounting records and audited financial statements for all products sold by ratiopharm. The deductions filed are allocated to ratio HFA as a percentage of the company-wide deductions recorded by ratiopharm for all products.

96. The Panel notes that ratiopharm is on record as estimating that it has a portfolio of some 250 products for sale in Canada in a wide variety of dosage forms and therapeutic classes, and that, in the few documents filed by ratiopharm, the percentage used for CE and PEP rebates varies from 0% to 70% and specifically for ratio HFA, between 20% and 40%. Ms. Saracino testified that, for ratio HFA, the percentage applied in a given case could potentially be as low as 0%.

97. From the very outset of the review by the Board of the price at which ratiopharm was selling and had sold ratio HFA, Board Staff expressed to ratiopharm its concerns that the information it was providing to the Board in its Revised Form 2 Filings was not sufficient to enable the Board to confirm that the rebates and expenses claimed by ratiopharm in respect of the sale of ratio HFA were incurred for and properly related to the sale of ratio HFA. The Panel shared these concerns, and this led to the issuance of the Inspection Order by the Panel.

98. A significant portion of the Proceeding involved discussion of 1) whether the Panel needs product- specific documentation to verify the amounts claimed by ratiopharm as rebates in order to ensure that they are incurred, properly supported and directly related to the sales of ratio HFA; and 2) the adequacy of the supporting documentation provided by ratiopharm with regard to the rebates claimed by ratiopharm in respect of ratio HFA. In the Panel's view, as further outlined below, the debate raises questions regarding the *bona fides* of ratiopharm as a party in the Proceeding and the credibility of some of its witnesses.

99. The sworn testimony of Mr. Richard Monk, a certified management accountant with Welch, was that the on-site inspection ordered by the Panel in the Inspection Order, and conducted by Welch, and the documentation provided by ratiopharm during the inspection, did not yield the ratio HFA-specific information required to conclude that the deductions claimed by ratiopharm in its Revised Form 2 Filings were incurred specifically on account of ratio HFA or are otherwise properly

attributable to sales of ratio HFA. This information was not available to Welch or produced to the Board despite the sworn testimony of Ms. Saracino at the hearing of the Preliminary Motions that ratiopharm tracks and records the payment of discounts and rebates on a product-specific basis and that such product-specific documentation is maintained by ratiopharm.

100. During the on-site inspection, in addition to the provision of internal budgets, forecasts, estimates and audited financial statements, ratiopharm agreed to Welch sending a letter to a sample of sixteen pharmacies chosen in concert with ratiopharm, in an attempt to obtain third party confirmation of the percentage applied to sales of ratio HFA for the payment of CE and PEP rebates. Five responses were received. Two pharmacies confirmed the average rate used by ratiopharm, two indicated a different rate and one response was a refusal to provide any information.

101. Long after the on-site inspection ordered by the Panel, which lasted some thirteen days between October 6 and 30, 2009, and after the reply evidence of Welch in the Proceeding had been filed on January 6, 2010, ratiopharm produced examples of information of the type that, Mr. Monk testified at the Proceeding, would have been helpful had it been made available to Welch during the inspection process, but was not. It includes two product-specific CE agreements between ratiopharm and pharmacies, two product-specific CE-related invoices, one example of an internal product-specific sales data reconciliation related to rebates and a limited number of examples of purchase orders and proof of rebate-related payments. Mr. Monk considered in his testimony that this very type of product-specific information for all sales of ratio HFA is necessary to meet the requirements of the Panel in the Inspection Order and for any reliable conclusion to be drawn with respect to the connection between CE and PEP rebates and ratio HFA.

102. During the Proceeding, Ms. Saracino testified, as she had at the hearing of the Preliminary Motions, that ratiopharm retains product-specific information and supporting documentation for sales, as well as reconciliations supporting the payment of all CE and PEP amounts, by customer and by product, and that ratiopharm also tracks and documents returns and prompt pay discounts on a product-specific basis. This information and documentation was not made available to Welch or, other than the few examples tendered, filed with the Board.

103. The Panel notes that, of the seven ratiopharm witnesses who gave testimony during the Proceeding, not one claimed to have direct knowledge of the information used to generate the Revised Form 2 Filings, or to know who was responsible for their preparation. This is despite the fact that the Revised Form 2 Filings were certified to be true and correct by a ratiopharm representative and that the Revised Form 2 Filings were submitted by a representative of ratiopharm who attended most of the Proceeding, but did not testify, and who, according to Mr. Major, reports to Ms. Saracino. The inexplicable vacuum of data and the failure of any ratiopharm witness to speak directly to the significant revisions made to ratiopharm's pricing information made it impossible for the Panel to assess the integrity of the rebate information and therefore to give it any weight in this Proceeding. It should be noted that this is a separate matter from the interpretive question of whether *Pfizer* precludes the consideration of the rebates. This is an evidentiary matter: there is an unexplained failure by ratiopharm to file credible information about the rebates that the Board requires in order to calculate the ATP of ratio HFA – information that ratiopharm's witness swore that ratiopharm possesses.

c. The Debate

104. Mr. Monk and Mr. Andrew Milner, a chartered accountant with Welch, repeatedly recognized in cross-examination by ratiopharm counsel during the Proceeding that there is evidence that ratiopharm has paid out significant amounts in rebates across all the products it sells. These witnesses, however, cast the appropriate question as being whether there was sufficient evidence before the Panel connecting these payments to the ratio HFA product itself so that they could be legitimately used in reducing its net price.

105. Mr. Monk's expert opinion was that, in order to support claims for rebates for past transactions, at a minimum, ratiopharm should have provided: third party confirmation for CE and PEP percentage rates and sales data reconciliation information in respect of ratio HFA; documentation with respect to the terms and conditions of all amounts paid in respect of ratio HFA; and internal reconciliations supporting the payment of CE and PEP rebates given for ratio HFA. Only with this type of accurate ratio HFA-specific information can the Board, in his expert view, properly calculate the ATP and make other pricing calculations with respect to a medicine.

106. Dr. Ramy Elitzur, professor of financial analysis, gave expert evidence on behalf of ratiopharm as to whether the deductions claimed by ratiopharm in respect of ratio HFA and the documentation used by ratiopharm to calculate them are reasonable in the circumstances. In his expert opinion, from a management

accounting perspective, the test should be whether the rebates claimed are reasonably attributable to ratio HFA in the context of ratiopharm's business realities. It suffices, in his view, if disbursements are accurately tracked by ratiopharm in its books and records and reflected in its audited financial statements. He opined that it is reasonable to calculate Professional Allowances for ratio HFA based on the average Professional Allowances paid across all products.

107. Professor Elitzur expressed the view that management accounting posits specific guidelines and factors to be taken into account, including not only financial accounting and auditing standards and effective control procedures but also certain criteria such as business realities and situational relevance related to a specific business context. He would not, however, relate his analysis to a regulatory context or to whether information useful for business needs, internal management accounting and decision-making is necessarily sufficient to verify compliance with regulatory requirements. He stated that this was not part of the mandate given to him, although the questions for which his opinion was sought by ratiopharm had included a request to relate his comments "to the matter involving ratiopharm and the PMPRB in respect of ratio-Salbutamol HFA."

108. Mr. Scott Davidson, a chartered accountant and specialist in investigative and forensic accounting and Mr. Larry Andrade, a chartered accountant, both with Cole Partners, commented on the report filed by Welch following the on-site inspection and gave opinion evidence on behalf of ratiopharm similar to Professor Elitzur's with regard to the adequacy of the supporting information filed by ratiopharm with respect to rebates. Their view was that a "reasonably attributable" test is adequate, in light of the absence of established specific Board standards, guidelines and policies, in the Board's Guidelines, the Guide or elsewhere, with respect to the information and documentation to be filed in support of rebates claimed pursuant to the *Regulations*. They acknowledged that their evidence was prepared without independent verification of the accuracy of the information provided to them by ratiopharm.

d. Conclusion

109. Paragraph 80(1)(*b*) of the *Act* specifies the information that must be provided to the Board by a patentee of a medicine, in accordance with the *Regulations*, respecting the price at which the medicine is being sold or has been sold in any market in Canada. For the purposes of paragraph 80(1)(*b*), the information required by subparagraph 4(1)(*f*)(i) of the *Regulations* is the average price of and net revenue from sales of the medicine and, pursuant to paragraph 4(4)(*a*),

rebates with respect to the specific medicine at issue must be taken into account ("le" médicament in the French-language version).

110. In the reasons for its decision leading to the Inspection Order, Decision: PMPRB-08-D2-ratio-Salbutamol ratio HFA – Preliminary Motions (May 22, 2009), at paragraph 29, the Panel emphasized that there is a responsibility on a party subject to ongoing statutory regulation to produce, as required by the regulator in the legitimate exercise of its jurisdiction, the information that it requires for the purpose in a form reasonably capable of permitting that exercise. At paragraph 30, the Panel concluded that the information required in the Inspection Order is necessary for the making of an informed decision in the case before it and in the circumstances surrounding it. Those circumstances include the very substantial increase in ratiopharm's list price for ratio HFA in 2004, the magnitude of its 2009 revisions in its Revised Form 2 Filings for ratio HFA for a number of years, the size and nature of the rebate amounts deducted from its gross revenues in respect of ratio HFA for many years and the impossibility of verifying, in respect of ratio HFA, ratiopharm's pricing and cost information using external sources.

111. The Panel remains of the view that a patentee, in reporting the average price at which a patented medicine is being sold or has been sold, or the net revenue from its sale, is required to file supporting documentation of any rebate claimed in respect of the medicine and that is clearly, directly and verifiably related to the medicine involved. The Panel concludes that, on the basis of its Form 2 Filings and the evidence in the Proceeding, ratiopharm has not met this requirement in respect of the sale of ratio HFA, despite sworn testimony that it has such evidence, and the issuance of a Panel order to produce it. ratiopharm has failed throughout to respond to repeated requests by Board Staff and by the Panel, even during the Proceeding, for information that would allow the Panel to determine the specific pricing issue before it. ratiopharm had a number of opportunities to make available and/or submit the evidence that its representative swore that it had with respect to both the originally claimed and then substantially revised rebate claims, but ratiopharm failed to do so.

112. The Panel concludes that it cannot, in the circumstances, take into account any of the rebates claimed by ratiopharm in respect of the sale of ratio HFA in determining the price at which ratiopharm has sold ratio HFA for the periods involved and whether the price of that specific medicine was excessive contrary to the *Act*.

113. This conclusion is consistent not only with the provisions of the *Act* and the *Regulations,* the filing requirements for the proper discharge of the Board's mandate under sections 83 and 85 of the *Act* and reasonable realities in a regulatory environment but also, as testified by Ms. Tognet, with the type of information filed in support of deductions claimed by patentees in other proceedings before the Board.

114. Subsection 4(4) of the *Regulations* requires the Board to determine the actual price of a medicine after the reductions or rebates set out in that paragraph. Patentees thus have the obligation to keep the records required to support the reductions and rebates attributable to that medicine and to file them with the Board. A panel of the Board must determine their adequacy after reasonable requests for further production for the purpose of applying subsection 4(4) and has the discretion not to consider rebates which are not, in its view, specifically supported by the evidence provided.

e. The applicability of the *Pfizer* judgment

115. Both Board Staff and ratiopharm raised the applicability of *Pfizer* to the issue of the rebates, discounts, refunds and other deductions to be considered by the Panel pursuant to paragraph 4(4)(*a*) of the *Regulations* in calculating the average price of ratio HFA.

116. At issue in *Pfizer* was a Board Stakeholder Communiqué issued on August 18, 2008 (the "Communiqué"). The Communiqué required patentees to include henceforth, as part of their reporting of the net price of a patented medicine pursuant to subparagraph 4(1)(*f*)(i) and paragraph 4(4)(*a*) of the *Regulations,* all rebates, discounts, refunds and other deductions, including payments made to a province as consideration for the province's agreement to list the medicine on the provincial formulary at a specified price.

117. The applicants in *Pfizer* sought judicial review of the Communiqué, on the ground that the Board's jurisdiction is limited to reviewing prices associated with sales of patented medicines made at the factory gate and does not extend to transactions involving third parties that may take place further downstream in the supply chain.

118. In *Pfizer,* Mactavish, J. held that the Board did not have jurisdiction to enforce the requirement that patentees include, as part of the reporting of the net prices of their patented medicines, pursuant to subparagraph 4(1)(*f*)(i) and subsection 4(4) of the *Regulations*, payments made to a province in respect of those medicines, on the ground that such payments are made to third parties.

119. Since *Pfizer* was issued, interpreting the scope of the decision beyond the specific question that was raised in the judicial review proceedings has caused the Board and patentees considerable difficulty.

120. Board Staff takes the position that broad language is used in *Pfizer* that has the impact of excluding payments made by patentees to third parties who are not, in the words of *Pfizer,* a customer of the patentees contemplated by subparagraph 4(1)(*f*)(i) of the *Regulations,* from being taken into account for the purpose of establishing the net price at which a patented medicine is being sold, or has been sold. This would have the effect of excluding from the ATP of ratio HFA, as a matter of law, all of the rebates claimed by ratiopharm. The Panel agrees that there is support for this interpretation in the decision. Both the opening paragraphs of *Pfizer*, as well as the order, provide that subparagraph 4(1)(*f*)(i) and paragraph 4(4)(*a*) of the *Regulations* do not authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines. This is stated to be the central issue in the decision. Even had the question been framed more narrowly, the underlying rationale provided by Mactavish, J. to exclude the payments to the provinces relies upon an interpretation of the legislation that is consistent with commercial law applicable to the sale of goods and is in turn dependent on limiting the scope of reporting to the relationship of privity between a buyer and a seller. Given the rationale used in *Pfizer*, based on the technical private law meaning of "customer", it is difficult to apply *Pfizer* to exclude third party payments to a public party such as the government while ignoring the applicability of *Pfizer* in the private chain of distribution that would fall squarely within the traditional purview of the retail sale of goods.

121. The position of ratiopharm is that *Pfizer* can be read more narrowly. Again, there is support for this position in the decision. The specific question before the Court in *Pfizer* was, as indicated, whether payments to the provinces under expenditure limitations agreements related to the price of patented medicines must be reported under subparagraph 4(1)(*f*)(ii) and subsection 4(4) of the *Regulations*. Furthermore, in *Pfizer*, Mactavish, J. supported the decision in *Leo Pharma*. In *Leo Pharma*, the Court determined that the free distribution of a patented medicine by a patentee to doctors for their patients must be considered, pursuant to the *Regulations*, in establishing the average net price of the medicine. Support for *Leo Pharma* is not consistent with an expansive exclusion of all third party transactions in the calculation of the net price of a medicine.

122. It should also be noted that ratiopharm made a further argument in passing to the effect that *Pfizer* can be read as providing patentees with the discretion to include or exclude payments made to third parties. However, this argument was not pressed very hard before us and for the reasons set out below, the Panel does not accept this argument.

123. Since *Pfizer* was decided, the Supreme Court of Canada has provided further guidance to the Board in matters requiring statutory interpretation. *Celgene* supported the decision of the Board to reject the technical commercial law definition of the words "sold" and "selling" in the *Patent Act* when guided to do so based upon the purpose and legislative history of the *Act* and consumer protection as the Board's mandate recognized by the courts. Furthermore, the Supreme Court of Canada stated in *Celgene* that, when the Board interprets its enabling legislation, it should be accorded deference and only if the Board's decision is unreasonable should it be set aside.

124. In *Pfizer*, the Court had before it an executive Board decision and therefore a limited record and no detailed evidentiary documentation and argument as are developed in a hearing with regard to the operations common to the pharmaceutical industry in the distribution of patented medicines. The business reality of the pharmaceutical industry is one that operates by providing rebates and other payments throughout a chain of distribution. Such business realities must be taken into consideration by the Board if it is to review the true price at which patented medicines are provided to Canadians, in accordance with its statutory mandate, and if it is to give effect to subsection 4(4) of the *Regulations* which remains in force.

125. Guided by the consumer protection goals of its mandate, the Panel is of the view that if it were required to do so, it would conclude that the interpretation of subparagraph 4(1)(*f*)(i) and paragraph 4(4)(*a*) of the *Regulations* set out in the Communiqué is the appropriate one except, given the decision in *Pfizer*, which is binding on the Board, as regards the payments that were at issue in *Pfizer*; i.e. payments to the provinces. In this case then, had the Panel determined that the pricing information filed with respect to ratio HFA was substantively sufficient and credible, it could have deducted payments made by ratiopharm as rebates. However, in light of the Panel's conclusion with regard to the inadequacy of the evidence provided in this regard in the Proceeding, and the resulting inappropriateness of considering rebates in its findings in the circumstances of the sale of ratio HFA by ratiopharm, the Panel need not finally assess the scope of *Pfizer* at this time.

V. What order, if any, should be made by the Panel with respect to the sale of ratio HFA by ratiopharm in Canada.

126. The Panel is satisfied that the evidence and argument of the Parties establish that the Board Guidelines provide for an appropriate implementation of subsection 85(1) of the *Act* in this case and accordingly it is of the view that excessive revenues arising from sales of ratio HFA should be calculated on the basis of the tests provided in the Board's Guidelines which indicate that ratio HFA was excessively priced by ratiopharm from the time of the 2004 price increase until sales ceased in 2010. In particular, the Panel finds that excessive revenues should be calculated using the CPI methodology following the establishment of an MNE for ratio HFA at the time of its introduction to the market in 2002.

127. The Panel reached this conclusion after hearing evidence that, even when using the various pricing tests in the Guidelines independently of CPI adjustments throughout the period from 2002 to 2008, there was compelling evidence that the price of ratio HFA was excessive within the terms of subsection 85(1) of the *Act* during that period.

128. Under subsection 85(1) of the *Act*, the price of a medicine can be excessive in two separate ways: (i) relative to the prices of comparable medicines; and (ii) relative to its own price in prior periods. The Board's Guidelines take the factor stipulated in paragraph 85(1)(*a*), the price of the medicine in Canada, and consider that price relative to the two comparative factors stipulated in paragraphs 85(1)(*b*) and (*c*), the prices of domestic comparators and the international prices of the medicine itself, and the temporal factor in paragraph 85(1)(*d*), changes in the CPI during the time that the medicine is marketed in Canada. The Guidelines as they existed during the relevant periods did not account for tests based on the international prices of comparators, but a panel of the Board in a review hearing will weigh that factor in its consideration of whether or not the price of the medicine is or has been excessive, as was done in this case.

129. The Guidelines combine the three factors by which subsection 85(1) of the *Act* instructs the Board to assess the price of a medicine in Canada by (i) establishing an initial non-excessive price for a medicine by reference to the prices of comparable medicines; and (ii) establishing its non-excessive price in subsequent periods by reference to increases in the CPI. Accordingly, the application of the Guidelines results in all of the factors in subsection 85(1) being considered and weighed in the analysis of whether or not ratio HFA has been excessively priced. In this case, Board Staff went on to confirm that this

conclusion from the Guidelines, which is based on CPI increases after initial comparative tests, is supported by supplemental testing of the price of ratio HFA throughout the period of its sale in Canada using all of the comparative factors in subsection 85(1) repeatedly for all reporting periods.

130. The Panel therefore orders that the MNE for ratio HFA sold by ratiopharm for the period September 2002 to January 2010, and the amount to be paid to the Crown by ratiopharm for excessive revenues derived from such sale, pursuant to paragraph 83(2)(*c*) the *Act*, be determined in accordance with this decision, based on ratio HFA's MNE at introduction, as adjusted for CPI in accordance with the methodology set out in the Board's Guidelines, but without taking into account any reduction of the ATP of ratio HFA for rebates, whether for prompt pay, returns, CE or PEP payments. The Panel requires that Board Staff present to it, within 30 days of this decision, on or before June 27, 2011, a draft order that implements the terms of this decision.

Board Members:	Dr. Brien Benoit Anne Warner La Forest
Board Counsel:	Gordon Cameron Andrée Wylie

Appearances

Board Staff:	David Wilson, Counsel Leslie Milton, Counsel Marisa Victor, Counsel
For the Respondent:	Gavin MacKenzie, Counsel Benoit Duchesne, Counsel Judith Parisien, Counsel

Original signed by

Sylvie Dupont
Secretary of the Board

TAB 3

Public Version

PATENTED MEDICINE PRICES REVIEW BOARD

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

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris"

DECISION

(Hearing on the Merits)

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Schedule A

Public Version

I. Summary of Decision

1. The Panel of the Patented Medicine Prices Review Board (the "**PMPRB**" or the "**Board**") seized with this proceeding has considered the evidence adduced (including expert evidence) and submissions made by Board Staff, Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**") and the intervenors,[1] and finds that the price of Soliris (eculizumab) 10mg/mL ("**Soliris**") was and is excessive under sections 83 and 85 of the *Patent Act.*[2] The Panel orders Alexion to (i) pay to Her Majesty in right of Canada an amount calculated by the parties in accordance with Schedule A to this decision, to be approved by this Panel, and (ii) lower the list price of Soliris in Canada as of the date of this decision to no higher than the lowest price in the seven comparator countries set out in the current *Patented Medicines Regulations* ("**Regulations**").[3]

II. Introduction

2. Soliris is a breakthrough drug indicated for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH), a rare and life-threatening blood disorder that is characterized by complement-mediated hemolysis (the destruction of red blood cells).

3. Soliris is also approved as a treatment for patients with atypical hemolytic uremic syndrome (aHUS), a rare and life-threatening genetic disorder characterized by "complement-mediated thrombotic microangiopathy" or TMA (blood clots in small vessels).

4. Soliris is sold in Canada by Alexion. Board Staff filed a Statement of Allegations on January 15, 2015 alleging that the price of Soliris was excessive between 2012 and 2014, and seeking an order from this Panel under section 83 of the *Patent Act* requiring Alexion to, *inter alia*, reduce the price of Soliris to a price that does not exceed the international highest price among the comparator countries, and pay $5,617,480.42 to offset the

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1 Ministers of Health, Canadian Life and Health Insurance Association Inc. and BIOTECanada.

2 RSC 1985, c P-4 [*Patent Act*].

3 SOR/94-688. These countries are France, Germany, Italy, Sweden, Switzerland, the UK and the US.

cumulative excess revenues Alexion had received during the period of January 1, 2012 to June 30, 2014.

5. On January 22, 2015, the Board issued a Notice of Hearing with respect to Board Staff's Statement of Allegations. After the filing of an Amended Statement of Allegations and numerous preliminary motions, this hearing was held on the following days in 2017: January 16 to 19, and 23 to 26; February 20 to 24, 27 and 28; March 1 to 3; and April 18 and 19. The purpose of the hearing was to determine whether, under sections 83 and 85 of the *Patent Act*, the Respondent is selling or, since 2012, has sold Soliris in any market in Canada at a price that, in this Panel's opinion, is or was excessive, and if so, what order(s), if any, should be made.

III. Interlocutory Decisions

6. Given the lengthy procedural history of this case, the Panel will summarize the main preliminary motions brought in this proceeding.

7. Alexion filed a motion on May 15, 2015 requesting that Board Staff be ordered to provide particulars of all allegations in the Statement of Allegations. This motion was heard on June 22 and 23, 2015 and granted by the Panel in an order dated June 23, 2015.[4]

8. Alexion brought a motion on August 21, 2015 raising allegations of conflicts of interest and reasonable apprehensions of bias on the part of a number of the individual counsel involved in this proceeding and the Chairperson of the Board. This motion was heard on September 16, 2015 and dismissed by the Panel in a decision dated October 5, 2015.[5]

9. At a pre-hearing conference held on October 28, 2015, the Panel heard various motions relating to procedural issues. In its decision dated November 24, 2015, the Panel:

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4 Board Decision – *Order Regarding Requests for Particulars and Scheduling of Filing of Amended Respond and Reply* (23 June 2015), online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/OrderregardingparticularsJune23.pdf>.

5 Board Decision – *Respondent's Motion Relating to Conflicts of Interest* (5 October 2015), online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/MotionRelatingtoConflictsofInterest-October5thdecision-Final.pdf>.

- dismissed Alexion's motion to strike certain parts of the Further Amended Notice of Appearance of the Minister of Health for British Columbia, in particular those parts related to the use of the Lowest International Price Comparator Test (or the "**LIPC**");

- dismissed Alexion's motion to strike certain parts of Board Staff's Amended Reply, in particular allegations related to section 85(2) of the *Patent Act* (but granted Alexion an option to file a Sur-reply); and

- granted Board Staff's motion to strike certain parts of Alexion's Amended Response, in particular inflammatory allegations relating to the integrity of counsel for Board Staff.[6]

10. On February 26, 2016, Alexion moved to strike certain parts of Board Staff's expert evidence. In a decision dated March 29, 2016, the Panel dismissed Alexion's motion, without prejudice to Alexion's right to challenge both the admissibility and the weight to be given to any of the expert evidence at the hearing on the merits.[7]

11. On May 20, 2016, Board Staff moved to (i) amend its Statement of Allegations to include alternate remedies in the event that the Panel finds that the price of Soliris is excessive, including *inter alia* the application of the LIPC test, and (ii) strike or require particulars of certain portions of the will-say statement of Mr. Barry Katsof. Through the requested amendments, Board Staff seeks (i) excess revenues in the range of $4,743,572.88 to $91,908,321.21, depending on the test adopted by the Panel, and (ii) an order requiring Alexion to reduce the price of Soliris to a price that does not exceed the LIPC. On June 10, 2016, the Panel granted Board Staff's motion to amend the Statement of Allegations,

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6 Board Decision – *Various Motions Related to Procedural Matters* (24 November 2015), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/SOLIRIS-PMPRBNovember24th2015decision.pdf> [Board Decision – *Various Motions Related to Procedural Matters*].

7 Board Decision – *Respondent's Motion to Strike Expert Evidence* (29 March 2016), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Solaris_Motion_to_Strike_Expert_Evidence_Decision_March_29_2016.pdf>.

and dismissed Board Staff's motion to strike portions of Mr. Katsof's will-say statement.[8] The hearing was adjourned for several months to allow Alexion to respond to the Amended Statement of Allegations.

12. At the commencement of the hearing, before the start of opening arguments and the hearing of any evidence, the Panel informed the parties that Mr. Normand Tremblay had resigned from the Panel due to personal reasons, and that the hearing would proceed with two Panel members, Dr. Mitchell Levine and Ms. Carolyn Kobernick, which is a quorum under Rule 4 of the PMPRB's *Rules of Practice and Procedure* (the "**Rules**").[9] On January 16, 2017, Alexion moved for an order requiring that the Panel be reconstituted to restore a third member for the purposes of the hearing. The Panel dismissed the motion on January 17 with reasons to follow, and these reasons were provided on February 1, 2017.[10]

13. On January 20, 2017, Board Staff moved for the issuance of subpoenas requiring Mr. Eric Lun and Mr. John Haslam to produce certain documents regarding Product Listing Agreements ("**PLAs**") negotiated between Alexion and various provinces concerning Soliris. On January 23, 2017, Alexion moved under Rule 24 of the Rules for an order requiring production of further documents from Board Staff. On January 24, 2017, the Panel granted Board Staff's motion and issued subpoenas to Messrs. Haslam and Lun, and dismissed Alexion's motion.[11]

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8 Board Decision – *Motion to Amend Statement of Allegations and Strike Certain Portions of Will-Say Statement* (10 June 2016), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Decision_Motion_to_Amend_Pleadings_and_Strike_Will_Say_Statement.pdf>.

9 SOR/2012-247.

10 Board Decision – *Motion to Reconstitute Panel* (1 February 2017), online: PMPRB < http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Panel_constitution_order.pdf>.

11 Board Decision – *Motion to Issue Subpoenas* (24 January 2017), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/DECISION_ON_SUBPOENA.pdf>; Board Decision – *Motion to Request Further Documents* (24 January 2017), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Panel_order_production_respondent.pdf>.

IV. Fact Evidence

14. Board Staff called one fact witness: Mr. Richard Lemay. Alexion called three fact witnesses: Mr. John Haslam, Mr. Barry Katsof and Mr. Matthew George. The fact evidence is briefly summarized in this section of the decision.

(a) Richard Lemay

15. Mr. Richard Lemay is the Manager of the Outreach and Investigations Unit of the PMPRB. He joined the PMPRB in 2015 and, as at the time of his testimony, reported directly to Ms. Ginette Tognet, Director of the Outreach and Investigations Unit. Mr. Lemay's testimony focussed on the various filings made by Alexion with the PMPRB in relation to Soliris, including the sources used for the calculations of excess revenues.

16. Mr. Lemay was not involved in the preparation of most of Board Staff's documents in this case, and was not able to answer questions or provide details about various aspects of the documents filed by Board Staff. It would have been much more helpful to the Panel if Board Staff had called a witness with direct involvement in, or knowledge of, Board Staff's investigation. However, Mr. Lemay's lack of knowledge was not material to the Panel's decision in this case, except with respect to the prices to be used for the purposes of calculating excess revenues (which the Panel deals with later in this decision).

(b) John Haslam

17. Mr. John Haslam is the President and General Manager of Alexion Canada. His testimony focussed on Alexion's activities in Canada, the discussions between Alexion and Board Staff related to Soliris, and the filings made with the PMPRB in relation to Soliris.

(c) Barry Katsof

18. Mr. Barry Katsof is a PNH patient and the founder of the Canadian Association of PNH Patients. His testimony discussed his experience with PNH, the benefits of Soliris, and the activities of the association that he founded.

(d) Matthew George

19. Mr. Matthew George is a PNH patient. He testified about the debilitating nature of PNH and the positive impact of Soliris on his life.

V. Evidence of the Ministers of Health

20. On March 9, 2015, the Minister of Health for British Columbia filed a Notice of Appearance (the "**Initial Notice of Appearance**"). In the Initial Notice of Appearance, the Minister of Health for British Columbia, on his own behalf and on behalf of the Minister of Health for the Province of Manitoba, provided notice of an intention to make representations pursuant to subsection 86(2) of the *Patent Act* supporting the orders requested by Board Staff in the Statement of Allegations. This is the first proceeding before the Board where a Minister of Health has exercised this right.

21. On March 13, 2015, the Secretary of the Board wrote to the Ministers of Health for British Columbia and Manitoba advising them that they had failed to meet the requirements of Rule 21(2) of the Rules. On March 17, 2015, the Ministers requested the right to amend the Initial Notice of Appearance to provide further particulars of the material facts upon which the Ministers intended to rely and to permit them to also make representations on behalf of the Ministers of Health for Ontario and for Newfoundland and Labrador (collectively, the "**Ministers of Health**"). On March 26, 2015, the Board issued an order extending the time to allow the Ministers of Health to file an Amended Notice of Appearance (the "**Amended Notice of Appearance**").

22. On April 2, 2015, the Ministers of Health filed the Amended Notice of Appearance, along with an affidavit sworn by Mr. Eric Lun, Executive Director of the Drug Intelligence and Optimization Branch, Medical Beneficiary and Pharmaceutical Services Division of the Ministry of Health of British Columbia.

23. In a letter dated April 16, 2015, Alexion objected to the filing of the Amended Notice of Appearance and sought leave to cross-examine Mr. Lun on his affidavit. In response, the Ministers of Health sought leave from the Panel to withdraw the affidavit and, on June 23, 2015, the Panel granted the Ministers of Health's request.

24. On June 26, 2015, the Ministers of Health filed a Further Amended Notice of Appearance, where they set out their intention to make additional representations as outlined in paragraphs 1 and 3 of the Further Amended Notice of Appearance. In paragraph 1, the Ministers of Health state that they intend to make representations supporting the orders sought by Board Staff, but also make representations to request that the Panel issue the following relief pursuant to section 83 of the *Patent Act*:

> "(a) the Respondent reduce the price of Soliris to a price that does not exceed the lowest price for Soliris among all comparator countries; and
>
> (b) the Respondent offset cumulative excess revenues that it has received by paying to the federal government an amount equal to the excess revenues the Board estimates that the Respondent has generated from the sale of Soliris at an excessive price, with the Board to use the lowest price for Soliris among all comparator countries as the basis for the calculation."

25. A statement of the representations that the Ministers of Health intended to make and the material facts on which the Ministers of Health were relying were referenced in paragraph 3 and set out in detail in Appendix A of the Further Amended Notice of Appearance.

26. Alexion brought a motion to strike out paragraphs 1 and 3, and Appendix A of the Further Amended Notice of Appearance. This motion was heard on October 28, 2015, and dismissed by the Panel in a decision dated November 24, 2015.[12]

27. At the hearing, Mr. Lun testified on behalf of the province of British Columbia, as well as on behalf of the Ministers of Health of Manitoba, Ontario and Newfoundland and Labrador. Mr. Lun's testimony focussed on, *inter alia*, the provinces' approach to funding medicines, including Soliris; negotiation of the PLAs for Soliris; the costs associated with Soliris, including in comparison to the costs of other expensive drugs for rare diseases ("**EDRDs**"); and the effects of EDRDs, including Soliris, on the provincial health budget. Mr. Lun testified that, in 2015/2016, British Columbia funded 14 EDRDs

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12 Board Decision – *Various Motions Related to Procedural Matters*, *supra* note 6.

at a total expenditure of approximately $[redacted] Soliris represented $[redacted] of that $[redacted], or almost [redacted]%. The average cost of EDRDs (including Soliris) in British Columbia was $[redacted] per patient per EDRD, an amount considerably less than the annual average cost of Soliris to treat adult patients with PNH or aHUS.[13]

VI. Expert Evidence

28. Board Staff and Alexion filed multiple expert reports on the issues in dispute in this proceeding. These reports were reviewed in detail by the Panel prior to the commencement of the hearing. During the hearing itself, the evidence of each expert was provided during an examination-in-chief[14] and was tested in thorough cross-examination by the other side. The expert evidence and the parties' submissions concerning its relevance and the weight that should be given to it were then the subject of detailed written closing submissions, as well as the subsequent oral closing submissions. The Panel has considered the evidence thoroughly and will not reproduce it in detail in this decision, but will only refer to it where salient to the Panel's determination of the issues before it.

29. Board Staff called two expert witnesses: Dr. Richard Schwindt and Dr. Sumanth Addanki. Alexion called three expert witnesses: Mr. Errol Soriano, Dr. Jonathan Putnam and Dr. Aslam Anis. Their expert evidence is very briefly summarized in this section of the decision. The Panel struck out portions of Dr. Addanki's expert report, and did not qualify Mr. Tom Brogan as an expert witness. The reasons for these decisions are also provided in this section of the decision.

30. For the most part, and except as noted in these reasons, the Panel did not find the expert evidence to be of assistance to it in determining the issues in this proceeding. The experts who testified were clearly qualified and their evidence was interesting, but a large portion of the expert evidence focussed on extraneous or tangential issues, and most of it

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13 BC Minister of Health Closing Submissions dated March 31, 2017 at paras 17–19.

14 With the exception of those portions of Dr. Addanki's report that were struck by the Panel, and the report of Mr. Brogan which was not admitted by the Panel, for the reasons expressed later in this decision. Also, Dr. MacLeod, one of Alexion's proposed witnesses, was not ultimately called to testify.

did not ultimately assist the Panel in determining whether the price of Soliris is or was excessive under sections 83 and 85 of the *Patent Act*.

(e) Richard Schwindt

31. The Panel qualified Dr. Schwindt as an expert in microeconomics and economics of industrial organization. Dr. Schwindt is an economist and a professor, and holds A.B. and Ph.D. degrees in economics.

32. Dr. Schwindt provided an opinion about the use of external reference pricing ("**ERP**") to set ceilings on prices of patented drugs. ERP, also called international reference pricing, involves a comparison of the prices in other jurisdictions to prices and price changes domestically.

33. Dr. Schwindt testified that there are numerous developed countries which impose restraints on the pricing of pharmaceutical products. In Dr. Schwindt's opinion, prices charged in other countries with similar conditions can provide a perspective on costs; in other words, if the comparator country has similar demand conditions, a conclusion can be drawn that a patentee is covering its costs and earning a normal rate of return selling at that price in that country. Overall, the tests currently set out in the Guidelines are reasonable and favourable to patentees in Dr. Schwindt's opinion.

(f) Sumanth Addanki

34. The Panel qualified Dr. Addanki as an expert in the economics of industrial organization and the economics of the pharmaceutical industry. Dr. Addanki holds a Ph.D. degree in economics and is currently the Managing Director of National Economic Research Associates, Inc.

35. Dr. Addanki provided an opinion on what economic measures, tests and considerations are appropriate for determining whether the price of Soliris in Canada is or was excessive under s. 85 of the *Patent Act*, and whether the application of these economic measures, tests and considerations indicates that the price of Soliris in Canada is or was excessive.

Dr. Addanki testified that price needs context, which can be provided by looking at median household income and Gross Domestic Product (GDP) per capita.[15]

36. After Dr. Addanki was qualified, Alexion brought a motion to exclude Dr. Addanki's expert report. The Panel granted Alexion's motion in part. The Panel did not permit Dr. Addanki to give evidence on the interpretation of section 85(1)(b)[16] of the *Patent Act* and struck paragraphs 18 to 23, 28 to 31, 34 to 44 and 46 to 50, and related exhibits from his report. In these paragraphs, Dr. Addanki proposes that the definition of "therapeutic class" should include "a class of medicines that are similar, in relevant economic respects, to the patented medicine at issue" and puts forth various comparators from an economic perspective (*e.g.*, based on an analysis of supply/demand factors, prevalence, duration of treatment, etc.) that he says should be considered by the Panel to be in the same therapeutic class as Soliris for the purposes of section 85(1)(b) of the *Patent Act*. The Panel struck these paragraphs because they are based on a concept of "therapeutic class" that is not based on clinical equivalence. As explained further below, the Panel concludes that clinical equivalence is the appropriate concept to use when defining a therapeutic class for the purposes of implementing section 85(1)(b) of the *Patent Act,* and Dr. Addanki's presentation of another definition of therapeutic class is not relevant or necessary to the Panel's determination of the issues in this proceeding.

(i) Decision to Strike Portions of Dr. Addanki's Report

37. The Panel considered the oral and written submissions of the parties, as well as the case law provided. The Supreme Court of Canada set out the basic test for the admissibility of expert evidence in *R v Mohan.*[17] To be admissible, expert evidence must be relevant, necessary to assist the trier of fact, not be subject to any exclusionary rules, and must be given by a properly qualified expert.

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15 GDP per capita is the total value of goods and services produced in Canada expressed on a per head basis; this is the measure of economic activity.

16 This factor requires the Panel to consider the prices at which other medicines in the same therapeutic class have been sold in the relevant market.

17 [1994] 2 SCR 9.

38. It is also important to note that the Rules give this Panel broad discretion with respect to the admissibility of evidence. In particular, Rules 6(1)(a) and (b) provide that the Board may "receive any evidence that it considers appropriate" and "take notice of any generally recognized scientific or technical facts, information or opinions concerning patented medicines".

39. As discussed in more detail later in this decision, section 85(1) of the *Patent Act* sets out the factors that this Panel is required to consider in determining whether the price of Soliris is or was excessive. In particular, section 85(1)(b) states that the Panel shall consider "the prices at which other medicines in the same therapeutic class have been sold in the relevant market". [emphasis added]

40. Previous panels of this Board have consistently defined therapeutic class to mean clinical equivalence, and this Panel agrees with that interpretation. For example, the panel in *Dovobet* noted that "the therapeutic class of a medicine includes those medicines that are similar to the medicine under review in ways that are relevant to the pricing of the medicine, such as the condition the medicines treat, the way the medicines are delivered to the body, their chemical compositions, and the way they work in the body."[18]

41. Further, in *Penlac*, the panel noted that therapeutic class should be defined as "clinical equivalence" and "[i]f the new medicine is not demonstrated to be comparable in efficacy and safety to existing medicines in Canada, it will not be considered to be clinically equivalent and thus there will be no therapeutic class for price comparison purposes."[19] This approach was also adopted by the panel in the *Quadracel and Pentacel* proceeding.[20]

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18 Board Decision –*Leo Pharma Inc. and the Medicine "Dovobet"* (19 April 2006), online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=827&lang=en> [*Dovobet*], rev'd in part *Leo Pharma Inc. v Canada (Attorney General)*, 2007 FC 306 [*Leo Pharma*].

19 Board Decision –*Sanofi-Aventis Canada Inc. and the Medicine "Penlac Nail Lacquer"* (31 January 2011) at paras 18 and 20, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=848&lang=en> [*Penlac*].

20 Board Decision –*Sanofi Pasteur Limited and the Medicines "Quadracel and Pentacel"* (21 December 2009) at para 68, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Quadracel-Pentacel-

42. This Panel is of the view that the concept of "therapeutic class" is within its area of expertise, and it does not require expert evidence to assist it in giving meaning to that phrase in this proceeding. The Panel concludes that clinical equivalence is the correct principle to use when defining a therapeutic class for purposes of section 85(1)(b) because it reflects the wording and intent of the *Patent Act*. Therapeutic class connotes a group of medicines that share a common feature or features. As to what that commonality should be, the Panel agrees with the panel in *Penlac* that clinical equivalence captures the intent of the *Patent Act*; section 85(1)(b), as well as 85(1)(c), deal with price comparisons and the main factors in that regard are the relative efficacy and safety of the medicines being compared.[21]

43. The Panel notes that the Guidelines are consistent with this interpretation, and concludes that this aspect of the Guidelines appropriately implements the term "therapeutic class" in section 85(1) of the *Patent Act*.[22]

44. Applying this interpretation for purposes of section 85(1), there are no medicines in the same therapeutic class as Soliris. The expert Human Drug Advisory Panel (**"HDAP"**), although not binding on this Panel, reached the same conclusion for Soliris. For this reason, the prices of medicines that are not in the same therapeutic class as Soliris are not a factor for consideration under section 85(1).[23]

45. For these reasons, the Panel did not accept Dr. Addanki's alternative interpretation of therapeutic class and its application to Soliris. Those portions of his report are neither relevant nor necessary to the Panel's determination of the issues in this proceeding. As a result, the Panel struck paragraphs 18 to 23, 28 to 31, 34 to 44 and 46 to 50, and related exhibits as they related to section 85(1)(b) of the *Patent Act*, and the Panel did not permit

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Merits-Reasons-D5-Amended-March-1-2010.pdf> [*Quadracel* (2009)], amended 1 March 2010, implemented by order issued March 16, 2010, rev'd on other grounds *Sanofi Pasteur Ltd. v Canada (Attorney General)*, 2011 FC 859.

21 *Penlac*, *supra* note 19 at paras 18, 22.

22 Canada, Patented Medicine Prices Review Board, "Compendium of Policies, Guidelines and Procedures", (February 2017) at C.8 [*Guidelines*].

23 *Penlac*, *supra* note 19 at para 86.

Dr. Addanki to give oral evidence on the interpretation of section 85(1)(b) of the *Patent Act* at the hearing.

(g) Errol Soriano

46. The Panel qualified Mr. Soriano as an expert in valuation, financial analysis and quantification of financial loss. Mr. Soriano holds an H.B.A. degree, and is qualified as a FCPA, FCA, Chartered Business Valuator and a Certified Fraud Examiner. Mr. Soriano was the Managing Director of Campbell Valuation Partners Limited, which was recently acquired by Duff & Phelps.

47. Mr. Soriano's report, among other things, provides a calculation of the Canadian price of Soliris from year to year using the CPI methodology in the Guidelines, and the additional profit that Alexion could have realized during the period under review if it had increased the price by the CPI factor year after year. Mr. Soriano further testified that although the nominal price of Soliris has not changed from 2009 to 2015, in "real dollars" the price of Soliris has decreased by 9.7% (based on inflation).

48. Mr. Soriano also proposed two alternative approaches to compare Canadian and foreign prices, that he argued would be more consistent with the principles of fairness as compared to the current Guidelines. First, a "Comprehensive Test" that compared prices based on price inflation in Canada with prices in the comparator countries – applying this test would result in excess revenues of $[redacted], which Mr. Soriano opined would be reduced to zero if certain offsets were permitted. Second, the use of Purchase Price Parity ("**PPP**") Benchmarking, which takes into account relative purchasing power in Canada and the comparator countries. Mr. Soriano testified that the application of this approach would result in the Canadian price of Soliris never being the highest among the comparator countries.

(h) Jonathan Putnam

49. The Panel qualified Dr. Putnam as an expert in economics of patents, and international trade involving patents. Dr. Putnam is the founder and principal of Competition

Dynamics LLC, a litigation and management consulting firm in Boston, and holds B.A., M.A. and Ph.D. degrees in economics.

50. Dr. Putnam's opinion focussed on the current methodologies employed by the Board, in particular the use of exchange rates to compare prices across the comparator countries. Dr. Putnam also responded to the reports of Drs. Schwindt and Addanki.

51. In Dr. Putnam's opinion, the Board: fails to employ the CPI methodology, as required under section 85(1)(d) of the *Patent Act*; then introduces foreign exchange rates to implement section 85(1)(c), even though such rates are not mentioned in section 85 and are neither necessary nor sufficient to implement s. 85(1)(c); and then avoids using exchange rates adjusted by the CPI (or any other adjustment that removes the effects of currency fluctuations on price levels). Dr. Putnam also notes that Soliris is a non-traded good, and thus, in his view, an exchange-rate converted price is not a "price" and should not be used to conduct an analysis under s. 85(1). Contrary to Dr. Schwindt, Dr. Putnam ultimately concludes that the Board's methodology as set out in the Guidelines is unreliable.

(i) Aslam Anis

52. The Panel qualified Dr. Anis as an expert in health economics and pharmacoeconomics. Dr. Anis holds Bachelors, Masters and Ph.D. degrees in economics, and holds various positions, including Professor of Health Economics at University of British Columbia, Director of the Centre for Health Evaluation and Outcomes Sciences, and National Director of the CIHR Canadian HIV Trials Network.

53. Dr. Anis responded to Drs. Addanki and Schwindt. Dr. Anis testified that the health gain from a drug is disease-specific, and the methodology used to compare the relative cost-effectiveness of various drugs is to convert their disease specific effectiveness to a common metric known as the Quality-Adjusted Life Year (QALY) Gained. Dr. Anis testified that for orphan drugs, the standard Cost/QALY approach is generally not used for various reasons, and that such drugs have to be priced at a higher level due to both

market factors and the difficulties inherent in quantifying the cost-effectiveness threshold for rare diseases.

54. Dr. Anis testified that there is an internal inconsistency in the Guidelines because patentees are asked to control prices in conjunction with exchange rates and CPI, neither of which is within the patentee's control. His opinion is that PPP exchange rates are more appropriate than market exchange rates for making more equitable comparisons to assess the financial burden of acquiring the same commodity in different countries.

(j) Tom Brogan

55. At the hearing, Mr. Tom Brogan was proffered by Alexion as an expert in Canadian drug pricing and reimbursement; market access for drug companies in Canada; and collection and interpretation of data concerning drug sales in Canada. Mr. Brogan is an independent consultant and holds a B.A. degree in economics. Mr. Brogan's expert report, which was filed prior to the hearing, focussed on issues related to compliance with, or reliance on, the Guidelines (and not on the matters in which Alexion proposed to qualify Mr. Brogan as an expert at the hearing).

56. The Panel decided not to qualify Mr. Brogan as an expert in this proceeding because he was sought to be qualified on matters outside his expert report and, in any event, his evidence was not relevant and/or necessary for the Panel's determination of the issues in this proceeding.

57. The Panel recognizes that Mr. Brogan has significant experience with domestic and international pharmaceutical companies, particularly in respect of filings with the PMPRB. As noted above, the matters in which Mr. Brogan was proposed to be qualified as an expert were not dealt with in his report. The Panel has reviewed the mandate which was provided to Mr. Brogan by Alexion, as set out in paragraph 10 of his report. In particular, Mr. Brogan was "asked to comment on the following questions:

> (a) Had you advised a company like Alexion in 2009 on the introductory price of a new drug like Soliris, what test under the Guidelines would you have indicated would apply in setting the introductory or benchmark price if the

drug was a breakthrough medicine without domestic or foreign comparators?

(b) In 2009, would you have cautioned a company like Alexion that at some future date the price of the company's medicine could be retroactively "re-set" back to the date of first sale to some other price and that the "other" price would be either a re-calculation of the median international price comparison test ("MIPC') or a new test like the so-called lowest international price comparison test ("LIPC") and that the company could be liable for any consequential excess revenues?

(c) Was there any basis in 2009 to provide advice to Alexion that the Board would change the basis for calculating "excess revenues" based on tests or price sources that were not in the Guidelines, including the so-called LIPC?

(d) Do patentees, in your experience, generally rely upon the Guidelines in setting, maintaining, or increasing the price of patented medicines?

(e) Are you familiar with any circumstances in which the Board has departed from the Guidelines to a patentee's detriment to seek increases in excess revenues based on factors or tests not found in the Guidelines? In what circumstances, to your knowledge, has the Board, or a hearing panel, departed from the Guidelines?

(f) Are you familiar with any circumstances in which the Board has held a patentee responsible for excess revenues based solely on fluctuations in foreign exchange rates?

(g) Is IMS Health data publicly available in Canada, or internationally, as you understand the term "publicly available"?

(h) In its Reply to Alexion's Supplementary Response, the Board has indicated that Alexion's relies "at its own peril" on "publications, practices, and representations of the Board" (including presumably the Guidelines) because only a hearing panel can determine "whether the price of Soliris is excessive". Does this statement reflect your understanding of how the industry, in particular patentees, regard the regulatory system?"

58. As noted above, the Panel is of the view that the matters set out in this mandate (*i.e.*, related to compliance with, or reliance on, the Guidelines) are either not relevant or not necessary to the Panel's determination of whether the price of Soliris during the relevant periods is or was excessive based on sections 83 and 85 of the *Patent Act*. What Mr. Brogan may have advised a patentee does not assist the Panel in determining whether the price of Soliris is or was excessive. As explained in the section of this decision below dealing with the role of the Guidelines, the Guidelines are not binding on this Panel, and the past practices of the Board or Board Staff are not determinative of the issues in this proceeding. Furthermore, Mr. Brogan is not qualified to opine on legal questions, such as the definition of "publicly available" or the legal status of the Guidelines.

59. For these reasons, the Panel did not qualify Mr. Brogan as an expert in this proceeding, and his report was not considered by the Panel in reaching its decision.

VII. Key Documents and Chronology

60. Given the long and rather complex factual background, the Panel provides a chronology of key events in this section of the decision.

61. On February 4, 2009, RTI Health Solutions Inc. ("**RTI**"), on behalf of Alexion, provided the PMPRB with the product monograph and Form 1 for Soliris.[24] Shortly thereafter, on March 18, 2009, RTI provided the Board with the new medicine submission for Soliris for consideration by the HDAP.[25]

62. HDAP reviewed Soliris at its May 15, 2009 meeting. HDAP's report, provided to Alexion on June 2, 2009, recommended that Soliris be classified as a category 2 new drug product.[26] Based on the then (and current) Guidelines, the highest possible price at introduction, known as the Maximum Average Potential Price or "MAPP",[27] for a breakthrough drug is the median price of the seven comparator countries set out in the

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24 Exhibit 1, Tabs 4, 5.

25 Exhibit 1, Tab 6.

26 Exhibit 1, Tab 85.

27 Under the then Guidelines, this was referred to as the Maximum Non-Excessive (or "MNE") price.

Regulations (known as the Median International Price Comparison, or "**MIPC**" test). The ceiling or maximum price for breakthrough drugs in subsequent years, referred to as the Non-Excessive Average Price or "NEAP", is the lower of (i) the price from the previous year increased by the allowable increase based on the Canadian Consumer Price Index (CPI), or (ii) the highest price in the comparator countries (known as the Highest International Price Comparison, or "**HIPC**" test). These price comparison tests and methodologies are commonly referred to as External Reference Pricing, or "ERP".

63. Soliris was first sold in Canada in June 2009. At that time, Soliris was sold in six of the seven comparator countries. The list price of Soliris in Canada at introduction was $224.7333 per unit; this is not the cost of one package, as Soliris is supplied as a 10mg/ml solution in 30ml single-use vials, and a vial (containing 30 units) of Soliris costs $6,742.[28] The product monograph sets out the dosing information for Soliris, and the maintenance dose of Soliris for PNH for an average adult costs approximately $20,000 every two weeks.[29]

64. On June 25, 2010, approximately a year after the first sale of Soliris in Canada, the PMPRB sent a letter to David Hallal of Alexion, advising him that Board Staff had commenced an investigation into the price of Soliris after reviewing the introductory price and sales data (for July to December 2009) filed by Alexion.[30] The MAPP for Soliris, calculated using the MIPC, was $217.6772, and the $224.7333 price being charged by Alexion at the time exceeded that by 3.2%. The letter indicated that Alexion had generated excess revenues of $78,322.61 during that period. Board Staff also advised that they were unable to find a public price for Soliris for Germany and France, and had found discrepancies between the public prices and the prices filed by Alexion for the United Kingdom and the United States.

65. On July 5, 2010, PDCI Market Access Inc. (previously RTI) responded to the June 25, 2010 letter (referenced above), noting that Alexion was in the process of assembling

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28 Exhibit 1, Tab 12.

29 Estimate based on dosing information in product monograph.

30 Exhibit 1, Tab 14.

source materials for prices reported in its filings, and that the method used by the PMPRB to remove the mark up in the UK is not consistent with the Board's reference publication.[31]

66. On July 13, 2010, PDCI filed Alexion's Form 2 for Soliris for January to June 2010.[32] A Form 2 contains information about the sales and prices of the drug product in Canada and the comparator countries. Patentees are required to file this pricing information with the PMPRB twice a year (for January to June and July to December of each year).

67. On August 25, 2010, PDCI provided Board Staff with the requested source materials for France (*Theriaque*) and Germany (*Medikamente-per-klick*).[33]

68. On October 21, 2010, PDCI sent Board Staff revised Block 5 data for Soliris for January 2009 to June 2010, which reflected the "correct distribution chain for [Soliris]". Block 5 data on Form 2 is the data related to sales and prices of the drug in the comparator countries. PDCI noted that the "previous reports incorrectly included wholesale and pharmacy classes for Europe" but "with the exception of Germany, Soliris is supplied directly to hospitals."[34] On November 30, 2010, PDCI corrected an error in the forms filed on October 21, 2010 – PDCI had inadvertently entered a non-hospital customer code for France (even though Soliris was supplied only directly to hospitals in Europe except for Germany).[35]

69. On February 1, 2011, PDCI filed the Form 2 for Soliris for July to December 2010.[36]

70. On June 21, 2011, Board Staff sent a letter to Alexion in regard to Board Staff's investigation into the price of Soliris that had been commenced on June 25, 2010. Board Staff accepted the amended Form 2 information filed on October 21 and November 30,

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31 Exhibit 1, Tab 16.

32 Exhibit 1, Tab 15.

33 Exhibit 1, Tab 17.

34 Exhibit 1, Tab 18.

35 Exhibit 1, Tab 19.

36 Exhibit 1, Tab 20.

2010, and noted that there were cumulative excess revenues remaining as of December 2010 of $16,946.37:

> Alexion Pharma is being given the opportunity to take a voluntary price reduction to offset the cumulative excess revenues. To offset excess revenues via a price reduction, the average price will be considered to have been reduced if it is below the previous year's national non-excessive average price (N-NEAP). The current Guidelines state that excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six-month reporting periods (three years) will be expected to be offset through a Voluntary Compliance Undertaking (VCU). Alexion Pharma is expected to offset the outstanding $16,946.37 excess revenues by December 31, 2012 or it may be subject to a VCU for that amount.[37]

71. Mr. Lemay testified that this amount was eventually offset by the deadline.

72. On August 25, 2011, the PMPRB sent Alexion a Compliance Status Report ("**CSR**") for Soliris for the period January to June 2011.[38] The cover letter explained that Board Staff reviews prices on an annual basis (*i.e.*, any investigations are commenced on a review of the full-year data). In other words, although the PMPRB issues CSRs twice a year following the reporting of the relevant information by the patentee, compliance is determined on a full-year basis (and not for each reporting period individually). The N-NEAP for this reporting period was calculated at $231.6936.

73. On January 31, 2012, PDCI filed the Form 2 for Soliris for the July to December 2011 reporting period.[39]

74. On February 27, 2012, Board Staff provided Alexion with the CSR for Soliris for 2011. The N-NEAP for Soliris for 2011 was calculated at $226.5297 and the compliance status

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37 Exhibit 1, Tab 116.

38 Exhibit 1, Tab 24.

39 Exhibit 1, Tab 25.

was "Within Guidelines".[40] The cumulative excess revenues were "0" because they had been offset.

75. On July 9, 2012, PDCI filed the Form 2 for Soliris for the January to June 2012 reporting period.[41]

76. On August 2, 2012, Board Staff sent Alexion a CSR for Soliris for January to June 2012. The N-NEAP for this reporting period was calculated at $222.2143; the average price of Soliris in Canada, referred to as the National Average Transaction Price or the "N-ATP", during this time period was $224.7333, and thus was above the N-NEAP.[42]

77. On October 25, 2012, PDCI corresponded with Board Staff, referencing a telephone conversation between PDCI and Board Staff, and requesting a meeting "to discuss an emerging international price comparison / exchange rate issue concerning Soliris."[43]

78. On December 11, 2012, a meeting between Board staff, Alexion and PDCI took place. Meeting notes indicate that Alexion is expected to "have a problem in 2012 [and] possibly 2013", "certainty is important for [the] company" and Alexion is "prepared to make commitments" or "could agree to a price freeze".[44]

79. On January 30, 2013, PDCI filed the Form 2 for Soliris for July to December 2012.[45]

80. On February 25, 2013, Board Staff provided Alexion with the CSR for Soliris for 2012.[46] The investigation criteria for Soliris was triggered in 2012 because the N-ATP of Soliris ($224.7333) was above the N-NEAP for that year ($214.2568), and Board Staff asked Alexion to lower the price to the N-NEAP by December 31, 2013. The compliance status was "Investigation" and the excess revenues for the period (as well as the cumulative

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40 Exhibit 1, Tab 26.

41 Exhibit 1, Tab 28.

42 Exhibit 1, Tab 29.

43 Exhibit 1, Tab 86.

44 Exhibit 1, Tab 103A.

45 Exhibit 1, Tab 31.

46 Exhibit 1, Tab 32.

excess revenues) were calculated at approximately $1.7 million. The letter sent by Board Staff states:

> The PMPRB's policy with respect to the Highest International Price Guideline addresses situations where a drug product's price is within the Guidelines in one review period, but outside the Guidelines in a subsequent period as a result of events other than actions directly attributed to the patentee. In this situation, the patentee is notified of the commencement of an investigation and informed that it is expected to adjust the price of the drug product so that its price is within the Guidelines or be subject to a VCU and repayment of excess revenues dating back to the original excessive price. [emphasis added]

81. Alexion did not adjust the price of Soliris to the N-NEAP by December 31, 2013, nor did it enter into a VCU.

82. On March 1, 2013, Alexion received a Notice of Compliance (NOC) for Soliris for aHUS.[47] The current Guidelines do not provide for a rebenching of a price of a patented drug product in these circumstances and the price of Soliris remained at $224.733 per unit. However, the dosing regimen for aHUS is different than that for PNH. The maintenance dose of Soliris for aHUS for an average adult costs approximately $27,000 every two weeks.[48]

83. On July 25, 2013, PDCI filed the Form 2 for Soliris for January to June 2013, noting "that the Canadian average transaction price of Soliris (as reported on Block-4) has remained unchanged since introduction in 2009. As previously discussed with Board Staff, fluctuations in exchange rates and the appreciation of the Canadian dollar has resulted in the Canadian price of Soliris appearing to be higher than corresponding international prices. Alexion would like to meet with Board Staff to discuss this situation and find a resolution to this matter in an expeditious manner."[49] As noted below, Mr. Lemay testified that this (second) meeting did take place and the focus of the meeting was on certain benefits provided by Alexion, which Alexion proposed to include in its

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47 Exhibit 1, Tab 34.

48 Estimate based on dosing information in product monograph.

49 Exhibit 1, Tab 35.

Form 2 – Block 4 filings. Block 4 data on Form 2 is the data related to sales and prices of the drug product in Canada.

84. On July 26, 2013, Board Staff provided Alexion with a CSR for Soliris for January to June 2013. The N-NEAP was calculated at $214.7355; the N-ATP for Soliris during this time period was $224.7333, and thus was above the N-NEAP.[50]

85. On December 11, 2013, the second meeting between Board Staff, Alexion and PDCI took place. Meeting notes indicate that although exchange rates are the primary reason for Alexion being offside the Guidelines, a principled reason would be required to deviate from the Guidelines. The notes also reference that "no benefits filed" and Alexion "to get back to [the PMPRB] in mid-January 2014".[51]

86. On January 29, 2014, PDCI filed the Form 2 for Soliris for July to December 2013, as well as amended Block 4 information for July to December 2011, January to December 2012, and January to June 2013. The reason for the amendment, according to Alexion, was to "[include] the rebates given during that period."[52] On February 6, 2014, Board Staff advised Alexion that it requires evidence to support any revisions to Form 2 data.[53]

87. On February 12, 2014, PDCI responded to Board Staff as follows:

> Further to Alexion's meeting with Board Staff in December 2013, Alexion refiled its Form-2 Block-4 data for Soliris to include "benefits" that had not previously been reported to PMPRB (for the periods July to December 2011 through January to June 2013). The benefits in question were rebates paid to provincial drug plans under the terms of product listing agreements (PLAs).[54]

88. Board Staff responded to PDCI on February 20, 2014:

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50 Exhibit 1, Tab 36.

51 Exhibit 1, Tab 103B.

52 Exhibit 1, Tab 37.

53 Exhibit 1, Tabs 38, 39.

54 Exhibit 1, Tab 39.

> When the subject of including benefits was first raised at our meeting in December 2013, there was no mention of the fact that the benefits being referred to were in fact third party payments. Board Staff was under the impression that the benefits to be included in the anticipated re-filing of Block 4 data related directly to a sale or sales to customers.
>
> [...]
>
> Although Board Staff would not typically require evidence to support the reporting of third party payments, provided they had been consistently included or excluded in their Form 2 reporting from the outset, this is not the case for data revisions. With any and all data revisions, it is mandatory to provide verifiable evidence to support the revised data. As a result, the Soliris investigation team has determined that at a minimum, the company shall be required to provide copies of the Product Listing Agreements entered into in 2011 with the provinces of Nova Scotia, Ontario and BC.[55]

89. On February 25, 2014, Board Staff provided Alexion with a CSR for Soliris for 2013.[56] The N-NEAP for this reporting period was calculated at $213.9103; the N-ATP for Soliris during this time period was $216.4597, and thus was still above the N-NEAP. The N-ATP for Soliris was not $224.7333 because the original Form 2 filed for July to December 2013 for Soliris included rebates.[57] With respect to a patentee's original Form 1, Form 2 and Form 3 filings, Mr. Lemay testified that Board Staff does not take any steps to verify the information filed by the patentee.[58] If a filing is amended, the amendment is verified by Board Staff. The compliance status for 2013 was "Investigation". The excess revenues for 2013 were approximately $572,697, and the excess cumulative revenues were approximately $2.24 million.

90. Also on February 25, 2014, PDCI advised Board Staff that "John Haslam will be in Ottawa on Tuesday March 4th and could be available to meet briefly with Board staff... Alexion will provide Board staff with an opportunity to review the PLA agreements...

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55 Exhibit 1, Tab 39.

56 Exhibit 1, Tab 41.

57 Exhibit 1, Tab 37.

58 Examination In-Chief of Mr. Lemay (Cont'd), January 17, 2017, Hearing Transcript, Vol 2 (Confidential) at p. 8, lines 5-25.

and ask any questions... it is not Alexion's intention to leave copies of these documents with Board [Staff]".[59] This meeting did not take place.

91. On April 29, 2014, Board Staff advised Alexion that it would not accept data revisions to past filings related to rebates under PLAs, and asked Alexion to refile the Form 2 for July to December 2013 removing the rebates.[60] Board Staff's letter shows cumulative excess revenues of approximately $4 million as at the end of 2013, attaches a draft VCU and states:

> Based on our review of the price and sales data for the January to December 2013 reporting period, the N-ATP of Soliris in 2013 was $216.4597. As the 2013 N-ATP is not lower than the 2012 N-NEAP, in accordance with the Board's Guidelines, Alexion is being given the opportunity to provide a Voluntary Compliance Undertaking (VCU).
>
> [...]
>
> Since the N-NEAPs for 2012 and 2013 were established by the Highest International Price Comparison (HIPC) tests, Board Staff verified the Block 5 International prices filed by Alexion for Soliris for 2012 and 2103 [sic]. There appears to be discrepancies with the German price which is the highest priced country in 2012. From 2009 to 2011 and for 2013, Alexion filed a Pharmacy and a Wholesale price for Germany. For 2013, the highest priced country based on the Block 5 information submitted by Alexion is Sweden. There was no price for Sweden in Board Staff's publicly available sources. Attached is a comparison of Board Staff's publicly available prices and the Block 5 information submitted in [Alexion's] Form 2 filing for 2012 and 2013.
>
> Given the discrepancies between [Alexion's] Form 2, Block 5 international prices and Board Staff's public sources, Alexion is requested to provide an explanation of the discrepancies and copies of the source documents that the company relied upon for the Block 5 information.[61]

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59 Exhibit 1, Tab 127.

60 Exhibit 1, Tab 117.

61 Exhibit 1, Tab 117.

92. Charts attached to Board Staff's letter note that the German price filed by Alexion in 2012 (which is the highest price in the comparator countries in 2012) is $214.2588, and the German price found by Board Staff through its price verification process is $212.8455. As noted above, the N-ATP for 2012 for Soliris is $224.7333, higher than both of these prices. The highest price filed by Alexion in 2013 was the Swedish price ($213.9103).

93. On May 28, 2014, PDCI advised Board Staff that the "Canadian price of Soliris is expected to be lower than the Swedish price based on the expected 2014 exchange rates." Board Staff replied on June 25, 2014, stating, "Board Staff is not prepared to rely on forecast compliance based on expected exchange rates in order to delay compliance with the [HIPC]… [t]he price of Soliris has been the highest of the comparator countries since 2012."[62]

94. On July 30, 2014, PDCI filed the Form 2 for Soliris for January to June 2014.[63] On August 5, 2014, Board Staff sent Alexion a CSR for Soliris for that reporting period. The N-NEAP was calculated at $220.3276; the N-ATP for Soliris during this period was $224.7333, and thus was above the N-NEAP.[64]

95. On August 6, 2014, PDCI filed amended Block 4 data for Soliris for July to December 2013 reporting period, removing the rebates/benefits to the provinces, as requested by Board Staff.[65]

96. On August 20, 2014, Board Staff asked PDCI for international price sources for Germany (July to December 2012), Sweden (July to December 2013 and January to June 2014) and Italy (January to June 2014). PDCI responded the same day attaching the price sources, which included *Rote Liste* for Germany, *Apoteket* for Sweden and *Pagine Sanitarie* for Italy.[66]

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62 Exhibit 1, Tab 88.

63 Exhibit 1, Tab 43.

64 Exhibit 1, Tab 44.

65 Exhibit 1, Tab 45.

66 Exhibit 1, Tab 46.

97. On September 23, 2014, in response to the price sources provided by PDCI, Board Staff rejected the German and Italian prices (and asked Alexion to refile), and accepted *Apoteket* as a pricing source for Sweden.[67]

98. On January 15, 2015, Board Staff filed the Statement of Allegations alleging that the price of Soliris was excessive between 2012 and 2014, and seeking an order under section 83 of the *Patent Act*. On January 22, 2015, the Board issued the Notice of Hearing.

99. There is no cover e-mail or date, but Alexion filed the Form 2 for Soliris for July to December 2014.[68] Block 4 data on this form (as well as previously filed Block 4 data by Alexion) reflects two customer classes: hospital and pharmacy customers (class 1 and 2, respectively), and not wholesalers (class 3).

100. On January 29, 2015, PDCI filed amended Form 2s for Soliris for 2012, 2013 and for January to June 2014, as requested by Board Staff on September 23, 2014.[69]

101. On February 18, 2015, Board Staff provided Alexion with a CSR for Soliris for 2014. The compliance status was "Notice of Hearing" and the N-NEAP, N-ATP and excess revenues were not calculated.[70] Mr. Lemay testified that once a case proceeds to this stage (*i.e.*, a hearing before the Board), these values are not calculated by Board Staff.

102. On June 30, 2015, Board Staff wrote to PDCI about the Block 4 information for Soliris for July to December 2014, noting that it appears very different from all other reporting periods since the date of first sale, and not all sales of Soliris in this filing were reported at the list price. PDCI replied on July 2, 2015, that "[t]he lower average prices reported for the July to December 2014 reporting period accurately reflect reductions from the List Price of Soliris provided by Alexion to its wholesaler/distributor and reported as required

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67 Exhibit 1, Tab 47.

68 Exhibit 1, Tab 89.

69 Exhibit 1, Tab 49.

70 Exhibit 1, Tab 119.

under the Regulations."[71] Block 4 data for July to December 2014 (as noted above), as well as previously filed Block 4 information for Soliris reflects only two customer classes: hospital and pharmacy customers (class 1 and 2, respectively), and not wholesalers (class 3).[72]

103. During the hearing, Mr. Haslam testified that Alexion's only customer in Canada is Innomar, and put into evidence credit memos from Alexion to Innomar (two dated November 7, 2014, one dated December 16, 2014, and one dated June 16, 2015) which reflect the different prices reported in Alexion's Form 2 for 2014.[73] These credit memos and the rebates to Innomar will be addressed by the Panel later in these reasons when dealing with the appropriate order under section 83 of the *Patent Act*.

104. There is no cover e-mail or date, but Alexion filed the Form 2 for Soliris for January to June, and for July to December, 2015.[74] On February 2, 2016, Board Staff provided Alexion with a CSR for Soliris for 2015. The compliance status for 2015 was "Notice of Hearing" and the N-NEAP, N-ATP and excess revenues are not calculated.[75]

105. Form 2s for the two reporting periods in 2016 were not in evidence at the hearing, nor was the CSR for 2016.

VIII. Issues in this Proceeding

106. There are two issues for the Panel to determine:

(i) Is or was the price of Soliris excessive within the meaning of sections 83 and 85 of the *Patent Act*?

(ii) If the answer to issue (i) is yes, what order(s), if any, should this Panel make?

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71 Exhibit 1, Tabs 55.

72 Exhibit 1, Tab 89.

73 Exhibit 46; Exhibit 47.

74 Exhibit 1, Tabs 90, 91.

75 Exhibit 1, Tab 97.

IX. Analysis

(k) The correct benchmark for determining whether the price of Soliris is excessive is the LIPC test

(i) The Consumer Protection Mandate of the PMPRB

107. Amongst other things, this Board has a consumer protection mandate, which was affirmed by the Supreme Court of Canada in *Celgene.*[76] In particular, the Supreme Court of Canada in *Celgene* references the Hansard and notes:

> [27] When the *Patent Act* was further amended in 1993 (*Patent Act Amendment Act*, 1992, S.C. 1993, c. 2), the then Minister of Consumer and Corporate Affairs and Minister of State (Agriculture), the Hon. Pierre Blais, reiterated the Board's consumer protection mandate:
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> > With Bill C-91, we also wanted to strengthen consumer protection, so that consumers can continue to obtain patented medicine at reasonable prices. I think that all Canadians are entitled to that.
> >
> > ...
> >
> > ... The board will thus be able to provide all Canadian consumers with even more effective price control. These new powers will authorize the board to order a reduction of prices it considers too high...
> >
> > ... I am convinced that these new provisions will assure Canadian consumers, of reasonable prices, like those they have had since 1987.
> >
> > (House of Commons Debates, vol. XII, 3rd Sess., 34th Parl., December 10, 1992, at pp. 14998 and 15001)

108. The Panel recognizes and accepts that, when making its determination under section 85, it must consider the Board's consumer protection mandate – specifically, the Board's role in ensuring that all Canadians are able to obtain patented medicines at "reasonable prices"

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76 *Celgene Corp. v Canada (Attorney General)*, 2011 SCC 1 at para 27 [*Celgene*]; see also, *ICN Pharmaceuticals Inc. v Patented Medicine Prices Review Board*, [1996] FCJ no 206 at para 24 (FC), aff'd [1996] F.C.J. No. 1065 (FCA).

and that prices of patented medicines do not rise to "unacceptable levels."[77] As noted by the hearing panel in the *Celgene* proceeding, this mandate applies to all purchasers – there is no indication in the *Patent Act* that Parliament intended the Board to leave any purchaser unprotected from the general remedial powers of the Board, whether the purchaser is a government, insurer, wholesaler or consumer.[78]

109. Alexion went to considerable efforts in the hearing to try to convince the Panel that it acted responsibly and fairly, that it did nothing wrong, and that it was a victim of forces outside of its control. It is not necessary for this Panel to decide whether Alexion has accurately described its conduct and the situation because, as set out in greater detail below, such factors are irrelevant to the Panel's determination under section 85(1). As confirmed by the Federal Court of Appeal, this Panel's focus must be on the persons who are in need of protection from excessive pricing, and not on the conduct of the patentee alleged to have excessively priced.[79] In other words, a Panel can certainly find that Canadians are in need of protection from excessive pricing of a patented medicine through an order from the Panel even where the situation is caused by forces outside of the patentee's control.

(ii) The Role of the Guidelines

110. The Guidelines were first published in 1994 and, since then, have been revised on an ongoing basis. The current version of the Guidelines was released on June 9, 2009, implemented on January 1, 2010, and last updated in February 2017. For the purposes of the Panel's decision in this proceeding, any revisions that have been made to the version of the Guidelines implemented on January 1, 2010 are not material.

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77 *Celgene*, *supra* note 76 at paras 25-28; Board Decision –*Ratiopharm Inc. and the Medicine "ratio-Salbutamol HFA"* (27 May 2011) at para 13, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/ratio-Salbutamol-HFA-Merits-Reasons-D3-May-27-2011.pdf> [*ratio-Salbutamol* (Board Decision)], rev'd on other grounds *Ratiopharm Inc. v Canada (Attorney General)*, 2014 FC 502, Federal Court decision rev'd and Board Decision aff'd *Canada (Attorney General) v Sandoz Canada Inc.*, 2015 FCA 249 [*Sandoz* (Appeal Decision)].

78 Board Decision –*Celgene Corporation and the Medicine "Thalomid"* (21 January 2009) at para 23, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=881&lang=en>.

79 *Sandoz* (Appeal Decision), *supra* note 77 at para 67.

111. The Guidelines were prepared in consultation with relevant stakeholders. Amongst other things, they advise patentees how Board Staff will approach compliance, how Board Staff reviews the prices of patented drug products, and when an investigation by Board Staff will be triggered. The Guidelines do not address how a hearing panel will apply the *Patent Act* to determine whether a price is excessive, or to impose a remedy should the hearing panel conclude that a price is excessive.

112. Board Staff applies the factors set out in section 85 of the *Patent Act* to determine if the price of a patented drug product sold in Canada is excessive, and the Guidelines are meant to provide assistance in the application of these factors. There is also a complementary *Patentee's Guide to Reporting*, which sets out technical and other details related to a patentee's reporting obligations.[80]

113. The Guidelines deal with both the introductory price and the price going forward of patented drug products. For breakthrough drugs, such as Soliris, the Guidelines adopt the MIPC test for the introductory price, and the maximum price is set as the median ex-factory price of the same strength and dosage of the drug for France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. As noted above, at introduction the price of Soliris in Canada exceeded the MIPC, and an investigation was triggered because the excess revenues were calculated at approximately $78,000 (which was above the $50,000 threshold for triggering an investigation under the Guidelines). However, Alexion amended its filings, reducing the amount of excess revenues to an amount (approximately $16,000) that was not sufficient to trigger the investigation criteria in the Guidelines (albeit the price was still above the MIPC).

114. For the price going forward, the Guidelines adopt the HIPC or CPI tests – the ceiling price for a breakthrough drug going forward is the lowest of either the HIPC test or the CPI test set out in the Guidelines.

115. The current Guidelines state at section A.5.3:

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80 Exhibit 2, last updated July 2015.

> The Board, following considerable deliberation and consultation with all stakeholders, pursuant to subsection 96(5) of the Act, published the PMPRB's Guidelines pursuant to subsection 96(4) of the Act. Although the Guidelines are not binding on the Board or the patentee, they establish an approach and methodology in applying the factors set out in subsection 85(1) of the Act. (emphasis added)

116. There is no doubt that the Guidelines are advisory only and are not binding on this Panel.[81] While not binding, the Panel will give the Guidelines due consideration in light of their provenance and the role that they play in assisting patentees in the application of the provisions of the *Patent Act*.[82] There is a need to balance certainty and consistency (which the Guidelines promote) with the need to be flexible and have fact-specific solutions. In any event, this Panel cannot apply the Guidelines as if they are the law, and cannot rely on them in a manner that inappropriately limits the discretion conferred on this Panel by the *Patent Act*.[83] To the extent that the Guidelines conflict with the *Patent Act* or the Regulations, the latter must prevail.[84]

117. For this Panel to rely on the provisions of the Guidelines to reach a conclusion on whether Soliris has been or is excessively priced, it must be satisfied that the Guidelines provide an appropriate implementation of the *Patent Act* specifically in relation to Soliris. This Panel can reach that conclusion as a result of the evidence and argument provided by the participants in this proceeding, or the Panel's own expertise, or a combination of the two.[85]

118. The hearing panel in the *Adderall* case provided a helpful summary of the role of the Guidelines:

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81 *Patent Act, supra* note 2, s. 96(4).

82 *Dovobet*, *supra* note 18; *Quadracel* (2009), *supra* note 20 at paras 13, 14, 16; *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 57-58.

83 *Gordon v Canada (Attorney General)*, 2016 FC 643 at paras 29, 40, 41; *Thamotharem v Canada (Minister of Citizenship & Immigration)*, 2007 FCA 198 at paras 55-62, leave to appeal refused [2007] SCCA no 394 (SCC).

84 *Sandoz* (Appeal Decision), *supra* note 77 at para 75; *Teva Neuroscience G.P.-S.E.N.C. v Canada (Attorney General)*, 2009 FC 1155 at para 32 [*Teva Neuroscience*].

85 *Quadracel* (2009), *supra* note 20 at para 16; *ratio-Salbutamol* (Board Decision), *supra* note 77 at para 60.

> 15. The Guidelines were established after consultation with stakeholders, as mandated by subsection 96(5) of the Act. The Guidelines aim to provide a structure for the necessary particularization and integration of the general factors listed in section 85, to provide fairness through consistent treatment among patentees, and to give patentees guidance on the process that will be used in establishing the MNE for their medicines, both when the medicines are first introduced to a market in Canada and each year thereafter that they are sold in Canada.
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> 16. On the other hand, the Guidelines are not binding on the Board. Furthermore, situations could arise that are not contemplated by the Guidelines, or changes in medicine or the marketing of medicines in Canada could give rise to situations that are no longer covered appropriately by the Guidelines. In each case, where the review of the pricing of a medicine comes before a panel of the Board, the panel must determine whether the medicine is priced excessively within the terms of section 85 of the Act. To the extent that the Guidelines speak to this issue, the panel must determine whether the Guidelines provide for an appropriate and reasonable implementation of the factors in section 85 of the Act before establishing an MNE by the terms of the Guidelines. If the Guidelines do not result in an appropriate implementation of section 85 of the Act, the panel must depart from the Guidelines.
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> 17. Board Staff suggested in final argument that the Guidelines establish an MNE for a medicine that should be presumed by a panel of the Board, in a price review hearing, to be excessive unless the patentee can satisfy the Board otherwise. The Panel believes that this over-states the role of the Guidelines. In each case, a hearing panel must be satisfied, through evidence, argument, the application of its own expertise and judgment or a combination of all of those factors that the Guidelines provide for a reasonable implementation of section 85 of the Act. In deciding whether to reach this conclusion, appropriate weight will be given to the provenance and role of the Guidelines, but they will not be presumed to correctly implement the Act.[86] [emphasis added]

119. This is a unique case in terms of the parties' respective positions on the application of the Guidelines. Generally, in past hearings, one party (usually the patentee) argues that a certain aspect of the Guidelines should not be applied to the particular facts of the medicine at issue, and the other party (usually Board Staff) argues that the Guidelines

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86 Board Decision –*Shire BioChem Inc. and the Medicine "Adderall* XR" (10 April 2008) at paras 15-17, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=808&lang=en> [*Adderall*].

should be adhered to. In this case, both parties argue that the Guidelines should not be strictly applied, but they differ on what aspects of the Guidelines should be applied and what aspects should not.

120. Board Staff argues that the Guidelines are an appropriate implementation of the *Patent Act* except for the benchmark test that should be used to determine whether Soliris has been excessively priced and to calculate the amount of excess revenues. Board Staff argues that the LIPC test, which is not a test in the Guidelines, should be applied. On the other hand, Alexion submits that it is critical that the Panel adhere to the benchmark tests in the Guidelines (for reasons of transparency, fairness and certainty), but argues that it should be relieved from the consequences of foreign exchange rate fluctuations, which the Guidelines clearly say are the responsibility of patentees.

121. Based on a thorough consideration of the submissions of the parties and the evidence in this proceeding, and after applying its own expertise and judgment, this Panel is of the view that the Guidelines are appropriate for the application of section 85(1) of the *Patent Act* to Soliris, subject to one exception which is necessary to properly implement the *Patent Act* (through the order to be issued by this Panel).[87] The Panel has concluded that the MIPC and HIPC tests do not appropriately implement the *Patent Act* in the case of Soliris. Rather, the appropriate benchmark to determine whether the price of Soliris is excessive is the LIPC. The reasons for the Panel's decision in this regard are contained in the section of this decision dealing with the application of the factors in section 85(1), which follows this discussion of the role of the Guidelines.

122. In deciding to depart from the Guidelines on the issue of the benchmark test, the Panel is certainly aware of the important role played by the Guidelines and the fact that stakeholders generally rely on the consistent application of the Guidelines to provide certainty and predictability. However, the Panel has no choice but to deviate from the Guidelines if and to the extent they do not result, in a reasonable implementation of the factors in section 85(1) of the *Patent Act*. In those circumstances,

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87 *Quadracel* (2009), *supra* note 20 at para 19.

the Panel must apply its own judgment to the factors in section 85, and apply them appropriately to evaluate the price of Soliris.[88]

123. Before proceeding further with these reasons, the Panel will address the position of Alexion and the intervener, BIOTECanada, that it is not open to this Panel to deviate from the benchmark tests that are set out in the Guidelines.

124. First, Alexion argues that while previous hearing panels have deviated from the Guidelines where they were found to not properly implement the *Patent Act*,[89] they have only done so in a manner that was favourable to the patentee. Whether this is true or not is of no consequence in this proceeding as this Panel must deviate from the Guidelines in the case of Soliris to the extent they are not an appropriate implementation of section 85(1) of the *Patent Act*, regardless of whether that deviation favours the position of Board Staff or the patentee.

125. Second, Alexion and BIOTECanada argue that this Panel cannot apply any benchmark test that is not in the Guidelines until the Guidelines are changed, and that the consultation process required by the *Patent Act* must occur before any changes to the Guidelines are made. The Panel disagrees – if the Panel accepted this submission, it would in effect be treating the Guidelines as binding and thus fettering the discretion afforded to it by sections 83 and 85 of the *Patent Act*. The Panel is not amending the Guidelines and the Panel's decision is applicable only to Soliris.

126. Third, Alexion places emphasis on the fact that Board Staff's ultimate position in this proceeding departs markedly from the approach it originally took in this case, and has taken in past cases (where Board Staff has advocated that the Guidelines are appropriate to determine whether a medicine is or has been excessively priced and to calculate excessive revenues). The Panel notes that Board Staff's Amended Statement of Allegations charts a markedly different course than the original allegations, as well as the position taken by Board Staff generally in other cases. However, how Board Staff

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88 *Adderall*, *supra* note 86 at para 36.

89 See for example, *Adderall*, *supra* note 86 at paras 5, 16, 34, 46.

reached its ultimate position in this case, and whether that position is consistent with Board Staff's usual or past practices or conduct, is not relevant to the Panel's determination under section 85(1) of the *Patent Act*.[90] And, while the amendments did alter this proceeding in some respects, the Panel is satisfied that Alexion was given a full and fair opportunity to respond to the amendments. As noted above, the hearing was adjourned for several months to allow Alexion to respond to the Amended Statement of Allegations.

127. Fourth, Alexion argues that the doctrine of legitimate expectations supports its argument that the Panel in this proceeding is restricted to the tests and methodologies set out in the Guidelines. The Panel disagrees. The doctrine of legitimate expectations is part of the rules of procedural fairness that govern administrative bodies – it provides that where a government official makes a clear, unambiguous and unqualified representation within the scope of his or her authority to an individual about an administrative process that the government will follow, the government may be held to its word as long as the representations are procedural in nature and do not conflict with the decision maker's statutory duty. Where it applies, the doctrine can create a right to make representations or to be consulted. The doctrine of legitimate expectations cannot create substantive rights. And, it cannot serve to fetter the discretion of the decision maker following the representations or consultation.[91]

128. There is no clear, unambiguous and unqualified representation to Alexion that the Board would apply the tests set out in the Guidelines in an excessive pricing proceeding. In fact, the *Patent Act* states the exact opposite. Section 96(4) of the *Patent Act* provides that "the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any rights holder or former rights

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90 *Dovobet*, *supra* note 18.

91 Board Decision –*Galderma Canada Inc. and the Medicines Containing "Adapalene"* (19 December 2016) at para 69, online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Galderma_Decision_December_19_2016.pdf>, citing *Canada (Attorney General) v Mavi*, 2011 SCC 30 at para 68; *Moreau-Bérubé c Nouveau*-Brunswick, 2002 SCC 11 at para 78; *Reference Re Canada Assistance Plan*, [1991] 2 SCR 525 at para 67; *Malcolm v Canada (Minister of Fisheries and Oceans)*, 2014 FCA 130 at paras 47-49 [*Malcom*]; *Sanofi-Aventis Canada Inc v Canada (Attorney General)*, 2009 FC 965 at paras 53, 54.

holder." The Guidelines do not purport to advise how a panel of the Board will apply section 85(1) of the *Patent Act* in an excessive pricing hearing. Further, even if there had been a representation that the Guidelines would be applied in a hearing concerning Soliris, it would conflict with the Panel's statutory duty to apply section 85(1) without fettering its discretion. And, even if the doctrine did apply, it only gives Alexion the right to notice and to be consulted, both of which have been provided. Alexion has always been aware that the Guidelines are not binding and that the Board may choose not to follow them in an excessive pricing hearing.[92] In fact, Alexion itself urged the Panel to deviate from the Guidelines with respect to foreign exchange rate fluctuations. Alexion has had ample notice of the alternative tests ultimately advanced by Board Staff, and a full opportunity to respond to Board Staff's position and to make its position clearly known to this Panel.

129. Lastly, BIOTECanada submitted that the doctrine of promissory estoppel precludes this Panel from deviating from the tests and methodologies set out in the Guidelines. In particular, BIOTECanada asserts that since Board Staff used the MIPC test to initially determine the MAPP, and Alexion based its initial price based on that, estoppel applies so as to prevent the Board from "changing course" and using the LIPC test to determine excessive pricing or forfeitures. The Panel also rejects this submission. Promissory estoppel requires proof of a clear and unambiguous promise made to a citizen by a public authority in order to induce the citizen to perform certain acts. The citizen must have relied on the promise and acted on it by changing his or her conduct. However, promissory estoppel cannot interfere with the proper administration of the law – it cannot be invoked to preclude the exercise of a statutory duty, or to avoid the application of a clear legislative provision.[93]

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92 The Panel notes that, in the 10-K (annual report) filed by Alexion in the United States for the year ending December 31, 2008, Alexion states that, in certain foreign countries, pricing of drugs is subject to governmental control, and Alexion may be unable to negotiate pricing on terms that are favorable to it. Similar statements are found in subsequently filed reports.

93 *Immeubles Jacques Robitaille Inc. c Quebec (Ville)*, 2014 SCC 34 at paras 19, 20; *Lidder v Canada (Minister of Employment & Immigration)* [1992] 2 FC 621 at para 17 (FCA); *Malcolm, supra* note 91 at paras 38, 39.

130. The Panel agrees with Board Staff that, to establish promissory estoppel, the elements of estoppel must be proven with respect to Alexion itself (and not stakeholders generally), and that no evidentiary basis was provided to establish the elements of the test with regard to Alexion. Further, even if the evidentiary basis had been provided, estoppel cannot operate to require this Panel to apply the benchmark tests set out in the Guidelines where doing so would not be an appropriate implementation of section 85(1) of the *Patent Act*, which is exactly the Panel's conclusion in this case.

131. The Panel has set out below its analysis of the various factors in section 85(1) of the *Patent Act*, resulting in the Panel's decision to apply the Guidelines in the case of Soliris, with the exception that the benchmark for determining whether the price of Soliris is excessive is the LIPC.

(iii) The price of Soliris is excessive based on an analysis of the factors in section 85(1) of the Patent Act

132. Section 85(1) of the *Patent Act* states: "In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

(a) the prices at which the medicine has been sold in the relevant market;

(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

(d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection."

133. The *Patent Act* does not define "excessive" price. Further, it does not prescribe any price tests or methodology in sections 83 and 85 for determining whether the price of a medicine is or was excessive. Parliament clearly contemplated that different tests and approaches may be appropriate for different patented medicines, and it chose to give the Panel the discretion to determine what tests and approaches should be applied in an excessive pricing hearing. Parliament clearly chose not to give patentees the certainty and predictability that would come with a legislatively mandated test for determining whether a price is excessive.

134. This Panel is required to formulate an opinion as to whether the price of Soliris is or was excessive and, in doing so, it must give due consideration to all of the factors in section 85(1). Section 85(1) leaves it to the Panel's discretion to determine the relevance and weight of each factor and of all of the factors taken together.[94] In any event, the Panel is obligated to provide clear and intelligible reasons as to the consideration and weight given to each factor in reaching its decision.[95]

135. The Panel must consider the factors set out in section 85(1) according to some rationale, methodology or approach, which may be derived from the Guidelines, or it may be *ad hoc*.[96] As discussed above, there is certainly no requirement on the Panel's part to apply the Guidelines, in whole or in part.

136. If the Panel is able to make a determination by reference only to section 85(1), it is to limit itself to a consideration of the factors under that section. If not, this Panel can, under section 85(2), take into consideration the costs of making and marketing the medicine.[97] This Panel agrees with other hearing panels who have concluded that there would have to be compelling reasons to determine the issue of excessive pricing on the

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94 *Adderall*, *supra* note 86 at para 14.

95 *Teva Canada Innovation v Canada (Attorney General)*, 2013 FC 448 at para 42 [*Teva Canada*]; *Teva Neuroscience*, *supra* note 84 at para 76.

96 *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)*, [1996] FCJ No 1112 at paras 6, 8 (FC) [*ICN*].

97 *ICN*, *supra* note 96 at para 3; *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 56, 86.

basis of the costs of making and marketing the medicine, and it is only appropriate to do so in exceptional circumstances and on the basis of clear and reliable evidence.[98]

137. Board Staff and Alexion agree that this Panel can reach a determination under section 85(1), and the Panel need not and should not resort to section 85(2). The Panel agrees – the Panel is able to reach a decision based on the factors in section 85(1), and as such, did not have regard to the factors in section 85(2). The Panel also agrees with Alexion that there is no clear and reliable evidence in the record that would allow the Panel to make a determination based on the factors in section 85(2) in any event.

138. Section 85(3) of the *Patent Act* provides: "In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales."

139. The evidence about research and development costs offered at the hearing was limited. Between 2010 and 2014, Alexion reported a total of approximately $[redacted] of Research and Development expenditures in its Form 3s for Soliris.[99] Mr. Haslam also testified about R&D expenditures generally in Canada (but not specifically for Soliris in Canada).[100]

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98 Board Decision –*ICN Canada Ltd. and ICN Pharmaceuticals Inc.* (26 July 1996) at pp. 11, 12, online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/db-95d5v-e14LGJ-492003-8710.pdf> [*Virazole*]; application for stay of board decision dismissed *ICN*, *supra* note 96; Board Decision –*Teva Neuroscience and the Medicine "Copaxone"*, (25 February 2008) at para 48, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/COPAXONE_Merits-Reasons_-_D2-_Feb_25_0838KCU-3102008-2953.pdf > set aside on other grounds in *Teva Neuroscience*, *supra* note 84.

99 Exhibit 1, Tabs 21 (2010), 27 (2011), 33 (2012), 42 (2013), 50 (2014).

100 Examination In-Chief of Mr. Haslam, February 24, 2017, Hearing Transcript, Vol 13 (Public) at p. 1839, line 23 – p. 1844, line 1.

140. R&D spend is not one of the factors required to be considered under s. 85(1) of the *Patent Act*, and the Panel has not considered it. Even if the Panel was willing to consider this factor, the Panel agrees with Board Staff that it did not receive the necessary evidence that would allow it to do so. In particular, the Panel did not receive cogent and reliable evidence of the specific R&D costs it is entitled to consider, as set out in section 85(3) of the *Patent Act*.

(A) Section 85(1)(a) – the prices at which the medicine has been sold in the relevant market

141. Board Staff submits that section 85(1)(a) is a stand-alone factor which requires the Panel to conduct a contextual analysis of the price of Soliris. Board Staff submits that the Panel should consider factors such as the annual cost of treatment, social or opportunity costs, median household income and per capita GDP. Board Staff submits that all of these factors point to the price of Soliris being excessive.

142. The Ministers of Health make a similar argument. They argue that section 85(1)(a) allows the Panel to assess the annual treatment cost of Soliris in the context of its broader effect on payors, including the opportunity costs resulting from the public funding of Soliris, the cost pressures under which public payors operate, and the rising costs of EDRDs. In particular and as noted above, Mr. Lun testified that, in 2015/2016, British Columbia funded 14 EDRDs at a total expenditure of approximately $[redacted]. Soliris represented $[redacted] of that $[redacted], or almost [redacted]. The average cost of EDRDs (including Soliris) in British Columbia was $[redacted] per patient per EDRD, an amount considerably less than the annual average cost of Soliris to treat adult patients with PNH or aHUS.[101]

143. Alexion disagrees with Board Staff's and the Ministers of Health's interpretation of section 85(1)(a). Alexion submits that the price at which the medicine has been sold in the relevant market (being Canada in this case) is based on the information filed by the patentee under the *Patent Act* and Regulations, and that price is then used as the basis for the comparisons mandated by sections 85(1)(b), (c) and (d) of the *Patent Act*. Alexion

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101 BC Minister of Health Closing Submissions dated March 31, 2017 at paras 17–19.

argues that section 85(1)(a) does not permit comparisons with factors such as GDP or median family income.

144. As confirmed by the Federal Court, a plain reading of the *Patent Act* leads to the logical conclusion that it is on the basis of the information provided by the patentee under section 80(1)(b) of the *Patent Act* that the Board will be able to determine the price at which the medicine is being sold in the relevant market.[102] This interpretation was applied by the hearing panels in both the *Penlac* and *Quadracel and Pentacel* proceedings, and the Panel agrees with this approach.

145. In *Penlac*, the panel concluded that the price at which the medicine is being sold is the starting point of the section 85(1) assessment, and that this price, which is based on information on file with the Board, is then considered in light of the other factors in section 85(1).[103]

146. In *Quadracel/Pentacel*, the patentee argued that the panel should take into account factors unique to vaccines in considering section 85(1)(a). The hearing panel rejected this argument, concluding that section 85(1)(a) required the panel to establish a means of determining the price at which a patented medicine is or has been sold in Canada, but does not direct the panel to engage in an open inquiry into the price excessiveness (or not) of a medicine. Rather, having established the price at which the medicine is sold in Canada under section 85(1)(a), the Board is instructed by the balance of section 85(1) to consider whether that price is excessive based on the other factors listed in section 85(1).[104]

147. The Regulations require patentees to file, pursuant to section 80(1) of the *Patent Act*, the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in Canada, as well as the publicly available ex-factory prices in

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102 *Leo Pharma*, *supra* note 18 at para 47.

103 *Penlac*, *supra* note 19 at para 14.

104 *Quadracel* (2009), *supra* note 20 at para 48.

Canada and the comparator countries.[105] This information allows the Board to determine the first factor as listed under paragraph 85(1)(a) of the *Patent Act*, namely the price at which the medicine has been sold in the relevant market.[106]

148. For Soliris, the Panel considers the "relevant market" to be Canada, and the "prices" to be the N-ATP as disclosed in Alexion's filings with the Board. In this case, Alexion has consistently maintained that the price of Soliris in Canada has not changed since its introduction and is $224.7333 per unit (notwithstanding any rebates or discounts).

(B) Section 85(1)(b) – the prices at which other medicines in the same therapeutic class have been sold in the relevant market

149. If there is no other medicine in the same therapeutic class, this Panel should disregard s. 85(1)(b), and will (assuming changes in the CPI are not in issue) consider only the price of the medicine under review in Canada and outside Canada.[107]

150. As already noted in the reasons for striking portions of Dr. Addanki's evidence, the Panel accepts that Soliris is a breakthrough medication for which there are no other medicines in the same therapeutic class that have been sold in Canada. This factor is therefore not applicable to Soliris.

(C) Section 85(1)(c) – the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada

151. Since there are no other medications in the same therapeutic class as Soliris, the Panel is left to consider the prices at which Soliris has been sold in countries other than Canada. Section 85(1)(c) of the *Patent Act* does not prescribe how this should be done nor does it set out the list of countries that must be considered.[108]

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105 *Patented Medicines Regulations*, SOR/94-688, s 4(f).

106 *Leo Pharma*, *supra* note 18 at para 47.

107 *Penlac*, *supra* note 19 at para 21; *Virazole*, *supra* note 98 at p.7.

108 The Regulations contain a list of seven countries for which a patentee must file pricing information under s. 80 of the *Patent Act*. However, there is no requirement in the *Patent Act* or the Regulations that these are the countries that must be considered under s. 85(1)(c) of the *Patent Act*.

152. The Panel notes that the price of Soliris has been under scrutiny in countries, other than the comparator countries. For example, the Health Service Executive in Ireland has indicated that the cost of Soliris is "exorbitant" and "astronomical", and that Alexion refused to provide a reasonable and sustainable price.[109] Initially in 2013, Ireland declined to fund Soliris for PNH[110] but the National Centre for Pharmacoeconomics reviewed the matter again in 2015, and decided to cover the costs. Similarly, PHARMAC in New Zealand refused to fund Soliris for PNH in October 2013, noting that the price is "extreme" and "out of line with other comparable innovative new medicines supplied by other companies".[111] In particular, PHARMAC notes that "Eculizumab could benefit up to 20 people, at a cost of approximately $10 million per year." This translates to an annual cost of treating a PNH patient as NZ$500,000 or approximately CDN$437,000 (at market exchange rates in December 2013).[112]

153. The question for this Panel is whether the relevant sections of the Guidelines, including the MIPC and HIPC tests, are an appropriate implementation of the requirement in the *Patent Act* that the Board consider the international prices of Soliris when determining whether the price of Soliris is or was excessive in Canada. The current ERP system in the Guidelines is meant to apply section 85(1)(c) of the *Patent Act* and uses as comparators the seven countries set out in the Regulations.

154. The countries which are used for comparison under this factor are the seven countries set out in the Regulations. These seven countries were selected by Parliament in the Regulations and are the only other countries for which price information for Soliris was available in this proceeding. Furthermore, several of the seven comparator countries had a higher GDP per capita than Canada (including if adjusted for PPP) in 2009 when Soliris was introduced, reflecting that the set of comparators does not only include "poor" countries which may bias price downwards. Dr. Schwindt also testified that the "set of comparator countries used by the PMPRB… does not contain countries with significantly

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109 Exhibit 1, Tab 71(a).

110 Exhibit 1, Tab 71(b).

111 Exhibit 1, Tab 72.

112 Board Staff Written Closing Submissions dated March 24, 2017 at para 16, n 1).

lower standards of living, which could bias relative prices down, and does include countries with significantly higher per capita GDP. It is also worth noting that the set of comparators includes the U.S., a pharmaceutical market viewed as high priced amongst developed countries."[113]

155. The Panel recognizes that, in performing the comparison required under section 85(1)(c), it is limited to comparing the price in Canada with the publicly available ex-factory prices in the comparator countries (which are often subject to discounts) filed by Alexion under the Regulations.[114] No evidence regarding any rebates or discounts provided in comparator countries was filed in this proceeding, and the Panel does not know whether the publicly available ex-factory price of Soliris in the comparator countries is in fact the actual price due to any discounts or rebates.

156. Using the publicly available ex-factory price in the comparator countries filed by Alexion as the reference point allows the Panel to conduct an apples-to-apples comparison when it comes to comparing the price of Soliris in Canada to the price of Soliris in the other jurisdictions because the list price of $224.7333 in Canada does not include any discounts or rebates and, as noted above, no evidence regarding any rebates or discounts provided in comparator countries was filed in this proceeding. These are also the prices used by Board Staff in the various price tests set out in the Guidelines, and the Panel is satisfied that the use of the publicly available ex-factory price for these purposes is an appropriate implementation of section 85(1)(c) of the *Patent Act*.

157. The fact that the Board may not be comparing actual prices does not render the factor in s. 85(1)(c) unreliable or inherently deserving of less weight. As the Federal Court explained in *Teva Canada*, having enacted section 85(1)(c), Parliament is presumed to be aware of the difficulties in comparing the prices of medicines across borders and, despite

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113 Exhibit 8, pp. 11-12.

114 *Virazole*, *supra* note 98 at p.10.

this, section 85(1)(c) is a factor that must be considered. For this Panel to conclude otherwise would be to subvert the will of Parliament.[115]

158. In Board Staff's submission, there "is nothing unfair or unreasonable in conducting such an analysis which is referred to as ERP. There is also nothing unfair or unreasonable in conducting ERP analysis based on "nominal" prices (*i.e.* the actual list prices in each country) in foreign currency that is converted to Canadian currency using market exchange rates." Board Staff submits:

> "ERP for pharmaceutical prices is used in many other countries. Professor Schwindt noted that it is used by 24 of the EU member states.
>
> [...]
>
> Professor Schwindt noted that the use of ERP is also a substitute for the fact that pharmaceutical consumers for the most part cannot engage in arbitrage. If a market was competitive and there were no constraints on purchasing products from other jurisdictions, then the buyers would purchase their products in countries with lower prices and then import the product. (In particular, this would be the case for pharmaceuticals with a high value to weight ratio.) Arbitrage would then take place at current market exchange rates."[116]

159. The Panel agrees with this submission. The Panel found Dr. Schwindt's evidence on this point helpful, in particular his reference to the article titled *"Differences in external price referencing in Europe—A descriptive overview*," which shows that price comparison tests are widely used in Europe.[117] Dr. Schwindt testified that prices in other countries demonstrate a patentee's willingness and ability to supply at that price (and assume a normal rate of return). In particular, Dr. Schwindt stated:

> Prices in other developed countries disclose the patentee's willingness to supply other, roughly comparable, markets. Presumably, these prices compensate the patentee's costs. If a patentee willingly supplied other, comparable markets at prices

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115 *Teva Canada*, *supra* note 95 at para 41.

116 Board Staff Written Closing Submissions dated March 24, 2017 at paras 92, 95.

117 Exhibit 9.

> significantly below the Canadian price, this would call for a justification of the Canadian price. Comparison with foreign prices also addresses, to a limited extent, the fact that Canadian pharmaceutical consumers cannot arbitrage across international markets as is possible in other jurisdictions.[118] [footnotes omitted]

160. Dr. Anis argued that one cannot infer a patentee's willingness to supply in a country based on price alone, and we have to consider supply and demand factors.[119] Dr. Schwindt acknowledged that price is not a perfect surrogate for estimating costs, but is reasonable.[120] The Panel agrees.

161. The Panel understands that countries may have different supply and demand characteristics, but is satisfied that ERP systems such as the one in the Guidelines are widely used in developed countries to compare prices, and are appropriate to evaluate section 85(1)(c) of the *Patent Act* in this proceeding. Although the comparison methodology (*i.e.*, the ERP system) set out in the Guidelines is appropriate, the Panel concludes after considering all of the evidence and submissions that the application of the HIPC benchmark to the price of Soliris is not an appropriate implementation of sections 83 and 85 of the *Patent Act*. Rather, for the reasons set out below and in order to fulfill the Panel's consumer protection mandate, price excessivity for Soliris should be determined by reference to the LIPC test.

162. The Panel notes that even the lowest price for Soliris among the comparator countries has been under attack for being unreasonable. The United Kingdom is the comparator country that has had the lowest international price since 2011. In 2015, the price of Soliris in the UK was approximately $188 – the Canadian list price of approximately $224 is about 20% higher. Nonetheless, the National Institute for Health and Care Excellence (NICE) in the UK noted in 2015, in the context of aHUS, that "it had not been presented with enough justification for the high cost per patient of eculizumab, or for the

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118 Exhibit 8, p. 4.

119 Examination In-Chief of Dr. Anis, March 1, 2017, Hearing Transcript, Vol 16 (Public) at p. 2026, line 25 – p. 2027, line 8.

120 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 834, line 8 – p. 835, line 14, p. 842, lines 3-16, p. 893, lines 4-18.

overall cost of eculizumab with reference to what could be expected to be reasonable in the context".[121] While this Panel cannot comment on whether the UK price of Soliris is excessive under the regime in the UK, this certainly suggests to the Panel that permitting Alexion to sell at a price up to the UK price is generous to Alexion.[122]

163. While Alexion tried to refute this fact, the evidence establishes that patented medicines are generally more expensive internationally (especially in the United States) than in Canada.[123] The House of Commons debates in 1986 surrounding the then amendments to the *Patent Act* refer to drug prices in Canada being approximately 80% of those in the United States.[124] The House of Commons debates in 1992 surrounding the subsequent amendments to the *Patent Act* refer to a (then) recent study from the United States' General Accounting Office that concluded that medicines in Canada are priced 32% lower than in the United States,[125] and refer to the PMPRB as being successful in keeping Canadian prices lower than in the US.[126] Lastly, an article in the 2016 Journal of the American Medical Association refers to prices being 10 to 15% higher in the US than they are in Canada.[127] Drs. Addanki, Schwindt and Putnam agreed that Canadian prices of pharmaceuticals are generally lower than in the United States (where prices are not regulated).

164. In light of this, one would expect the price of Soliris in Canada to have been lower than the price in the US, which it was not.

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121 Exhibit 69, p.27.

122 The Panel agrees with the principle adopted by previous hearing panels that establishing the maximum allowed price of a medicine by reference to the price of a medicine that is itself excessively priced should be avoided. See, Board Decision –*Hoechst Marion Roussel Canada Inc. and the Medicine "Nicoderm"* (9 April 2010) at para 13, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/NICODERM-Merits-Reasons-D10-April9-2010.pdf>; *ratio-Salbutamol* (Board Decision), *supra* note 77 at para 68.

123 *Penlac, supra* note 19 at para 88.

124 *House of Commons Debates*, 33rd Parl, 2nd Sess, Vol 1 (20 November 1986) at 1372.

125 *House of Commons Debates*, 34th Parl, 3rd Sess, Vol 10 (16 November 1992) at 13417; *House of Commons Debates*, 34th Parl, 3rd Sess, Vol 12 (9 December 1992) at 14935, 14943; *Debates of the Senate*, 34th Parl, 3rd Sess, Vol 3 (15 December 1992) at 2467.

126 *House of Commons Debates*, 34th Parl, 3rd Sess, Vol 11 (17 November 1992) at 13482.

127 Exhibit 42 at p.859.

165. When Soliris was introduced in Canada, and in 2010, the price of Soliris in the US was the lowest international price. In his report, Dr. Addanki showed that, between 2009 to 2016, the Canadian price of Soliris exceeded the US wholesale or "WAC" price when converted at the market exchange rate for most of the period (and by almost 20% as late as January 2016). He opined that this was even more remarkable given that the US WAC price was steadily increasing during this period. Professor Schwindt opined that the US price of Soliris shows Alexion's willingness to supply a market like the US at a much lower price than the Canadian price, which, Dr. Addanki argues, is useful information indicating that the Canadian price may be excessive. The Panel agrees with Drs. Schwindt and Addanki in this regard.

166. This Board's mandate, amongst other things, is to ensure that all Canadians are able to obtain patented medicines at reasonable prices. This Panel concludes, based on a thorough consideration of all of the evidence and the unique circumstances of this case, that the reasonable price for Soliris in Canada is one that does not exceed the lowest international price ("**LIP**") in the seven comparators. Based on the most recent evidence available to the Panel, the LIP is the price charged in the United Kingdom. Using the UK price as an example (because it is the current LIP), Alexion is willing to supply Soliris in the UK at the LIP. The Panel accepts Dr. Schwindt's evidence that a price charged in another country can provide a reasonable (although admittedly not perfect) perspective on costs, in that one can reasonably assume that by selling at the LIP in the UK, Alexion is covering its costs and earning a normal rate of return. No explanation or justification was provided to the Panel as to why Canadians should be paying significantly more for Soliris than comparable developed countries, including the United States and the United Kingdom.

167. In these circumstances, the Panel can see no justification why Canadians should not have the benefit of the lowest price being paid in any of the comparator countries, such as the UK (or the United States for that matter), especially considering the significant impact that the cost of Soliris is having on the provinces' health care budget even as compared (in the case of British Columbia as explained by Mr. Lun) to other EDRDs.

168. Since the date of first sale in Canada and continuing to the present, Soliris has been priced above the lowest price in the comparator countries specified in the Regulations. Accordingly, the Panel concludes that the price of Soliris is, and has been since 2009, excessive within the meaning of sections 83 and 85 of the *Patent Act*.

169. The Panel wishes to make clear that Board Staff's submission that Alexion's market power requires this Panel to apply greater scrutiny to its prices, and that this justifies the LIPC test, is rejected by the Panel and did not form any part of its decision. The Federal Court of Appeal has clearly stated that the existence of market power is not a pre-condition to the Board's exercise of its jurisdiction, nor is it relevant to the exercise of that jurisdiction.[128] This Panel also agrees with the statement made by the hearing panel in *Quadracel and Pentacel* that it is not necessary or appropriate for the Board to inquire into the existence of market power of either the patentee or the purchaser, in exercising its discretion under sections 83 and 85 of the *Patent Act*.[129]

170. In the remainder of the analysis of section 85(1)(c), the Panel will address the issues raised regarding exchange rates and the credibility of some of the data and calculations relied on by Board Staff.

Exchange Rates

171. The parties disagreed on the use of foreign exchange rates to compare prices of Soliris in the comparator countries to the Canadian price.

172. Alexion's position is that it has not changed the price of Soliris since its introduction in Canada, and the only reason it is non-compliant with the Guidelines is because of exchange rate fluctuations. Alexion submits that it should not be held responsible for forces outside its control.

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128 *ratio-Salbutamol* (Board Decision), *supra* note 77 at para 89, citing *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)*, [1996] F.C.J. No. 1065 (FCA).

129 *Quadracel* (2009), *supra* note 20 at paras 44-47.

173. The Guidelines are clear in respect of the situation in which Alexion found itself. Schedule 6 of the Guidelines provide:

> **3. Existing Drug Products with Unusual Circumstances**
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> 3.1 The Guidelines require that patentees take appropriate action when an investigation concludes that the price of its patented drug product appears excessive. There are, however, circumstances where a patented drug product whose price does not appear to be excessive in one review period then appears excessive in a subsequent period, due to the application of the HIPC test. This could be as a result of events beyond the control of the patentee. The following are examples of three such circumstances:
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> - Exchange rate variations;
> - A foreign regulator forcing price reductions; or
> - The highest priced drug product is removed from the market.
>
> Under the circumstances identified above, patentees will be notified that the patented drug product's price appears excessive and will be expected to adjust the National Average Transaction Price and Market-Specific Average Transaction Prices for the pharmacy and hospital customer classes, and for each province and territory by the end of the next two reporting periods, in which case the price will not be presumed to have been excessive. Failing this, the patentee would be requested to submit a Voluntary Compliance Undertaking (VCU) and repay any excess revenues dating back to the first period in which the price exceeded the HIPC test. If the patentee declines to submit a VCU, then the matter would be reported to the Chairperson with the recommendation that a Notice of Hearing be issued. [emphasis added]

174. The Panel notes that this section was not in the 2003 version of the Guidelines, but that fact is not material. It is clear that such a situation (*i.e.*, exchange rate fluctuations leading to breaches of the price test) could occur, even if this warning was not explicitly included. In any event, section 3.1 of Schedule 6 was contained in the Guidelines implemented on January 1, 2010, giving Alexion more than sufficient notice that Board Staff considers exchange rate fluctuations to be the responsibility of the patentee.

175. The Panel agrees that exchange rates are not within a patentee's control but, this is not relevant for the reasons already provided in the Panel's discussion of section 85(1) above.

176. In any event, Alexion was aware during the relevant time of the potential impact of currency exchange rate fluctuations on its business and has adopted business strategies to hedge against this risk. In its annual report for the fiscal year ended December 31, 2008, filed with the Securities Exchange Commission prior to the sale of Soliris in Canada, Alexion notes that its business is subject to the risk of "fluctuations in currency exchange rates".[130] In particular:

> While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have caused foreign currency transaction gains and losses in the past and will likely do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced.
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> [...]
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> In the first quarter of 2008, we began a program to limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet. In the third quarter of 2008, we commenced a program to hedge a portion of our forecasted product sales to mitigate fluctuations in foreign exchange rates. Both programs utilize forward foreign exchange contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.
>
> [...]
>
> We operate internationally and, in the normal course of business, are exposed to fluctuations in foreign currency exchange rates. The exposures result from portions of our revenues, as well as the related receivables, that are denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. We do not use derivatives for speculative trading purposes.[131] [emphasis added]

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130 Exhibit 1, Tab 58, p. 41.

131 Exhibit 1, Tab 58, pp. 41, 76, F-24.

177. Similar statements are found in Alexion's other annual reports filed in this proceeding, making it clear that Alexion is aware of the risk of fluctuations in currency exchange rates, and has adopted practices to manage this risk.[132] For example, Alexion notes:

> We enter into foreign exchange forward contracts, with durations of up to 60 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Further, we enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results.[133] [emphasis added]

178. Alexion chose not to comply with the Guidelines to address the excess revenues generated by the exchange rate fluctuations. It could have easily done so by reducing the N-ATP of Soliris. Instead, it decided to attempt to negotiate a resolution with Board Staff outside of the Guidelines. [134] Alexion was of course free to take this approach, but it did so with full knowledge that it was not complying with the Guidelines. Alexion was well aware of the appreciating Canadian dollar and the 36-month flexibility provided for by the Guidelines, as well as the risk that a hearing panel may conclude (as this Panel does) that the Guidelines' treatment of foreign exchange fluctuations is an appropriate implementation of section 85(1)(c) of the *Patent Act*.

179. Alexion also argues that this Panel should not convert international prices into Canadian dollars for the purposes of the section 85(1)(c) comparison. Relying on Dr. Putnam's evidence[135], Alexion submits that foreign exchange rate fluctuations are irrelevant to the evaluation of the price of a non-traded good like Soliris, and an exchange-rate converted price is not a "price" that should be used for comparison purposes under section 85(1)(c).

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132 Exhibit 1, Tabs 59-64.

133 Exhibit 1, Tab 64, p. 43.

134 Exhibit 1, Tabs 103A, 103B.

135 Exhibit 34, paras 41-57.

180. The Panel disagrees. The Panel concludes that foreign prices of Soliris must be converted into Canadian dollars for the purpose of conducting the comparison mandated by section 85(1)(c). This Panel agrees with the conclusion reached by the hearing panel in *Dovobet* that "[i]nternational price comparisons over time must take account of fluctuations in exchange rates in order to be appropriately accurate."[136]

181. The Panel heard evidence about two possible methods for conducting the conversion into Canadian dollars: using (i) market exchange rates, or (ii) PPP rates. As noted previously, PPP rates adjust market exchange rates for differences in local purchasing power. The Guidelines require the use of market exchange rates averaged over a 36-month period of time.[137] The Panel has considered both methods for conversion and, for the reasons set out below, the Panel concludes that the method for conversion in the Guidelines is an appropriate implementation of section 85(1)(c) of the *Patent Act* in the case of Soliris.

182. As explained by Dr. Schwindt, market exchange rates are appropriate and used in many jurisdictions that use ERP, and he was not aware of any jurisdiction that used PPP rates instead of market exchange rates. Noting that the purpose of ERP is to reflect a willingness of a patentee to supply, he explained that market exchange rates are appropriate because they demonstrate the price at which Alexion is prepared to supply Soliris, and it is fair to assume that the price in the comparator countries is set so as to cover the patentee's costs.[138]

183. Also, importantly, market exchange rates are more straight-forward to determine as compared to PPP rates. For example, there are difficulties associated with assembling the identical basket of goods in the countries being compared, and there is no clear consensus

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136 *Dovobet*, supra note 18.

137 More specifically, the Guidelines provide that the exchange rates to be used to convert international prices into Canadian dollars are the simple average of the 36 monthly average noon spot exchange rates for each country (taken to eight decimal places) as published by the Bank of Canada.

138 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 880, line 13 – p. 881, line 5, p. 882, line 6 – p. 883, line 5. Dr. Addanki was of a similar view – he believes that market exchange rates are appropriate because what should be measured is what would occur if the goods had been tradable. In other words, for example, what would Canadians have paid if they purchased Soliris in the US at the US price. See Examination In-Chief of Dr. Addanki, February 22, 2017, Hearing Transcript, Vol 11 (Public) at p. 1287, line 22 – p. 1289, line 4.

in respect of the right basket of goods for determining PPP rates. Dr. Putnam also agreed that there were issues with PPP rates.[139]

184. In addition, the 36-month period provided in the Guidelines is generous to patentees in that it irons out the volatility that can happen with market exchange rates and means that patentees are not forced to immediately adjust prices based on market exchange rates. In other words, the Guidelines provide enough time to eliminate the effects of any sudden fluctuations in exchange rates, and give patentees a reasonable period of time to monitor and react to changes in exchange rates. Dr. Schwindt testified that some jurisdictions provide for a much shorter time frame (*e.g.*, six months in Norway).[140]

185. The Panel acknowledges that Mr. Soriano and Dr. Putnam advocated various alternative approaches to conducting the comparison required by section 85(1)(c) of the *Patent Act*. The Panel was not persuaded that these alternative approaches appropriately implement that section.

186. For example, Mr. Soriano assumes that Alexion raised its price by the relevant CPI in Canada and in the comparator countries, both of which did not occur. The Panel agrees with Board Staff that this comparison of hypothetical prices is not the appropriate analysis under section 85(1)(c). The Panel also notes that Mr. Soriano used PPP rates for the purposes of his analysis. The Panel was not persuaded that Mr. Soriano's approach would lead to an appropriate implementation of section 85(1)(c) of the *Patent Act* for the following two additional reasons: first, he did not apply PPP rates consistently, but only for the years 2010 forward.[141] Second, his analysis applied the PPP rates but the prices were not constrained by the CPI methodology as set out in the Guidelines. As explained when discussing the factor in section 85(1)(d) below, the Panel is of the view that the

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139 Cross-Examination of Dr. Putnam (Cont'd), February 24, 2017, Hearing Transcript, Vol 13 (Public) at p. 1798, line 11 – p. 1799, line 19.

140 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 887, lines 11-22.

141 There was general consensus amongst the experts, and the Panel agrees, that whatever exchange rate is used, it should be used consistently. Using PPP rates from the price at introduction forward for Soliris would have made Alexion worse off in that the ceiling for the introductory price would have been set at approximately $200, as compared to the actual introductory price of $224.7333. *See* Dr. Schwindt's Expert Reports, Exhibit 8, Table 5, p. 15 and Exhibit 81, Table 1, p. 6.

Guidelines' use of the CPI as a price constraint (*i.e.*, ceiling price must be the lower of CPI and ERP benchmark) is an appropriate implementation of section 85(1) of the *Patent Act*.

187. Dr. Putnam argues that an exchange-rate converted price is not a "price" and should not be used for comparison purposes under s. 85(1)(c). Dr. Putnam's analysis also conflates subsections (c) and (d), as discussed later in these reasons when the Panel considers section 85(1)(d).

188. Alexion also appears to have accepted the appropriateness of using market exchange rates with respect to Soliris. In its negotiations with the provinces, Alexion took the position that the exchange rate methodology in the Guidelines was well-established and appropriate.[142] The Panel also notes that Alexion uses market exchange rates for its financial reporting – its financial statements are consolidated and denominated in US dollars with conversion based on market exchange rates.[143]

189. Furthermore, in July 2008, a Working Group on Price Tests that was set up by the Board specifically considered and rejected the idea that conversion of international prices should be based on PPP rates, and reaffirmed that the 36-month market exchange rate methodology was appropriate.[144]

190. Based on the considerations above, the Panel is of the view that the market exchange rate methodology set out in the current Guidelines is an appropriate implementation of section 85(1) of the *Patent Act*.

Disputes About Price Sources, Back-out Formulas and Data

191. An argument advanced by Alexion throughout the proceeding was that Board Staff had failed to meet its burden of proof. Alexion argued that Board Staff failed to adequately prove the underlying data for Board Staff's calculations of excess revenues, and provided

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142 Exhibit 23, Tab 7, p. 2.

143 Exhibit 1, Tab 61, p. F-8; Exhibit 1, Tab 64, p. F-8; Cross-Examination of Mr. Haslam, February 28, 2017, Hearing Transcript, Vol 15 (Confidential) at p.664, line 13 – p. 667, line 19.

144 Exhibit 1, Tab 109, p.3.

numerous conflicting charts showing different prices and amounts of excess revenues for 2012 to 2015, without an adequate explanation as to why the numbers differed. Alexion also argued that its inability to cross-examine those persons at the Board who were directly involved in the preparation of the charts and calculations was a denial of natural justice.

192. The Board's regulation of the prices of patented medicines is based on self-reporting. In other words, the patentee is required to file the relevant pricing information in its Form 2. The role of Board Staff is to verify the information, and it can only do so using publicly-available information (because that is the only information it has access to, unless the patentee volunteers additional information).

193. The dispute in this case largely centered on some of the sources used by Board Staff to verify the international prices, as well as the appropriateness of "back-out" formulas used to ensure the price reflected the ex-factory price. In some instances, the price source or the back-out formula used by Board Staff for Soliris was not listed on the Board's website. Alexion also strongly objected to the use by Board Staff of IMS MIDAS data for verifying prices.

194. The Panel agrees with Alexion that the various charts and calculations filed by Board Staff were unclear and, despite being repeatedly addressed at the hearing, the Panel did not receive a clear explanation of the differences in the charts. The Panel also agrees with Alexion that the confusion surrounding the use of certain foreign price sources, the relevance of back-out formulas, and the inconsistent disclosure was not adequately resolved by the evidence adduced in the hearing. Lastly, while it is certainly conceivable that in any given case Board Staff may have to look beyond its usual sources to verify foreign prices, the Panel concludes that Board Staff did not meet its evidentiary burden of establishing that the IMS MIDAS data was an appropriate source of foreign price verification in the circumstances of this case. For example, Board Staff did not call any witness who had direct and relevant knowledge of the nature and composition of the IMS MIDAS data.

195. This general state of confusion in the evidence was certainly not assisted by the fact that Board Staff's sole fact witness, Mr. Lemay, was not personally involved in the preparation of any of the relevant documents or the investigation itself, and therefore could not assist in resolving the uncertainty surrounding Board Staff's approach to foreign price verification.

196. However, it is important to note that none of the sources in dispute, including IMS MIDAS data, have any impact on the determination of whether Soliris was priced above the lowest priced comparator country – in all cases, Soliris would fail the LIPC test – which the Panel has determined is the correct benchmark. Accordingly, the confusion noted above has no impact whatsoever on the Panel's decision that the price of Soliris is and was excessive in Canada.

197. This issue is relevant in respect of the calculation of excess revenues to be paid by Alexion, which is addressed by the Panel later in these reasons. Any potential concerns that Alexion may have with the information relied on by Board Staff are, in the Panel's view, completely resolved by the Panel's requirement that the parties use only the information provided by Alexion in its Form 2s (except for any claimed rebates to the provinces or Innomar) for the purpose of calculating excess revenues.

198. The Panel rejects Alexion's submission that it has not received procedural fairness in this proceeding. The Panel concludes that Board Staff has complied with its disclosure obligations in that Alexion was advised of the case it had to meet, and was provided with all of the documents that Board Staff intended to rely on.[145] When Board Staff filed the Amended Statement of Allegations, Alexion received sufficient time to review and respond to it, including through its detailed fact and expert evidence at the hearing. Alexion's response included submissions as to why Board Staff's amended position should be rejected and why the evidence provided by Board Staff, including the inconsistencies and confusion noted above, could not be relied on. The Panel has taken

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145 *Ciba-Geigy Canada Ltd., Re*, [1994] 3 FC 425 at para 32 (FC), appeal dismissed [1994] FCJ No 484 at paras 5, 6 (FCA).

all of this (including Alexion's evidence and submissions) into account in reaching its decision, including the terms on which the excess revenues are to be calculated.

(D) Section 85(1)(d) – changes in the Consumer Price Index

199. The current Guidelines provide that the "National Average Transaction Price and the Market-Specific Average Transaction Prices of an existing patented drug product will be presumed to be excessive if they increase by more than that allowed under the Board's CPI-Adjustment Methodology, as long as this price does not exceed the HIPC test." The CPI Adjustment Methodology is set out in Schedule 9:

> 1.2 The CPI-Adjustment Methodology involves the following calculations:
>
> - Adjusting the benchmark prices of the drug product for the cumulative change in the CPI from the benchmark year to the year under review (CPI-Adjusted Price); and
>
> - Applying a cap on the maximum price increase in any one year, equal to 1.5 times the change in the latest actual lagged CPI. In periods of high inflation (over 10%), the limit will be five percentage points more than the latest actual lagged change in the CPI.
>
> 1.3 The lower of the results of both calculations will set the Non-Excessive Average Price for a particular year. (footnotes omitted)

200. Board Staff argues that section 85(1)(d) should be given less weight than section 85(1)(c) because CPI is not relevant to the introductory price of Soliris, and Alexion did not ever adjust its price in Canada based on CPI.

201. Alexion submits that the predominant consideration under section 85(1)(d) is that the price of Soliris in Canada has never increased and, in fact, has decreased by approximately 10% based on changes to the CPI.[146]

202. In the Panel's view, the methodology in the Guidelines reasonably and appropriately applies the factor in section 85(1)(d) for Soliris, except that, going forward, a price

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146 *See*, Exhibit 40, p. 11, where Mr. Soriano calculated the 2016 inflation-adjusted price to be $199.05.

increase based on CPI cannot exceed the LIPC test (instead of the HIPC test). The Panel acknowledges that a patentee should be able to take price increases based on inflation, but at no time in the future should Canadians be paying a higher price for Soliris than the price in the lowest priced comparator country. The Panel accepts Dr. Schwindt's evidence that using the lower of the two tests provides an indication that the patentee has covered costs and is willing to supply at a certain price.[147]

203. The Panel acknowledges that the price of Soliris in Canada has not changed since its introduction and notes Mr. Soriano's evidence that in "real dollars" the price of Soliris has decreased due to inflation. The Panel found Mr. Soriano's evidence in this regard to be unhelpful as it is not based on an appropriate comparison – for example, in devising his proposed Comprehensive test in Appendix B, Table 3 of his report, Mr. Soriano adjusts the ex-factory prices in comparator countries upwards based on CPI in those countries (even if the actual price in those countries did not change but in fact decreased in "real dollars" based on the same reasoning that Alexion uses to argue that the price in Canada has decreased due to inflation), and then Mr. Soriano does not adjust the Canadian price upwards based on CPI in Canada in the same table, thus comparing the nominal price in Canada with CPI-adjusted prices elsewhere.[148] This is not an appropriate comparison in the Panel's view. Considering inflation in Canada while disregarding the effect of inflation in the comparator countries does not allow for a meaningful comparison.

204. Mr. Soriano also presents in his report an analysis of additional revenues that Alexion could have realized had it increased its price by the CPI factor each year. This analysis is not helpful to the Panel because it ignores the fact that there is no guaranteed yearly CPI increase under the *Patent Act*, and that between 2012 and 2015, a price increase by the CPI factor would not have been available to Alexion under the Guidelines.[149]

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147 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 846, line 25 – p. 847, line 24.

148 Exhibit 40.

149 The Panel also relies, by way of analogy, on the decisions of previous hearing panels that it is not appropriate for a patentee to bank price increases that were not made in a given year to be used in some fashion by the patentee in future years to justify a price. See Board Decision –*Sanofi Pasteur Limited and*

205. Dr. Putnam argued that section 85(1)(d) requires this Panel to convert the nominal price of Canadian Soliris and of international Soliris to its "real price" by applying CPI adjustments, and then compare the CPI-adjusted price. The Panel rejects Dr. Putnam's analysis because it is not supported by the wording of section 85(1)(d). Section 85(1)(d) simply requires the Panel to "consider changes in the CPI" – it does not require the Panel to apply CPI to the nominal price and then do a comparison of the Canadian price and the international prices using the CPI-adjusted price.

206. Further, as already mentioned in its discussion of section 85(1)(c), the Panel agrees with Board Staff that Dr. Putnam's analysis inappropriately conflates the consideration of the factors in sections 85(1)(c) and (d) by advocating that the international prices that 85(1)(c) requires the Panel to consider need to be adjusted by the CPI in order for the Panel to comply with 85(1)(d). Lastly, the Panel agrees with Board Staff that the wording of section 85(1) is clear that the change in CPI referred to in section 85(1)(d) is to be considered with respect to the Canadian price which is under review, not the prices in the comparator countries it is being compared against.

207. As noted above, section 85(1)(d) only requires the Panel to consider changes in the CPI. The Panel has considered that the price of Soliris in Canada did not change even though there was a positive rate of inflation between 2012 and 2015. However, the Panel notes from Mr. Soriano's report that the price in the lowest priced comparator in 2012 to 2015 (United Kingdom) also did not change, even though there was a positive rate of inflation in the United Kingdom. In fact, in 2011, 2012 and 2013, the United Kingdom had a higher CPI factor than Canada.[150]

208. In light of the above, the Panel is of the view that the current methodology in the Guidelines (adjusted to refer to the LIPC test on a go-forward basis) correctly implements this factor of the *Patent Act* for Soliris.

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the Medicines "Quadracel and Pentacel" (14 June 2012) at para 6, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=860&lang=en> [*Quadracel* (2012)].

150 Exhibit 40, Table 3, p.5, and Appendix B.

(E) Section 85(1)(e) – such other factors as may be specified in any regulations made for the purposes of this subsection

209. No regulations have been passed and this factor is therefore not applicable.

(F) Summary of Analysis under Section 85(1) of Patent Act

210. Irrespective of any discrepancies with foreign price verification sources, the price of Soliris in Canada (s. 85(1)(a)) at all times since its introduction has been above the LIPC (s. 85(1)(c)). Given that the Panel has concluded that the LIPC is the correct benchmark for Soliris, even considering changes in the CPI (s. 85(1)(d)), in respect of the first issue then the Panel finds that the price of Soliris is and was excessive for the purposes of s. 83 and 85 of the *Patent Act*. The Panel rejects Alexion's submission that Board Staff did not meet its burden of proof on a balance of probabilities.

X. Order

211. Sections 83(1) and (2) of the *Patent Act* provide this Panel with broad remedial discretion:

> **83 (1)** Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.
>
> **(2)** Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:
>
> **(a)** reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

> **(b)** reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or
>
> **(c)** pay to Her Majesty in right of Canada an amount specified in the order.

212. Board Staff argues that this Panel is entitled to calculate excess revenues under section 83(2) on a different basis than the setting of the price of Soliris going forward under section 83(1).[151] This Panel agrees that it has such discretion and has exercised it in the circumstances of this particular case.

213. The Panel has found that Alexion is selling Soliris in Canada at a price that is excessive. Based on its analysis of the factors in section 85(1) and the discretion granted to it under section 83(1) of the *Patent Act*, the Panel orders Alexion to reduce the price of Soliris in Canada to no higher than the price in the lowest priced comparator country in the Regulations as of the date of the decision.

214. The Panel has also found that Alexion was selling Soliris in Canada at a price that was excessive during 2009 to 2015 in that the price exceeded the price in the lowest priced comparator country in the Regulations, and thus generated excess revenues. Based on the discretion granted to it under s. 83(2), the Panel orders Alexion to pay to Her Majesty in right of Canada the amount calculated by the parties and approved by this Panel in accordance with Schedule A to this decision, in order to offset these excess revenues.

215. Although the Panel is of the view that the correct benchmark for Soliris is the LIPC as of the date of first sale in Canada, the Panel is not prepared to order Alexion to pay past excess revenues based on this benchmark and is only requiring Alexion to comply with the LIPC test going forward from the date of this decision.

216. In light of all of the evidence and the unique circumstances of this case, the Panel concludes that requiring Alexion to make a payment to address past excess revenues

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151 Submissions by Mr. Migicovsky, April 18, 2017, Hearing Transcript, Vol 19 (Public) at p. 2787, line 19 – p. 2788, line 20.

calculated on the basis of the HIPC test is the remedy that is appropriate, fair and consistent with the Panel's mandate. In reaching this conclusion, the Panel took into consideration the fact that the LIPC test was not proposed as the appropriate benchmark for Soliris until 2015, several years after Soliris was first sold in Canada and, up until 2015, Board Staff had consistently applied the HIPC test in the Guidelines to the pricing of Soliris. Fashioning a remedy to address past excess revenues in this particular case that is based on the lowest international price comparison test (the LIPC test) is inconsistent with an environment that encourages the supply of patented medicines at reasonable prices to Canadians.

217. Alexion submits that if any one of a number of "offsets" is taken into account, the quantum of excess revenues (calculated on the basis of the current Guidelines) is completely offset. Alexion refers to four potential offsets (discussed below).

218. First, approximately $[redacted] in rebates paid under the PLAs in 2011 to 2013. As discussed above in the factual history of Board Staff's investigation, Board Staff rejected these rebates in reliance on the *Pfizer* decision.[152] Alexion argues that Board Staff's reliance on *Pfizer* is misplaced, and conflicts with the decision in *Leo Pharma* that the distribution of free goods voluntarily reported to the Board could be taken into account.[153]

219. Mr. Haslam testified that Alexion refiled its Block 4 information as a result of the December 2013 meeting with Board Staff. He believed that a solution to Alexion being offside the Guidelines was to refile 2011 to 2013 with the provincial rebates included, as doing so would bring the ATP of Soliris down below the maximum non-excessive price for 2012 and 2013.

220. Board Staff rejected the refiled information because, in its view, the rebates were not payments to customers. Board Staff took the position that *Pfizer* stands for the proposition that rebates to third parties cannot be taken into account to reduce the ATP

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152 *Pfizer Canada Inc. v Canada (Attorney General)*, 2009 FC 719 [*Pfizer*].

153 *Leo Pharma*, *supra* note 18 at para 57.

because reporting of rebates to third parties (such as the provinces) is outside the Board's jurisdiction.

221. While disagreeing with Board Staff on its interpretation of *Pfizer*, Alexion acceded to Staff's request and refiled its Form 2s without the rebates to the provinces.

222. The Federal Court made it clear in its decision in *Leo Pharma* that the determination of the ATP of a patented medicine must take into account any reduction given in the form of rebates.[154] The Panel interprets this direction as referring to rebates given to customers.

223. The Panel notes that Alexion appears to have taken conflicting positions on the meaning of *Pfizer* during the course of this proceeding. In its closing argument, Alexion argues that *Pfizer* does not prevent the distribution of free goods (or similar benefits) voluntarily reported to the Board from being taken into account when determining the ATP. This would, of course, require this Panel to consider the relationship between Alexion and a third party (in this case, the provinces). On the other hand, in its objection to the intervention request filed by the Ministers of Health, Alexion argued that this Panel lacks jurisdiction to consider any submissions by the Ministers about the downstream arrangements for the sale of patented medicines.[155] And, in its reply closing submissions,[156] Alexion argues that *Pfizer* expressly holds that the Board's jurisdiction is subject to a constitutional limitation that does not permit consideration of contractual arrangements involving patentees and entities further down the distribution chain.

224. *Pfizer* was a case where a Board's policy requiring patentees to report rebates to third parties (in that case, provinces) was challenged. The Federal Court concluded that the Board cannot require patentees to report rebates paid to third parties because federal jurisdiction is confined to the regulation of the factory gate prices of patented medicines.

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154 *Leo Pharma*, *supra* note 18 at para 69.

155 Alexion's Reply Submissions - *Motion to Strike Portions of the Minister of Health of B.C.'s further Amended Notice of Appearance* (23 October 2015) at para 13, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Respondent_reply_to_Board_Staff_response_to_motion_to_strike_BC.pdf>. This is summarized by the Panel in Board Decision – *Various Motions Related to Procedural Matters*, supra note 6 at para 43.

156 Alexion Reply Closing Submissions at paras 9-10.

The Court noted that the provinces never take title or possession to the medicines, are not parties to the sale at factory gate, and do not provide payment to the patentees. The Court concluded that the provinces are not customers, but more akin to public insurers.[157] The Court also clarified the meaning of "rebate" and found that to qualify as a rebate, there must be a return of a portion of money actually paid, and the payment cannot be paid to a stranger to the sale transaction.[158]

225. This Panel agrees with the comments made by the panel in the *ratio-Salbutamol* proceeding that there is some confusion as to how far the Court's decision in *Pfizer* extends.[159] This Panel does not need to resolve this confusion in order to make a decision concerning these rebates in the case of Soliris. The Panel concludes that the rebates that Alexion provided to the provinces do not qualify as rebates within the meaning of the Regulations as interpreted by the Federal Court. The provinces are not customers but akin to public insurers and were a stranger to the sale transaction (*i.e.*, not a party to the sale at factory gate since Mr. Haslam testified at the hearing that Alexion's only customer in Canada is Innomar) and therefore even if payments were made directly to the provinces by Alexion, those payments do not qualify as rebates. Further, in the end, Alexion adhered to Board Staff's request to refile the relevant Form 2s without the provincial rebates, and has always maintained throughout this proceeding that the ATP of Soliris has remained unchanged since introduction. For these same reasons, it is not appropriate for this Panel to allow Alexion to use these rebates to offset any excess revenues.

226. Second, Alexion refers to approximately $[redacted] in rebates provided by Alexion to Innomar. As discussed above in the factual history of Board Staff's investigation, Alexion filed Block 4 information for July to December 2014 showing a reduced ATP which was described as "accurately reflect[ing] reductions from the List Price of Soliris

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157 *Pfizer*, *supra* note 152 at paras 61-62, 73, 80.

158 *Pfizer*, *supra* note 152 at para 88.

159 *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 118-125.

provided by Alexion to its wholesaler/distributor and reported as required under the Regulations."[160]

227. During his testimony, Mr. Haslam explained that, technically, Innomar is Alexion's only customer and all sales go through Innomar. He explained that Innomar is either a wholesaler or a pharmacy, with the majority of sales going through Innomar as a pharmacy and, on some occasions, sales were made to hospitals. The Form 2s filed by Alexion referred to hospitals and pharmacies, and not to a wholesaler because Alexion was, according to Mr. Haslam, trying to show where the product was going. Mr. Haslam explained that the amended Form 2s reflected Alexion's decision to share with Innomar the costs of the volume discount payments made to the provinces under the PLAs, and the mechanism used to share the payments was credit notes paid by Alexion to Innomar. The credit notes were issued in 2014 and 2015, and reflected what Alexion thought would be the amount by which the ATP exceeded the HIPC for 2014 and 2015. [redacted]

228. The Panel agrees with the comments made by the panel in the *ratio-Salbutamol* case that the patentee has the evidentiary burden to provide supporting documentation of any rebate that is claimed in respect of the medicine.[161] This Panel concludes that Alexion has failed to meet its evidentiary burden to show that these credit notes justify a reduction in the ATP for Soliris for 2014 or 2015, or should be permitted to be used as an offset for excess revenues. Alexion's position that Innomar, a wholesaler, is its only customer, conflicts with the information found in the Form 2s. In these circumstances, the Panel requires some corroboration of Mr. Haslam's statements at the hearing as to what Innomar is and what role it played. No documents were produced concerning Alexion's relationship with Innomar. Photocopies of what were described as credit notes produced for the first time during Mr. Haslam's examination-in-chief are insufficient proof in the circumstances as no explanation was provided as to why these credit notes were not

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160 Exhibit 1, Tabs 55.

161 *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 111-112.

produced earlier in this proceeding, no back up documentation was provided for the credit notes and, with only photocopies of what were described as credit notes, Board Staff did not have a fair opportunity to challenge this evidence.[162]

229. Based on the consistent position taken by Alexion throughout this proceeding that the price of Soliris in Canada has not changed since introduction, the Panel is not willing to accept these credit memos to reduce the ATP of Soliris in Canada in 2014 or 2015 for the purposes of this hearing; in the Panel's view, the price of Soliris in 2014 and 2015 for the purposes of determining price excessivity is $224.7333.

230. Third, Alexion argues that if infusion costs had been taken into account in the Form 2 filings, the price of Soliris would have decreased further and offset excessive revenues. This assertion was raised for the first time during the hearing and was not contained in Mr. Haslam's witness statement. Mr. Haslam testified that Alexion's contract with Innomar covers infusion costs for Soliris for Canadian patients and those costs can range between $[redacted] to $[redacted] per infusion.[163] The only evidence provided on this point was Mr. Haslam's oral testimony, subject to one document that was prepared by Alexion and produced for the first time during the hearing. Mr. Haslam's evidence in this respect conflicts, at least in part, with other evidence adduced at the hearing. In particular, Mr. Lun testified that the public payor system covers at least some of the infusion costs.[164]

231. The Panel rejects Alexion's argument concerning infusion costs for the same reasons it rejected the argument concerning rebates paid to Innomar. No credible evidence was provided demonstrating the relationship between Alexion and Innomar, as well as the arrangement between them related to infusion costs. Alexion has failed to meet its evidentiary burden to prove that these infusion costs were in fact covered by Alexion and the amount of relevant infusion costs covered, and thus it is not appropriate for this Panel to take them into account to reduce the ATP or to offset any excess revenues.

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162 Examination In-Chief of Mr. Haslam, February 27, 2017, Hearing Transcript, Vol. 14 (Confidential) at p. 501, lines 17-21, p.513, line 20 – p.514, line 4.

163 Examination In-Chief of Mr. Haslam, February 27, 2017, Hearing Transcript, Vol. 14 (Confidential) at p. 516, line 14 – p. 517, line 4.

164 Examination In-Chief of Mr. Lun (Cont'd), February 22, 2017, Vol. 11 (Confidential) at p. 339, lines 3-15.

232. Fourth, Alexion relies on Mr. Soriano's evidence that no inflationary increases were taken by Alexion and therefore the real price of Alexion decreased. The Panel concludes that this does not justify any offset of excess revenues. Amongst other things, it incorrectly assumes that Alexion would have been permitted to take yearly CPI increases.

233. The Panel concludes that the provisions of the current Guidelines dealing with permitted offsets are an appropriate implementation of the *Patent Act* in the circumstances of this case. They provide flexibility to the patentee while, at the same time, preventing the charging of excessive prices with the elimination of excess revenues at some future unknown date at the control of the patentee (which would, if permitted, frustrate the Board's consumer protection mandate and create volatility).[165]

234. The relevant provisions of the Guidelines, dealing with offsets, are as follows:

> **B.7 Policy on the Offset of Excess Revenues**
>
> B.7.1 The Board may allow a patentee to offset any excess revenues estimated by it to have been derived from the sale of the medicine at an excessive price through either: (i) the reduction of the price of the medicine or the price at which the patentee sells another patented medicine in Canada; or (ii) a payment to Her Majesty in right of Canada.
>
> B.7.2 To offset excess revenues via a price reduction, the average price of a patented drug product will only be considered to have been reduced if it is below the previous year's Non-Excessive Average Price; not taking an allowable price increase will not be considered for purposes of offsetting excess revenues.
>
> B.7.3 Cumulative excess revenues cannot fall below zero.

235. In relation to this Panel's jurisdiction to make an order under section 83, Alexion relied on several arguments – including the law of expropriation, NAFTA and the Canadian *Bill of Rights* – to argue that it would be an error for this Panel to interpret the *Patent Act* as allowing the Panel to make an order that is based on a methodology which is not contained in the Guidelines. The Panel disagrees – the Panel does not lack the ability to make an order under section 83 that deviates from the methodologies and tests in the

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165 *Quadracel* (2012), *supra* note 149 at para 14.

Guidelines for the reasons already articulated above and for the additional reasons set out below.

236. Principles of the law of expropriation do not assist Alexion. In making an order under section 83 of the *Patent Act,* this Panel is exercising statutory regulatory authority. An exercise of regulatory authority, even if its effects are significant or retroactive, is not an act of expropriation.[166]

237. NAFTA has no application to this proceeding. The Federal Court has made it clear that NAFTA is not part of Canada's domestic law, and does not have the force of an Act of Parliament. In relevant part, NAFTA allows an investor of a NAFTA signatory to initiate a claim to determine, through international arbitration, whether another signatory state has violated the obligations set out in NAFTA. No such claim or arbitration proceeding is at issue here, nor has the evidentiary foundation for such a claim (should the Panel have jurisdiction to consider it) been provided.

238. While an international treaty, like NAFTA, may be used to assist in interpreting domestic legislation, it cannot be used to override the clear words of a federal statute and, where legislation is clear, one need not and should not look to international law to interpret its meaning.[167] Sections 83 and 85 of the *Patent Act* are clear and unambiguous, and any suggestion that the Panel should look to international law to give them meaning is rejected.

239. Even if the Panel did turn to international law to interpret sections 83 and 85, international law supports the Panel's decision in this proceeding. NAFTA arbitration panels have rejected the claims of investors affected by the domestic law of a NAFTA signatory where the domestic law was in fact regulation for a public purpose, the law was non-discriminatory and was done with due process, and the investor was not promised that the law would not apply and invested in the signatory state with its eyes wide open as

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166 *A & L Investments Ltd. v Ontario (Minister of Housing)*, [1997] OJ No 4199 at paras 29-31 (Ont CA); leave to appeal refused [1997] SCCA No 657 (SCC).

167 *Baker Petrolite Corp. v Canwell Enviro-Industries Ltd.*, 2002 FCA 158 at para 25; *Pfizer Canada Inc. v. Canada (Attorney General)*, 2003 FCA 138 at para 20, leave to appeal refused 27 C.P.R. (4th) vi (SCC).

to what the regulatory context was in the signatory state.[168] The Panel concludes that this is exactly the context of this case. As referenced above, Alexion has consistently noted the potential impact of government regulation of the price of Soliris in its annual filings with the Securities Exchange Commission in the US.

240. The Canadian *Bill of Rights* also does not support Alexion's argument. It was unclear which provision of the *Bill of Rights* – section 1(a) and/or 2(e) – Alexion was relying on to argue that the Panel's remedial powers are limited to the methodologies and tests in the Guidelines. However, this is irrelevant as neither provision supports Alexion's position in this proceeding.

241. Section 1(a) provides the right of the individual not to be deprived of the enjoyment of property except by due process of law. Corporations are not entitled to make a claim under section 1(a).[169] In any event, even if the Panel's order qualified as expropriation of Alexion's property (which it does not), section (1)(a) does not protect against the expropriation of property by the passage of unambiguous legislation like the relevant provisions of the *Patent Act*.[170]

242. Section 2(e) guarantees the right to a fair hearing before an administrative body. The Panel does not have to resolve whether or not section 2(e) applies to corporations because, even if it does, the Panel concludes Alexion did receive a fair hearing in this proceeding.

243. In any event, the Panel has ordered that any excess revenues for 2012 to 2015 be calculated based on the Guidelines and using Alexion's filed Form 2 information (without rebates to the provinces or Innomar), and thus Alexion's concerns are not relevant in

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168 *Marvin Feldman v Mexico* (16 December 2002), Case No ARB(AF)/99/1 at para 103, online: International Centre for Settlement of Investment Disputes <http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C175/DC587_En.pdf>; *Methanex Corporation v United States of America* (3 August 2005) at Part IV, Ch D, para 15, online: UNCITRAL: < https://www.state.gov/documents/organization/51052.pdf>.

169 *Smith, Kline & French Laboratories Ltd. v Canada (Attorney General)*, [1985] FCJ No 501 at para 60 (FC), aff'd [1987] 2 FC 359 (FCA), leave to appeal refused 27 CRR 286 (SCC); *R. v Colgate-Palmolive Ltd.*, 5 CPR (2d) 179 at para 10 (Ont GSP Ct), aff'd 6 CPR (2d) 4 (Ont CA).

170 *Authorson (Litigation Guardian of) v Canada (Attorney General)*, 2003 SCC 39 at para 51.

respect of the calculation of excess revenues to be paid to the Crown. The required application of the LIPC to Soliris commences on the date of this decision, and Alexion now has notice that it will be subject to the LIPC test going forward. There are no issues of "notice" or "retroactivity" concerning the price of Soliris going forward.

244. The Panel wishes to reiterate that the Guidelines do not address the issue of remedy in an excessive pricing hearing, and that when a case proceeds to the hearing stage, the Panel is not restricted to remedies based on an application of the methodologies and tests in the Guidelines. The mandate of this Panel is to apply sections 83 and 85 of the *Patent Act* in accordance with the wording and intent of those provisions, as well as the Board's consumer protection mandate.

245. Lastly, the Panel wishes to address the remedy that was sought by CLHIA, an intervenor in this proceeding solely on the issue of remedy. CLHIA argued that in order for this Panel to deal effectively with past excess revenues, the price going forward for Soliris in Canada should be reduced even further (*i.e.*, below the LIPC) until those excessive revenues are wholly set off. Otherwise, CLHIA argues, private insurers will not benefit from the Panel's decision (assuming the Panel found the price was excessive and ordered a lower price). Alexion objected to this request, and argued that this Panel has no jurisdiction to make such an order.

246. Such an order would be punitive to Alexion, would be difficult to implement, and is not necessary, in the Panel's view, for it to fulfill its consumer protection mandate in this case. The Panel need not decide whether it has the jurisdiction to make the remedial order requested by CLHIA, as it has concluded that, even if it had the jurisdiction, it would not be an appropriate exercise of its discretion to make such an order in the circumstances of this case. The Panel also notes that section 83(2) specifies the payment being made to the Federal Crown, as opposed to any entity that ultimately covered the cost of the medicine at issue, reflecting Parliament's acceptance of the fact that a remedy may not "compensate" the ultimate payors of the excess revenues.

247. The Panel therefore makes the following two orders:

(i) Alexion shall reduce the price of Soliris in Canada to no higher than the price in the lowest priced comparator country set out in the Regulations from the date of this decision forward, applying the tests and methodologies in the Guidelines, except that the price excessivity benchmark to be applied is LIPC and not HIPC; and

(ii) Alexion shall pay to Her Majesty in right of Canada an amount calculated by Board Staff and Alexion, and approved by this Panel in accordance with Schedule A to this decision.

Dated at Ottawa, this 20th day of September, 2017.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members

Mitchell Levine
Carolyn Kobernick

Counsel for Alexion

Malcolm Ruby
David Woodfield
Alan West

Counsel for Board Staff

David Migicovsky
Christopher Morris

Counsel for Panel

Sandra Forbes
Adam Fanaki
Badar Yasin

SCHEDULE A

1. The relevant period is 2009 to the date of this decision (the "**Relevant Period**").

2. The relevant prices are those contained in Alexion's original Form 2, Block 4 and Block 5 filings (the "**Relevant Prices**"). The Relevant Prices shall not reflect any rebates or credits provided by Alexion to the provinces or Innomar even if such rebates or credits are included by Alexion in any original Form 2 filing during the Relevant Period.

3. The methodologies and tests set out in the Guidelines to calculate excess revenues shall be applied to the Relevant Prices for the Relevant Period for purposes of calculating the payment to be made by Alexion. For greater certainty, Alexion is entitled to an offset of any excess revenues in accordance with sections B.7.2 and B.7.3 of the Guidelines, as applicable.

4. The parties shall consult and submit a joint chart setting out the calculation of the payment as specified by this Schedule A to the Panel by 4 pm on October 20, 2017. If the parties cannot agree on a joint chart, each party shall provide by 4 pm on October 20, 2017 the chart that it submits is accurate along with brief written submissions clearly and concisely setting out the differences between the parties and why their chart should be approved by the Panel.

5. A case conference will be scheduled in the event the Panel has any questions about the chart(s).

6. The Panel will review the joint chart or separate charts, as applicable, and issue a decision confirming the amount of the payment. Alexion shall make the payment within 30 days following the Panel's decision.

TAB 4

2007 FC 1126, 2007 CF 1126
Federal Court

Eli Lilly Canada Inc. v. Novopharm Ltd.

2007 CarswellNat 3667, 2007 CarswellNat 7054, 2007 FC 1126, 2007 CF 1126, 161 A.C.W.S. (3d) 721

Eli Lilly Canada Inc., Eli Lilly and Company, Eli Lilly Company Limited and Eli Lilly Sa, Plaintiffs (Defendants by Counterclaim) and Novopharm Limited, Defendant (Plaintiff by Counterclaim)

J. Gauthier J.

Heard: October 29, 2007
Judgment: October 31, 2007
Docket: T-1048-07

Counsel: Mr. Anthony G. Creber, for Plaintiffs
Mr. Jonathan Stainsby, Mr. Andy Radhakant, Mr. Neil Fineberg, for Defendant

Subject: Civil Practice and Procedure; Intellectual Property

Related Abridgment Classifications

Civil practice and procedure
XIX Pre-trial procedures
XIX.7 Severance
XIX.7.b Of issues

Headnote

Civil practice and procedure --- Pre-trial procedures — Severance — Of issues

Table of Authorities

Cases considered by *J. Gauthier J.*:

Apotex Inc. v. Merck & Co. (2004), 34 C.P.R. (4th) 514, 2004 FC 1133, 2004 CarswellNat 2698, 271 F.T.R. 1 (F.C.) — referred to

Bristol-Myers Squibb Co. v. Apotex Inc. (2003), 2003 CarswellNat 1785, 2003 FCA 263, (sub nom. *Apotex Inc. v. Bristol-Myers Squibb Co.)* 26 C.P.R. (4th) 129, (sub nom. *Apotex Inc. v. Bristol-Myers Squibb Co.)* 308 N.R. 152 (Fed. C.A.) — considered

Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior" Girolamo Luxardo S.p.A. (1998), 157 F.T.R. 217, 1998 CarswellNat 2812, (sub nom. *Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior")* 84 C.P.R. (3d) 1, (sub nom. *Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior")* [1999] 1 F.C. 146, 1998 CarswellNat 2015 (Fed. T.D.) — referred to

Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior" Girolamo Luxardo S.p.A. (2000), 2000 CarswellNat 196, 183 F.T.R. 25 (Fed. T.D.) — referred to

Merck & Co. v. Apotex Inc. (2003), 2003 FCA 488, 2003 CarswellNat 4080, 30 C.P.R. (4th) 40, 315 N.R. 175, [2004] 2 F.C.R. 459, 246 F.T.R. 319 (note), 2003 CarswellNat 4501, 2003 CAF 488 (F.C.A.) — referred to

Merck & Co. v. Brantford Chemicals Inc. (2004), 2004 CarswellNat 5701, 2004 CF 1400, 262 F.T.R. 147, 2004 FC 1400, 2004 CarswellNat 3629, 35 C.P.R. (4th) 4 (F.C.) — referred to

Merck & Co. v. Brantford Chemicals Inc. (2005), 2005 FCA 173, 2005 CarswellNat 1239, 39 C.P.R. (4th) 524, 2005 CarswellNat 4857, 339 N.R. 238, 2005 CAF 173 (F.C.A.) — referred to

Realsearch Inc. v. Valon Kone Brunette Ltd. (2004), 2004 FCA 5, 2004 CarswellNat 107, 317 N.R. 38, 247 F.T.R. 158 (note), 31 C.P.R. (4th) 101, [2004] 2 F.C.R. 514, 2004 CarswellNat 751, 2004 CAF 5 (F.C.A.) — considered

Z.I. Pompey Industrie v. ECU-Line N.V. (2003), 2003 SCC 27, 2003 CarswellNat 1031, 2003 CarswellNat 1032, 2003 A.M.C. 1280, (sub nom. *Pompey (Z.I.) Industrie v. Ecu-Line N.V.)* 303 N.R. 201, 30 C.P.C. (5th) 1, [2003] 1 S.C.R. 450, 240 F.T.R. 318 (note), 224 D.L.R. (4th) 577 (S.C.C.) — considered

Rules considered:

Federal Courts Rules, SOR/98-106
R. 107 — referred to

J. Gauthier J.:

1 Novopharm appeals the Order of Prothonotary Tabib dated September 25, 2007 granting the plaintiffs' motion for bifurcation of the issues of quantum from those of validity and infringement of the patent in suit pursuant to Rule 107 of the *Federal Courts Rules*, 1998, SOR/98-106. It is to be noted that Prothonotary Tabib is the Case Manager in this matter.

2 All the principles applicable to this appeal are well known. As the matter before Prothonotary Tabib did not involve a question vital to the final issue of the case, the Court should not intervene on appeal unless her decision was clearly wrong, "in the sense that the exercise of discretion was based upon a wrong principle or a misapprehension of the facts" (*Z.I. Pompey Industrie v. ECU-Line N.V.*, [2003] 1 S.C.R. 450 (S.C.C.) at para. 461), *Merck & Co. v. Apotex Inc.* (2003), 30 C.P.R. (4th) 40, [2003] F.C.J. No. 1925 (F.C.A.) at para. 19). The principles or conditions for the making of an order pursuant to Rule 107 are also well established (see for example *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2003 FCA 263, 26 C.P.R. (4th) 129 (Fed. C.A.) at para. 7); *Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior" Girolamo Luxardo S.p.A.*, [1998] F.C.J. No. 1500 (Fed. T.D.); *Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior" Girolamo Luxardo S.p.A.*, [2000] F.C.J. No. 170 (Fed. T.D.) at para 8; *Merck & Co. v. Brantford Chemicals Inc.*, [2004] F.C.J. No. 1704, 35 C.P.R. (4th) 4 (F.C.), aff'd [2005] F.C.J. No. 837, 39 C.P.R. (4th) 524 (F.C.A.); *Apotex Inc. v. Merck & Co.*, [2004] F.C.J. No. 1372 (F.C.) at para. 3). It is trite law that the applicant bears the burden of convincing the Court on a balance of probabilities that in light of the evidence and all of the circumstances of the case (including the nature of the claims, the conduct of the litigation, the issues and remedies sought), bifurcation or severance is more likely than not to result in the just, expeditious and least expensive determination of the proceeding on its merits.

3 That being said, having carefully considered all the arguments put forth by the parties on this appeal, the Court is not persuaded that Prothonotary Tabib made any error that warrants the Court's intervention.

4 As mentioned at the hearing, given that time is of the essence here, the Court will not comment on each and every issue raised by Novopharm (such issues are summarised at paragraph 2 of the written representations). However, considering the importance given to the following issues at the hearing, it is worth noting specifically that the Court cannot agree with Novopharm that Prothonotary Tabib implicitly applied or assumed the existence of a presumption in favour of bifurcation in patent infringement cases, which had the effect of actually reversing the burden of proof so as to place it on the shoulders of Novopharm. There was evidence before Prothonotary Tabib dealing with bifurcation of quantum issues in cases involving patent infringement in the last fifteen years (such as the affidavits of Nancy Gallinger and of Alisha Meredith). Prothonotary Tabib expressly refers to *Bristol-Myers Squibb Co. v. Apotex Inc.* above; in that case, the Federal Court of Appeal agreed that "when an experienced specialist bar like the intellectual property bar commonly consents to the making of a bifurcation order, it is open to a judge to infer that, in general, such an order may well advance the just and

expeditious resolution of claims".

5 It is also absolutely clear from the decision that this was only one of many factors Prothonotary Tabib considered before making her order. Among many other things, she was satisfied based on the evidence before her, the pleadings, her knowledge of the history of the proceeding and the issues it involved, that not only would bifurcation likely have the advantage of speeding up the determination of the liability issues (which at this stage also involve novel questions of law particularly in respect of the section 8 counterclaim), but that bifurcation would also more likely than not avoid at least one side of the quantification exercise whatever the result of the trial on liability issues. (page 4 last sentence and page 6 and 7)

6 Evidently, the Prothonotary was satisfied that she did not require more specific evidence in respect of the number of days of discoveries or an exact quantification of the time and expenses that would be saved in order to determine whether this would necessarily result in a saving of time and money for the Court and the parties.

7 Novopharm says that this constitute an error of law as Prothonotary Tabib failed to heed the evidentiary requirements set out by the Federal Court of Appeal in *Realsearch Inc. v. Valon Kone Brunette Ltd.*, 31 C.P.R. (4th) 101, [2004] 2 F.C.R. 514 (F.C.A.).

8 Like Prothonotary Tabib, the Court does not believe that *Realsearch* establishes a new condition or standard for the making of an order under Rule 107. As any party who has a burden of proof to meet, the applicant seeking such an order must provide sufficient evidence to enable the Court to come to a conclusion on the matter before it. The fact that there was no evidence dealing with the specific saving of time and money that would result from the bifurcation in the case before the Court in *Realsearch* was worth noting and was particularly significant because the bifurcation sought in that case was in respect of a question of law (claims construction). Such request was an unusual and a somewhat novel use of bifurcation pursuant to Rule 107. In such a case, the Court could not rely on experience or on an inference based on a consistent practice in respect of the bifurcation of quantum issues in similar cases or on knowledge acquired while case managing the matter. The situation is quite different here.

9 It is clear from her order that Prothonotary Tabib knew perfectly well that the applicant had to satisfy her on a balance of probabilities. She was fully aware of all the arguments raised by Novopharm in respect of the quality (or rather lack thereof) of the evidence before her. Still, she concluded on page 9 that on the whole, she was satisfied that she could reach a conclusion that severance is more likely than not to result in the just, expeditious and least expensive determination of the proceeding on its merits.

10 In fact, even if Novopharm had convinced that the Court that it should exercise its discretion *de novo*, the Court would ultimately have reached the same conclusion as Prothonotary Tabib.

Order

THIS COURT ORDERS that:
The appeal is dismissed with costs.

End of Document

TAB 5

2003 CAF 263, 2003 FCA 263
Federal Court of Canada — Appeal Division

Bristol-Myers Squibb Co. v. Apotex Inc.

2003 CarswellNat 1785, 2003 CarswellNat 6749, 2003 CAF 263, 2003 FCA 263, [2003] F.C.J. No. 950, 124 A.C.W.S. (3d) 268, 26 C.P.R. (4th) 129, 308 N.R. 152

Apotex Inc., Appellant and Bristol-Myers Squibb Company, Bristol-Myers Squibb Company Inc. and The University of Kentucky Research Foundation, Respondents

Noël J.A., Pelletier J.A., Richard C.J.

Heard: June 4, 2003
Judgment: June 13, 2003
Docket: A-552-02

Counsel: *Mr. Nando De Luca*, for Appellant
Mr. Alexander Mackin, Ms Jennifer Wilkie, for Respondent

Subject: Intellectual Property; Property; Civil Practice and Procedure

Related Abridgment Classifications

Civil practice and procedure
XII Discovery
XII.2 Discovery of documents
XII.2.c Time of production

Civil practice and procedure
XIX Pre-trial procedures
XIX.7 Severance
XIX.7.b Of issues

Intellectual property
II Patents
II.8 Actions for infringement
II.8.e Practice and procedure
II.8.e.vi Discovery

II.8.e.vi.D Time for production

Intellectual property
II Patents
II.8 Actions for infringement
II.8.e Practice and procedure
II.8.e.xii Miscellaneous

Headnote

Intellectual property --- Patents — Actions for infringement — Practice and procedure — Miscellaneous issues
Plaintiffs brought motion under R. 107 of Federal Court Rules, 1998, for order that all issues of facts pertaining to extent of infringement, damages and profits arising from infringement of plaintiffs' rights be determined after trial on issues of liability for infringement of its patent for pharmaceutical product — Motion was granted on basis that in pharmaceutical cases, bifurcation order is commonly entered by parties — Plaintiffs showed on balance of probabilities that severance would more likely than not result in just, most expeditious and least expensive determination of proceedings on merits — Defendant had failed to convince court that circumstances or facts of this case were different or justified departure from past practice — Defendant appealed — Appeal dismissed — Motions judge addressed proper factors — Person seeking order under R. 107 has burden to show that conditions for making such order are met — One factor, but not decisive factor, is that where experienced specialist bar like intellectual property bar commonly consents to bifurcation order, it is open to judge to infer that in general such order may well advance just and expeditious resolution of claims.

Intellectual property --- Patents — Actions for infringement — Practice and procedure — Discovery — Time for production
In plaintiffs' motion under R. 107 of Federal Court Rules, 1998, for severance of trial on issue of liability from trial on issue of quantum of recovery in patent infringement action, plaintiffs requested that they be entitled to examination for discovery and documentary production from defendant before electing between profits and damages — Plaintiffs also requested that discovery of plaintiffs' damages occur after plaintiffs make their election and only if plaintiffs elect to recover damages — Motion was granted — Defendant appealed — Appeal dismissed — Plaintiffs ought not be required to submit to discovery unless they elected damages because any information relevant to remedy of accounting of profits would be wholly within defendant's knowledge and possession — It would cause unnecessary expense and delay if plaintiffs were to be discovered.

Table of Authorities

Cases considered by *Pelletier J.A.*:

Apotex Inc. v. Merck & Co., 2002 FCT 626, 2002 CarswellNat 1275, 2002 CFPI 626, 2002 CarswellNat 2499, 19 C.P.R. (4th) 460, 219 F.T.R. 259 (Fed. T.D.) — followed

Elcano Acceptance Ltd. v. Richmond, Richmond, Stambler & Mills, 9 C.P.C. (2d) 260, 55 O.R. (2d) 56, 16 O.A.C. 69, 1986 CarswellOnt 618 (Ont. C.A.) — considered

Eli Lilly Canada Inc. v. Canada (Minister of Health), 2001 FCA 108, 2001 CarswellNat 777, 11 C.P.R. (4th) 486, 289 N.R. 377, 213 F.T.R. 317 (note) (Fed. C.A.) — referred to

Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior" Girolamo Luxardo S.p.A., (sub nom. *Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior")* 84 C.P.R. (3d) 1, 1998 CarswellNat 2015, (sub nom. *Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior")* [1999] 1 F.C. 146, 157 F.T.R. 217, 1998 CarswellNat 2812 (Fed. T.D.) — referred to

Snell v. Farrell, 110 N.R. 200, [1990] 2 S.C.R. 311, 72 D.L.R. (4th) 289, 107 N.B.R. (2d) 94, 267 A.P.R. 94, 4 C.C.L.T. (2d) 229, (sub nom. *Farrell c. Snell)* [1990] R.R.A. 660, 1990 CarswellNB 82, 1990 CarswellNB 218 (S.C.C.) — referred to

Rules considered:

Federal Court Rules, 1998, SOR/98-106
R. 3 — referred to

R. 107 — referred to

APPEAL by defendant from bifurcation order in patent infringement action.

***Pelletier J.A.*:**

1 This is an appeal of an order severing the trial of issues of liability from issues of the quantum of recovery in an action in which the plaintiff alleges infringement of its patent with respect to a pharmaceutical product. The appellant, defendant in the action, alleges that the motions judge acted on a wrong principle in holding that, in pharmaceutical matters, bifurcation orders are the usual practice, and that it is the departure from that practice which must be justified. It is also urged upon us that the motions judge erred in his appreciation of the evidence when he found that the order he made would result in a reduction of the complexity, length and cost of the trial of this matter.

2 The Statement of Claim in this matter was issued on July 18, 2001. The Statement of Defence and Counterclaim was filed on September 4, 2001, and the Defence to Counterclaim was filed on October 18, 2001. The respondents have delivered three affidavits of documents

while the appellants have yet to deliver theirs. No examinations for discoveries have taken place. The reason for the motion for severance was to determine the scope not only of the trial, but of the production of documents and oral examinations which will precede it.

3 The judge's order recites that, in cases such as the present, bifurcation orders are commonly entered into by the parties, and that the appellants had failed to convince him that the usual practice should not be followed. The judge held that he was satisfied that there would be no overlap of witnesses as between issues of liability and issues of compensation, and that there would be a reduction in the complexity of the trial as well as a reduction in its cost. Declaring himself to have been satisfied that it would result in the just, most expeditious and least expensive determination of the issues, the judge made the following order:

> 1. The motion be granted with costs;
>
> 2. All issues of facts pertaining to:
>
> a) any questions as to the extent of any infringement of the plaintiff's rights;
>
> b) any questions as to the damages arising from any said infringement; and
>
> c) any questions relating to the profits arising from any such infringement;
>
> be determined after trial as the subject of a hearing, if it then appears that such issues are required to be decided.
>
> 3. The plaintiffs be entitled to an examination for discovery and production of documents from the defendants prior to making their election between profits and damages; and
>
> 4. Any examination for discovery and production of documents in respect of the plaintiff's damages only occur after plaintiff's make their election and only if plaintiffs elect to recover their damages.

4 This order is now challenged on a number of grounds which can be summarized as follows:

> 1. The judge erred is proceeding on the basis that it was for the appellant to convince him why an order should not be made when it was for the respondents to persuade him that an order should be made.
>
> 2. The judge erred in assuming that the respondent could elect the equitable remedy of an accounting as of right.
>
> 3. The judge erred in fact in finding that such an order would reduce length, cost and complexity of the trial, and in not taking into account the appellants to the opposite effect.

4. The judge erred in failing to provide for the appellant's right to oral and documentary discovery of the respondents on the issue of remedy.

5 As this is an appeal from a discretionary order of a judge, this Court will not intervene unless it is shown that the judge misapprehended the facts or committed an error in principle in deciding the matter as he or she did. *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2001 FCA 108, [2001] F.C.J. No. 613 (Fed. C.A.) .

6 The order in issue here was made pursuant to Rule 107 of the Federal Court Rules 1998, reproduced below:

107. (1) The Court may, at any time, order the trial of an issue or that issues in a proceeding be determined separately.	107. (1) La Cour peut, à tout moment, ordonner l'instruction d'une question soulevée ou ordonner que les questions en litige dans une instance soient jugées séparément.
(2) In an order under subsection (1), the Court may give directions regarding the procedures to be followed, including those applicable to examinations for discovery and the discovery of documents.	(2) La Cour peut assortir l'ordonnance visée au paragraphe (1) de directives concernant les procédures à suivre, notamment pour la tenue d'un interrogatoire préalable et la communication de documents.

7 It is true that an applicant seeking an order under rule 107 must satisfy the court that the conditions for the making of such an order have been satisfied. See *Illva Saronno S.p.A. v. Privilegiata Fabbrica Maraschino "Excelsior" Girolamo Luxardo S.p.A.* (1998), 84 C.P.R. (3d) 1 (Fed. T.D.) at paragraph 14. Beyond that, there is also the principle that "it is a basic right of a litigant to have all issues in dispute resolved in one trial". *Elcano Acceptance Ltd. v. Richmond, Richmond, Stambler & Mills* (1986), 55 O.R. (2d) 56 (Ont. C.A.) at p. 59. Consequently, I agree with the appellant that a party seeking an order severing the trial of some issues from the trial of others must justify the departure from the usual practice.

8 Counsel for the appellant suggested that no conclusion could be drawn from the evidence that a number of bifurcation orders had been made on consent, on the ground that each case stood on its own facts. However, such cases may also have certain things in common. William L. Hayhurst Q.C., a distinguished member of the intellectual property bar had this to say about the practice in patent litigation:

> Because the trial of an action for patent infringement may be lengthy and complex (largely because of the technology involved rather than because of any special difficulty about the applicable law), the parties have commonly agreed to an order deferring an inquiry into

> damages or an accounting until the court has decided whether the patentee has established its right to any remedy. This may eliminate some needless pre-trial discovery and avoid premature disclosure of confidential financial information. If discovery after trial is required, anything that may have been held not to infringe may be ignored, at least if no appeal is pending.
>
> Hayhurst, W.L. "Remedies" in Henderson, G. *Patent Law in Canada*, Carswell, Toronto 1994 at p. 289.

9 When an experienced specialist bar like the intellectual property bar commonly consents to the making of a bifurcation order, it is open to a judge to infer that, in general, such an order may well advance the just and expeditious resolution of claims. But this is only one factor to be considered, and it is not conclusive of the issue.

10 The onus in applications for a bifurcation order is always on the applicant. On the facts of this case, I am satisfied that the judge addressed his mind to the proper factors when, after reciting the criteria which he considered had been satisfied, he declared that he was satisfied that the severance of the proceedings would "more likely than not result in the just, most expeditious and least expensive determination of the proceedings on the merits". I do not take his reference to justifying a departure from past practice as imposing upon the appellant a burden which it would not otherwise have had. Once there was evidence before the judge upon which he could conclude that an order could properly be granted, the appellant was in the position where its failure to lead evidence exposed it to the risk of an adverse result. This has been referred to as the tactical burden:

> It is not strictly accurate to speak of the burden shifting to the defendant when what is meant is that evidence adduced by the plaintiff may result in an inference being drawn adverse to the defendant. Whether an inference is or is not drawn is a matter of weighing evidence. The defendant runs the risk of an adverse inference in the absence of evidence to the contrary. This is sometimes referred to as imposing on the defendant a provisional or tactical burden.

11 *Snell v. Farrell*, [1990] 2 S.C.R. 311 (S.C.C.) at p. 319-320 per Sopinka J.As a result, given that there was evidence before the judge capable of supporting the making of an order, the appellant was exposed to the risk of an adverse result unless it took steps to counter that evidence. In other words, it had the tactical burden. While it is not correct to say that the appellant had the burden of justifying a departure from past practice, the appellant did have the tactical burden of countering the effect of the evidence before the judge. To that extent, the judge did not impose on the appellant a burden which it would not otherwise have had.

12 The appellant questions the judge's conclusion that a bifurcation order reduces the length

and complexity of trials, relying upon its experience in three other matters. Such proof is ambiguous at best. It is as probative of the appellant's manner of conducting litigation as it is of the merits or demerits of any particular step in litigation. It would not be an error to assign little weight to this evidence, as the judge evidently did.

13 The appellant raises the fact that it has put into issue the question of the respondent's entitlement to the equitable remedy of an accounting, suggesting that a separate proceeding will be required to resolve that issue, after the trial on liability but before the issues of quantum can be addressed. However, when the respondent demanded particulars of its purported disentitlement to an accounting of profits, the appellant filed a Reply to Demand for Particulars in which it simply stood upon its position that the respondent must demonstrate its entitlement.

14 The fact that equitable remedies are discretionary means that the respondent cannot elect an accounting of profits as of right. That said, a discretionary remedy is not an arbitrary remedy. In the absence of proof of a bar to equitable relief, a claimant can expect to be granted the remedy it seeks in accordance with the principles governing its availability. Nor does the issue of a bar to equitable relief require the claimant to disprove every ground which could possibly disentitle it to that relief. It is not open to a party to argue that its opponent has not sufficiently disproven a given bar. All this to say that there is no reason why the issue of the respondent's right to elect an accounting of profits cannot be dealt with in the liability portion of the trial. The appellant having denied that it relies upon particular facts to say that the respondent is not entitled to an accounting, the trial judge can deal with the question of entitlement on the basis of the respondent's own evidence.

15 This leads to the final ground of appeal which is that the judge erred in failing to provide for the appellant's right of oral and documentary discovery prior to the respondent's choice of remedy. I am in agreement with the following passage from *Apotex Inc. v. Merck & Co.*, 2002 FCT 626, [2002] F.C.J. No. 840 (Fed. T.D.) cited in paragraph 59 of the Respondent's Memorandum:

> [para52] In my view, the procedure proposed by Merck is proper, and it ought not be required to submit to discovery unless it elects damages. In deciding this issue, regard again ought to be had for Rule 3 and considerations of time and efficiency. Unless Merck elects damages, any information relevant to the remedy of accounting of profits would be wholly within Apotex's knowledge and possession. I fail to see how Merck could have information relevant to this issue, and thus it would cause unnecessary expense and delay were they to be discovered.

16 In the end result, I am in agreement with the motions judge's conclusions and can see no reason to interfere with his order. I would, however, clarify the order to this extent. The judge has put over the issue of determining "any questions as to the extent of any infringement of the

plaintiff's rights". I take this to mean that the questions of when and where and for how long infringement occurred will be dealt with in the liability portion of the trial. The only questions remaining for the second portion of the trial as to the extent of the infringement, if any, are questions relating to the quantification of the infringement proven in the liability portion of the trial. There is to be no retrial of the issues of when, where and how long infringement occurred, if indeed it did, in the remedies portion of the trial under the guise of quantifying the plaintiff's remedy.

17 The appeal will be dismissed with costs.

***Richard C.J.*:**
I agree.

***Noël J.A.*:**
I agree.

Appeal dismissed.
Appeal dismissed.
Appeal dismissed.

TAB 6

Date: 20140220
Docket: T-1736-10
Citation: 2014 FC 159

Toronto, Ontario, February 20, 2014
PRESENT: Kevin R. Aalto, Esquire, Case Management Judge

BETWEEN:

APOTEX INC.

Plaintiff

and

PFIZER CANADA INC.,
WARNER-LAMBERT
COMPANY LLC
AND PFIZER INC.

Defendants

AND BETWEEN:

WARNER-LAMBERT
COMPANY LLC
AND PFIZER CANADA INC.

Plaintiffs by
Counterclaim

and

APOTEX INC.

Defendant by Counterclaim

REASONS FOR ORDER AND ORDER

Introduction

[1] Certainty in litigation is elusive. That is largely because frequently there are a number of variables that give different results and only after trial (or appeal) is there certainty of outcome. In this case, to its credit, the Defendants, Plaintiffs by Counterclaim (Pfizer) seek to establish certainty on one key issue in this complex case.

[2] The claim of Apotex in this proceeding is for Section 8 Damages pursuant to the *Patented Medicines (Notice of Compliance) Regulations (the Regulations)* while Pfizer counterclaims against Apotex for infringement. The drug in issue is Atorvastatin, the Pfizer brand name of which is Lipitor, a cholesterol drug said to be the highest selling drug in Canada.

[3] As Section 8 Damages are an issue, the parties are required to create the "but for" world as if Apotex had been in the market essentially as of the date when the Minister would have certified for sale the Apotex Atorvastatin product. The complicating factor in this case is that the Minister of Health has apparently certified two start dates for Apotex to enter the market with its Atorvastatin product.

[4] The first start date is the period beginning May 15, 2007, the date of the "patent hold" letter for an Apotex product for Amorphous Atorvastatin. A second date which the Minister has certified is February 22, 2010 for a different formulation of Atorvastatin by Apotex being an "atorvastatin calcium propylene glycol solvate" (Atorvastatin PGS). The parties agree the end date is May 19, 2010. This results in Apotex claiming its Section 8 Damages for the Amorphous Atorvastatin product being a three-year period while Pfizer alleges that the start date is February 22, 2010 being a three-month period.

[5] Pfizer's position that the three-month period is appropriate rests on the fact that Apotex came to market with only its Atorvastatin PGS product. It did not market and does not market its Amorphous Atorvastatin product to which the three-year period applies. Apotex's position is that, had it been able to do so it would have gone to market with its Amorphous Atorvastatin product in May, 2007.

[6] Thus, one of the great uncertainties in this litigation is the extent of the Section 8 Damages and whether it is a three-year period or a three-month period (the Start Date Issue).

[7] To provide further context for this motion, Pfizer has provided a proposed order which provides, *inter alia*, as follows:

1. In this Order:
   (a) **"Start Date Issue"** means the issue of the relevant date that the period of liability (if any) commenced pursuant to section 8(1)(a) of the *Patented*

Medicines (Notice of Compliance) Regulations, SOR/93-133 as amended. For greater certainty, the Start Date Issue shall include the determination of the issues raised in paragraphs 17-23 of the Amended Statement of Claim dated May 30, 2011; in paragraphs 10-17, 19-21 and 23-25 of the Further Fresh as Amended Statement of Defence and Counterclaim dated April 25, 2012; and in paragraphs 5-9 of the Fresh as Amended Reply and Defence to Counterclaim dated July 28, 2011.

(b) **"Start Date Phase"** means discovery and all other steps up to and including a trial or other determination of the Start Date Issue, including any appeals.

(c) "**Other Issues**" means all issues in the action other than the Start Date Issue.

2. The Start Date Issue shall be determined separately from, and prior to, the Other Issues.

3. Insofar as it raises the Other Issues, this action shall be stayed pending the completion of the Start Date Phase. During the Start Date Phase there shall be no documentary or other discovery on matter relating solely to the Other Issues.

4. The Parties shall confer on the schedule to be followed for the determination of the Start Date Phase. In the event that the parties are unable to agree on a schedule, either party may bring a motion to the Court for directions.

5. The Other Issues shall de determined separately from, and only after the completion of, the Start Date Phase.

Facts

[8] The motion for the Court is a bifurcation motion. What is sought to be bifurcated is a determination of the Start Date Issue for the "but for" world and to determine what would have happened had there been no prohibition application by Pfizer. This is not a garden variety bifurcation motion which in the ordinary course usually seeks to bifurcate liability issues from damages issues. The Start Date Issue on the facts of this case is a novel issue engaging not only factual issues but statutory interpretation of the *Regulations*.

[9] On this motion extensive affidavit material was filed by both Pfizer and Apotex including expert affidavits. Cross-examinations were conducted on several of the affidavits. On behalf of Pfizer, three affidavits were filed including one of W. Neil Palmer, a Consultant on Pharmaceutical Pricing and Reimbursement; Jonathan Cullen, Legal Counsel at Pfizer; and Ross Hamilton, a Chartered Accountant and Expert in Damages Quantification in the pharmaceutical industry.

[10] The thrust of these affidavits was to the effect that if the start date for the "but for" world could be determined at an early stage in these proceedings and it is determined to be the three-month period calculation of damages pursuant to Section 8 will be relatively simple and there is a significant prospect that the case would be settled. Both the Palmer Affidavit and the Hamilton Affidavit spoke to the complexity of developing a three-year "but for" world and the many permutations and combinations of possibilities arising from the entry of other generics into the marketplace and the timing of formulary listings across Canada during that three-year period.

[11] In response, Apotex filed four affidavits: Bernard C. Sherman, the Chair of Apotex; Gordon E. Fahner, the Vice-President, Business Operations and Finance at Apotex; Howard Rosen, a Damage Quantification Expert; and Nicole Roth, a Law Clerk with the firm of Goodmans LLP. The thrust of these affidavits were to the effect that it makes no difference whether it is a three-month or a three-year "but for" world, the work required would be similar and that quantification experts in Section 8 cases develop robust models for creating the "but for" world and that once they are created inserting however many variables is not significantly different between three-months and three-years.

[12] The affidavit of Dr. Sherman (who was not cross-examined) spoke to the issue of bifurcation in this case as generating unnecessary expense and delay for the parties and that considering all of these issues at one trial was the most efficient and cost effective way to proceed. Palmer, Hamilton and Rosen were all cross-examined on their affidavits. The focus of the cross-examinations was to demonstrate whether or not it would be in fact simpler to determine the Start Date Issue prior to commencing the massive undertaking of production, discovery and the preparation of expert reports relating to the Section 8 Damages quantification.

[13] Pfizer has certain patents listed on the Patent Register against the drug Lipitor including patents relating to various polymorphic forms of Atorvastatin. Pfizer sells generic pharmaceutical products in Canada through its GenMed Division and received an NOC in respect of GD- Atorvastatin on November 15, 2006.

[14] On September 27, 2006 Apotex served two Notices of Allegation (NOA) in respect of Pfizer's polymorphic patents. Apotex's submission for its Amorphous Atorvastatin product was placed on "patent hold" by the Minister of Health on May 15, 2007.

[15] On February 19, 2009 Apotex delivered an NOA in relation to its submission to Health Canada for the Apotex Atorvastatin PGS in respect of Pfizer's polymorphic patents. An application under the *Regulations* was commenced by Pfizer in response to the February 19, 2009 Apotex NOA. Apotex's submission for the Atorvastatin PGS was placed on patent hold by the Minister of Health on February 22, 2010.

[16] Apparently, the Apotex Atorvastatin PGS indicates one of the problems the inventor sought to overcome was reduced stability associated with forms of Atorvastatin such as the Amorphous Atorvastatin.

[17] Apotex obtained NOC's for both its Amorphous Atorvastatin and Atorvastatin PGS products on May 19, 2010. Apotex markets in Canada only the Atorvastatin PGS product. At the time of Apotex's launch of its Atorvastatin PGS product, it issued a press release dated May 19, 2010 which explained that by virtue of its own crystal form of Atorvastatin it had essentially solved the stability issues associated with other forms of Atorvastatin. Apotex stated in its press release that it had "spent many years and many millions of dollars on the development and litigation processes for this product". The prohibition applications commenced by Pfizer in response to Apotex's NOA's were discontinued on consent on May 26, 2010.

[18] At this stage of the proceedings the parties have exchanged affidavits of documents related to issues but examinations for discovery have not yet been commenced nor scheduled.

[19] There are, apparently, a number of generic pharmaceutical manufacturers who have delivered NOA's in respect of one or more of the patents listed on the Patent Register against Lipitor. On May 19 and 20, 2010 Health Canada issued NOC's to Apotex and seven other generic pharmaceutical manufacturers in respect of generic Atorvastatin products. Subsequently, an additional six pharmaceutical manufacturers received NOC's for their respective Atorvastatin products.

Positions of the Parties

[20] As noted, in Section 8 Damages cases, the parties must construct for the Court's consideration a hypothetical "but for" world during the defined period of time in the past to determine the damages that Apotex suffered because it was unable to sell its Atorvastatin product during that defined period. Madam Justice Judith Snider in *Apotex Inc v Merck & Co., Inc.*, 2012 FC 620 (CanLII) has set out the requirements for determining the "but for" world. The elements required to be covered include the following:

(a) What is the relevant period?
(b) What is the overall size of the Atorvastatin market during the relevant period?
(c) What would the generic share of the Atorvastatin market be during that period?
(d) What would have been Apotex's share of the generic Atorvastatin market during the relevant period?
(e) What is the price that Apotex would have sold its Atorvastatin product?
(f) What deductions, if any, are there that should be applied to Apotex's selling prices to allow for rebates or other allowances?

[21] As noted, the relevant period of the "but for" world is the starting point for determination of the Section 8 Damages Claim.

[22] A further complicating factor in this case apart from the number of generic pharmaceutical companies granted NOC's is the changes to pricing in various provinces. For example, in Ontario the enactment of *Transparent Drug System for Patients Act to Patents Act* (Bill 102) affected prices upon which the first generic entered into a market could charge for a particular drug. Similarly, in British Columbia, PharmaCare which governs how pharmaceutical products are sold in British Columbia has changed its pricing structure and has introduced other programs including its Maximum Allowable List Price for generic products. Alberta and Quebec also have pricing policies relating to the sale of generic products.

[23] Another complicating factor is the time of listing on the provincial formularies. The Palmer Affidavit filed on behalf of Pfizer spoke at length about the issues surrounding when a generic product might be listed on a provincial formulary. There are many variations in respect of the time to listing which adds to the complexity of the quantification given the number of generics in the market.

[24] Finally, there is a consideration of rebates and allowances which generic drug

manufacturers offer to pharmacies to stock, and/or sell and substitute their Atorvastatin products for those of other generics. These rebates and allowances are regulated in some provinces and are capped in others and add another level of complexity to the quantification of Section 8 Damages.

Pfizer's Position

[25] In general, the argument of Pfizer is that the determination of the Start Date Issue will result in a more focused proceeding. The parties, rather than speculate and develop several different models of Section 8 Damages would only be developing one. Production and discovery would therefore be shortened as it would be clear which Section 8 Damages time frame was involved. And, especially if it is determined that it is a three month period for the Apotex Atorvastatin product, the number of variables and permutations and combinations thereof would be limited and the calculations of any such damages would be a far simpler and cost-effective exercise.

[26] In large part the bifurcation of the Start Date Issue will meet the requirements of Rule 3: "These rules shall be interpreted and applied so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits". Otherwise, so argues Pfizer, production will cover everything for a period of at least three-years, the discoveries will be endless and production will be an avalanche of paper.

[27] In support of its positions, Pfizer put forward the Palmer, Cullen and Hamilton Affidavits. These affidavits highlighted the many variables in play in this proceeding. The Palmer Affidavit speaks to the formulary listings and timing thereof; market access; reimbursement policies; and, the various damages scenarios. The Cullen Affidavit points out that other generics, as many as 8 may form part of the various scenarios to be worked out if there is no bifurcation. He also makes the statement that if it is determined that the three-month period is the correct start date, then the case will settle. Finally, the Hamilton Affidavit addresses damages quantification, the manner of determining lost profits and the complexity of the two scenarios involved in the Start Date Issue. Like his counterpart, Mr. Rosen for Apotex, Mr. Hamilton is a respected and experienced expert in this field.

Apotex's position

[28] Apotex argues that there is neither any time nor costs saved by bifurcating this action. It submits that on the basis of the evidence of the experts filed in this motion that it is simply a matter of changing the accounting and econometric models which need to be built in any event to adjust for whichever time frame is determined to be appropriate.

[29] Apotex argues that litigants have a "right" to a single proceeding unless the preponderance of evidence demonstrates a departure from this rule. As litigation is always subject to the right of a Court to control its own process, a litigant's preference for a single proceeding must always bow to the right of the Court to determine in the circumstances the appropriateness of a single proceeding versus a bifurcated proceeding.

[30] Apotex argues that the issue as posed by Pfizer in this motion does not dispose of the litigation, it merely doubles the effort and expenditure as two trials will be required. As such, there is no benefit to be obtained by bifurcating the issue. Apotex argues that the determination of the Section 8 time frame is not a "threshold" issue which will determine the case such as liability. Bifurcation would only lead to further proceedings as there is a claim

by Pfizer for damages in either of the two time frames alleged. Thus, a second trial is inevitable.

[31] As noted, there was a substantial record filed by both parties which contained not only expert affidavits but cross-examinations on those affidavits. Those affidavits and cross-examinations dealt with the issue of what, if any, time saving might be had if the issue of the Section 8 time frame was resolved first.

[32] The Court was encouraged to read all of the affidavits and cross-examinations carefully to understand fully the nature of the time period and the work required no matter which time period the Court will ultimately find. In particular, the admission that if the Court finds a period longer than three-months much if not all of the time savings and costs will be lost. It is pointed out that the Court has other options apart from the two time frames proposed and it is open to the Court to determine that an entirely different period applies.

[33] It is also argued that there is no benefit to bifurcation as there is still the counterclaim for infringement to be dealt with. There are no savings in time or cost as the Start Date Issue does not affect this issue. Thus, there will still be production necessary relating to financial information and all the other trappings of an infringement claim. The simple answer of course is to bifurcate damages on the infringement claim, an approach built into Pfizer's proposed order.

[34] In reviewing the evidence in detail, counsel for Apotex pointed out that Mr. Hamilton (a Pfizer expert) admitted that the assessment of the three-year period would only be "a little bit harder" than the three-month period.

[35] Dr. Sherman's evidence was unchallenged. He deposed to be concerned about the delay two proceedings would require as well as the expense of such proceedings. He also opined that in his opinion full disclosure helped accelerate and streamline resolution. He also observed that this motion could be the thin end of the wedge and that if this issue is bifurcated it could lead to further bifurcation regarding liability and quantum. However, this latter point is of no moment. The bifurcation sought will significantly reduce the time of this proceeding and no further bifurcation will be considered by the Court in this case managed proceeding. As well, given that Lipitor is said to be the highest selling drug in Canada, the expense involved in this case is not really an issue.

[36] Mr. Fahner addressed the scope of document production in his affidavit. He deposed that the productions relative to the longer period is not an onerous task as most of it is maintained electronically and lost revenues are "easily calculated". He is of the view that there would be no timesaving or otherwise from a bifurcation. That is not fact, it is merely speculation and opinion albeit based on Mr. Fahner's prior involvement in Section 8 proceedings.

[37] Mr. Rosen is an experienced accountant and expert in the quantification of damages. His evidence that no matter the time frame an identical analysis of available information is necessary. His opinion is diametrically opposed to Pfizer's experts, Messrs. Palmer and Hamilton. Mr. Rosen is of the view that while there may be more data to review for the longer period this does not make the task of analysing the data more complex. There is simply more of it.

[38] In his affidavit, Mr. Rosen provides a detailed step by step outline of the model which is developed to calculate the Section 8 Damages and the various scenarios. The models are developed for the most likely scenarios. Once those are completed the models can be adjusted to account for variations and findings of the Court.

[39] Having reviewed all of the evidence and the cross-examinations as the Court was invited to do by Apotex, the evidence for the most part is almost diametrically opposed between the parties.

ISSUE

[40] While the issue is simply stated – will bifurcation of the Start Date Issue lead to an efficient and cost effective resolution of this litigation both for the parties and the Court - the answer on these diametrically opposed motion records is not.

Analysis

[41] The law on bifurcation is relatively well-known. The tests for bifurcation flow from various cases [see, for example, *Garford Pty. Ltd. v. Dywidag Systems International, Canada, Ltd.*, 2010 FC 581 (CanLII) at para. 19; and *Merck & Co. v. Brantford Chemicals Inc.*, (2004) FC 1400].

[42] The *Merck* case provides a useful summary of principles to be considered:

> The onus on a motion for a bifurcation order is always on the applicant (*Apotex Inc. v. Bristol-Myers Squibb Co.*, 2003 FCA 263 (CanLII) at para. 10 (F.C.A.), (2003), 26 C.P.R. (4th) 120 (F.C.A.)). The order may be made where the Court is satisfied, on a balance of probabilities, that, in light of the evidence and all the circumstances of the case (including the nature of the claims, the conduct of the litigation, the issues and the remedies sought), severance is more likely than not to result in the just, expeditious and least expensive determination of the proceeding on its merits (*Illva Saronno S.p.A. v. Privilegiata Fabrica Maraschino "Excelsior"*, 1998 CanLII 9100 (FC), [1999] 1 F.C. 146 at para. 14 (F.C.T.D.); (1998), 84 C.P.R. (3d) 1; *Illva Saronno S.p.A. v. Privilegiata Fabrica Maraschino* (2000), 2000 CanLII 14897 (FC), 183 F.T.R. 25 at para. 8 (F.C.T.D.), [2000] F.C.J. No. 170 (F.C.T.D.) (QL)).
>
> > [5] At page 2 of her order, Prothonotary Milczynski sets out a number of "practical and economic considerations" for determining whether or not to order separate trials on the issues of liability and damages. Those include:
> >
> > - the complexity of issues to be tried;
> > - whether the issues of liability are clearly separate from the issues of remedy;
> > - whether the factual structure upon which the action is based is so extraordinary or exceptional that there is good reason to depart from normal practice requiring the single trial of all issues in dispute;
> > - whether the trial judge will be better able to deal with

the issues of the injuries of the plaintiff and the plaintiff's losses, by reason of having first assessed the credibility of the plaintiff during the trial of the issue of damages;

- whether a better appreciation of the nature and extent of injuries and consequential damages to the plaintiff may be more easily reached by trying the issues together;
- whether the issues of liability and damages are so inextricably interwoven if bound together that they ought not to be severed;
- whether, if the issues of liability and damages are severed, there are facilities in place which will permit these two separate issues to be tried expeditiously before one court or before two separate courts, as the case may be;
- whether there is a clear advantage to all parties to have liability tried first;
- whether there will be a substantial saving of costs;
- whether it is certain that the splitting of the case will save time, or will lead to unnecessary delay;
- whether, or to what degree in the event severance is ordered, the trial of the issue of liability may facilitate or lead to settlement of the issue of damages; and
- whether it is likely that the trial on liability will put an end to the action.

[6] Many of these factors are inspired or directly imported from *Bourne v Saunby* [1993], O.J. No. 2606 (Ont. Sup. Ct.). The same appears to have been recently considered, but not necessarily applied (at least as an integral part), by Rutherford J. in *Roche Palo Alto LLC et al. v. Apotex Inc.*, [2004] O.J. No. 3522. Rutherford J. noted in this regard that "[w]hile that list is helpful in that it sets out a number of very good lines of inquiry and although counsel touched on several of these factors in their arguments, the motion materials filed on both sides rely essentially on the opinion of counsel with expertise in patent litigation expressed in lengthy affidavits". In said case, Rutherford J., after summarizing the respective views of counsel, succinctly concluded that "after considering the materials filed and the submission of counsel, I am not persuaded that the circumstances are exceptional or such as to justify a departure from the normal procedures for trial of an action and I am not of the view that the issues for trial should be split off and the procedure bifurcated."

. . .

[9] Neither can I agree, as suggested in *Bourne*, that it must be "certain that the splitting of the case will save time, or will lead to unnecessary delay". As stated by Evans J. in *Illva Saronno,*

> *supra*, the applicant has the onus of convincing the Court that bifurcation will *inter alia* result in the saving of time and money, on a balance of probabilities standard, and not on the standard of beyond a reasonable doubt.

[43] Thus, based on all of the evidence on this motion, on a balance of probabilities, will bifurcation result in a saving of time and money to the parties, and of judicial resources?

[44] The answer to this question is not easy based on this record. There are very strong positions put forward by each side as well as very strong evidence supporting each position. A consideration of each factor is essential to a determination of this matter. There is much overlap among the factors and several appear to have evolved from personal injury cases rather than intellectual property cases and the complexities of the *Regulations*. However, an analysis of those factors which bear on the issues in this case must be conducted.

Complexity of the Issues

[45] Notwithstanding the argument and evidence of Apotex that it would be relatively easy to create a tool for the calculation of damages whether it be the three-month or the three-year period, this is still a very complex action. As noted by counsel, there is the issue of infringement, the issue of Section 8 Damages, and then the determination of the Start Date Issue. As noted above, the Start Date Issue is in and of itself filled with many variables and permutations of events in the creation of the "but for" world. A determination of the Start Date Issue will streamline this case. This factor favours bifurcation.

Whether the Issues of Liability are Clearly separate from Damages

[46] This consideration is unique to this case as it is not liability that is being sought to be bifurcated. Rather, it is an issue that will arguably lead to a saving of both time, judicial resources and money for the reasons mentioned elsewhere in these reasons. Although the jurisprudence speaks almost exclusively to bifurcation of liability and damages, there is no reason for that limitation in this Court given the wording of Rule 107(1) of the *Federal Courts Rules* which provides: "The Court may, at any time, order the trial of an issue or that issues in a trial be determined separately". It is open to the Court to bifurcate any issue which will result in the saving of time, cost and judicial resources.

[47] Apotex argues that the Start Date Issue is not a threshold issue which will dispose of the litigation. Rather it is an issue which is intertwined with all of the other issues and that it is but one of the variables which is best left to be sorted out at trial. However, in my view, the bifurcation of an issue need not inexorably lead to the resolution of the litigation in its entirety, it is sufficient that if, on a balance of probabilities, the determination of an issue will lead to a shorter trial, a more focused discovery, contained production and less expert evidence. Such is the expectation in this case if the Start Date Issue is first determined.

[48] As part of its argument, Apotex referred to the decision of Justice Judith A. Snider in *Apotex v. Merck & Co., Inc.*, 2012 FC 620 (CanLII) to support its position that the Start Date Issue is not novel and notwithstanding positions of the parties the Court may find another date that is appropriate other than the three month or three-years. In this case, the start date was an issue. Justice Snider made these observations:

> [13] The parties, however, disagree on the applicable commencement

> date. Apotex asserts that the appropriate date is April 30, 1996, the date on which it submits that the Minister would have issued an NOC to Apotex except for the *Regulations*. Merck submits that there is no proof of any date "certified by the Minister" on which Apotex would have received an NOC for the non-infringing AFI-4 process. In the alternative, Merck argues that the appropriate date is when Apotex was notified that the Minister had "no objection" to Apotex's Notice of Change switching to the AFI-4 process; specifically, that date was February 27, 1997.
>
> [14] Apotex initially filed a New Drug Submission (NDS) for approval of Apo-lovastatin made by use of a micro-organism referred to as *Aspergillus flavipes* on December 21, 1994. Label drafts were submitted to Health Canada and apparently approved on April 30, 1996. On May 25, 1996, Apotex's NDS was placed on "patent hold", meaning that an NOC for Apo-lovastatin manufactured with *Aspergillus flavipes* would not issue until resolution of the prohibition proceedings or the expiry of the relevant patents (including the '380 Patent)
>
> [15] Merck is correct that there is no Ministerial "certification" of May 25, 1996 as contemplated by s. 8(1)(a). However, I am satisfied that, but for the *Regulations*, Apotex would have received its NOC for Apo-lovastatin no later than May 25, 1996.
>
> [16] Apotex submits that April 30, 1996 is the more appropriate date for the commencement of the Relevant Period. I agree with Apotex that its labels for Apo-lovastatin were approved on April 30, 1996. In spite of the testimony of Mr. Hems that NOCs normally follow label approval within a matter of days, I am not persuaded that this date is more appropriate than the "patent hold" date. There can be no doubt whatsoever that the application would have been approved on May 25, 1996, the date of the "patent hold" letter from Health Canada.
>
> [17] In my view, the appropriate date, even though not certified by the Minister, would be the "patent hold" date of May 25, 1996.

[49] What is interesting about this case is that the very determination made by Justice Snider was the Start Date Issue as it applied in that case. Damages were not determined and were left to a subsequent trial. It was a bifurcated case very much the same as this motion seeks.

[50] Further, Apotex points to the cross-examination of Dr. Sherman in that case that Apotex would simply have gone to market with its first product and taken the litigation risks. Dr. Sherman is quoted as saying:

> [P]rior to the regulations, we simply would have launched [Apo-lovastatin]. Then if Merck sued, we would have defended, but we would be on the market getting the revenues. (para. 29)

[51] It may very well be that Apotex takes this position in this case and discovery and

production will have to be pursued but it still does not undermine the fact that the determination of the Start Date Issue will lead to clarity and certainty as to what Section 8 Damages, if any, Apotex is entitled to receive.

[52] This factor favours bifurcation.

Is the Factual Structure of the case Unique?

[53] As noted above the facts of this case are novel. There are unique factual issues and novel points of statutory interpretation relating to the *Regulations*. Factually, it is complex because the three month period relates to the drug which Apotex brought to market. That drug is different than the drug which related to the three year period. On discovery the differences between the drugs will need to be explored as well as why one was pursued and the other not as well as the damages which relate to each drug. The factor favours bifurcation.

Will there be a saving of cost and time?

[54] This issue is one of great debate between the parties. It is also a factor which should be given some extra weight in determining whether to bifurcate. There must be, in my view, a demonstrable saving of time and cost. The litigation system and access to justice is already overburdened with procedural and substantive processes and in this day and age the Courts and the parties should be striving to pursue litigation in a way that is both proportional and fair. On the importance of proportionality in litigation see, *Hryniak v Mauldin et al*, 2014 SCC 7 (CanLII) a recent decision of the Supreme Court of Canada.

[55] At first blush, the conclusion with respect to this factor seems simple enough in that determining which of two time periods should be a fairly straightforward part of the proceeding. If the determination is that is the three month period there will be much time and cost saving. There will also be better use of judicial resources. If it is the three year period, there will still be cost saving as the parties and their experts will not be required to develop different models although the time and cost savings will not be as much. The unknown is whether the Court could choose a third alternative as argued as a possibility by Apotex. It may be that a Court might do so although the likelihood is either of the two proposed scenarios. Even if a third scenario surfaced there would still be certainty as to the time frame for which the parties and their experts would focus their efforts.

[56] Notwithstanding the strong arguments of Apotex, and having considered all of the arguments and the evidence particularly the cross-examinations, I am of the view that on a balance of probabilities a determination of the Start Date Issue will lead to cost savings, time savings and better use of judicial resources. This factor favours bifurcation.

Is the factual structure extraordinary or exceptional that there is good reason to depart from normal practice requiring the single trial of all issues in dispute?

[57] This factor overlaps with prior considerations discussed above which will not be repeated. In my view, this factor favours bifurcation.

Whether the trial judge will be better able to deal with the issues of the injuries of the plaintiff and the plaintiff's losses, by reason of having first

assessed the credibility of the plaintiff during the trial of the issue of damages?

[58] This factor does not apply and so is a neutral consideration.

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Whether a better appreciation of the nature and extent of injuries and consequential damages to the plaintiff may be more easily reached by trying the issues together?

[59] Again, this factor appears more directed toward a different type of case and implicitly is subsumed in the discussion relating to other factors. Our Rules permit an issue to be bifurcated if on a balance of probabilities it can be reasonably said to reduce time, costs and judicial resources.

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Whether the issues of liability and damages are so inextricably interwoven if bound together that they ought not to be severed?

[60] This factor must be considered. Apotex forcefully argues that given the infringement counterclaim there is no real savings in cost or time as a full infringement trial would have to be conducted. However, the order sought by Pfizer seeks to sever this issue as well. The only issue to be determined on the bifurcation proceeding is the Start Date Issue. All other issues including infringement and damages which might flow from that are to be part of subsequent proceedings.

[61] This is what occurred in *Apotex v. Merck*. While that was only a Section 8 Damages case the parties must have understood that determining the period of Section 8 Damages would be beneficial. Given the proposed order and the facts of the case, I am not persuaded on a balance of probabilities that the issues are so inextricably interwoven so as to defeat the utility of bifurcation.

[62] This factor favours bifurcation.

Whether, if the issues of liability and damages are severed, there are facilities in place which will permit these two separate issues to be tried expeditiously before one court or before two separate courts, as the case may be?

[63] A long trial date has been set in 2016 for all of the issues in this case. This Court can and will accommodate a determination of the Start Date Issue so that the trail date is preserved and the issues for that trial will be focussed.

[64] This factor favours bifurcation.

Whether there is a clear advantage to all parties to have liability tried first?

[65] While Apotex argues at great length that there is no advantage, the Start Date Issue has the benefit of certainty for the parties. The "clear" advantage must be determined on a balance of probabilities. Having reviewed all of the evidence and cross-examinations it is my view that the balance of probabilities favours bifurcation. The advantage of certainty is a clear benefit to all parties and to the Court.

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Whether there will be a substantial saving of costs?

[66] This factor has been addressed above in some detail. In my view there is cost savings to be had. This is not a factor solely related to the interests of the parties. Judicial resources are costly. They must be considered as part of the equation. If the Start Date Issue can be solved in a short trial (five to ten days) it would inevitably lead to a shorter time for any subsequent damages/infringement case. One must not lose sight of the fact that there are factual issues which are unique to this case relating to Apotex' entering of the market with Atorvastatin PGS not Amorphous Atorvastatin. Surely some clarity on the meaning of the *Regulations* insofar as these facts are concerned will save judicial resources and cost to the parties.

Whether it is certain that the splitting of the case will save time, or will lead to unnecessary delay?

[67] Apotex argues emphatically that there will be no savings resulting from bifurcation - only delay. This is the focus of Dr. Sherman's affidavit and his strongly held views. There is no certainty in litigation – the proverbial two sides (or more) to every case. Time savings can be achieved by parties acting reasonably, co-operatively and using common sense. To quote the mantra of the Commercial List in the Superior Court – litigation should be conducted on the basis of the three C's – communication, common sense and co-operation. If applied to complex intellectual property cases such as this, combined with principles of proportionality, counsel following the three C's will most certainly lead to saving time.

[68] Applying the balance of probabilities standard, this factor favours bifurcation.

Whether, or to what degree in the event severance is ordered, the trial of the issue of liability may facilitate or lead to settlement of the issue of damages?

[69] Pfizer has provided direct evidence from in-house counsel that if the Start Date Issue is determined to be three-months the case will settle. There is no evidence whether any other scenario will also lead to this result. But, notwithstanding Apotex's position that the determination of the Start Date Issue will not likely or necessarily lead to settlement, there is some positive evidence that supports such a result. This issue favours bifurcation.

Whether it is likely that the trial on liability will put an end to the action?

[70] If this were the only factor, bifurcation would not be ordered. Bifurcating the Start Date Issue will not put an end to the action. There are other issues which must ultimately be resolved no matter which way the Start Date Issue is decided. Thus, while this factor does not favour bifurcation, as noted in the discussion above bifurcation does not need to result in the end of the proceeding. Rule 107 (1) allows an issue to be bifurcated. Such is the case here.

CONCLUSION

[71] In considering all the factors, on a balance of probabilities, it is my view that bifurcating the Start Date Issue will be lead to saving of cost, time and judicial resources.

[72] While a long trial date of some 35 days is already set for 2016 for all of the issues, the Court
will accommodate an early determination of the Start Date Issue.

[73] As for costs of this motion, while it is noted that Pfizer offered Apotex an opportunity to accept its proposed draft order so that there could be an earlier determination

of the issue and seeks its costs, in my view, this has been a very novel motion and each party should bear its own costs.

[74] The Court appreciates the excellent submissions of counsel and the courteous manner in which this motion was argued.

ORDER

THIS COURT ORDERS that:

1. The Motion is granted.

2. In this Order:
   (a) **"Start Date Issue"** means the issue of the relevant date that the period of liability (if any) commenced pursuant to section 8(1)(a) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended. For greater certainty, the Start Date Issue shall include the determination of the issues raised in paragraphs 17-23 of the Amended Statement of Claim dated May 30, 2011; in paragraphs 10-17, 19-21 and 23-25 of the Further Fresh as Amended Statement of Defence and Counterclaim dated April 25, 2012; and in paragraphs 5-9 of the Fresh as Amended Reply and Defence to Counterclaim dated July 28, 2011.
   (b) **"Start Date Phase"** means discovery and all other steps up to and including a trial or other determination of the Start Date Issue, including any appeals.
   (c) **"Other Issues"** means all issues in the action other than the Start Date Issue.

3. The Start Date Issue shall be determined separately from, and prior to, the Other Issues.

4. Insofar as it raises the Other Issues, this action shall be stayed pending the completion of the Start Date Phase. During the Start Date Phase there shall be no documentary or other discovery on matter relating solely to the Other Issues.

5. The Parties shall confer on the schedule to be followed for the determination of the Start Date Phase. In the event that the parties are unable to agree on a schedule, either party may bring a motion to the Court for directions.

6. The Other Issues shall de determined separately from, and only after the completion of, the Start Date Phase.

7. There shall be no costs of this motion.

"Kevin R. Aalto"

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1736-10
STYLE OF CAUSE:	APOTEX INC. v. PFIZER CANADA INC. ET AL
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	June 13, 2013
REASONS FOR ORDER:	AALTO P.
DATED:	February 20, 2014

APPEARANCES:

Jerry Topolski	FOR THE PLAINTIFF
John Laskin W. Grant Worden Sarah Whitmore	FOR THE DEFENDANTS

SOLICITORS OF RECORD:

Goodmans LLP Barristers & Solicitors	FOR THE PLAINTIFF
Torys LLP	FOR THE DEFENDANTS

TAB 7

PATENTED MEDICINE PRICES REVIEW BOARD

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

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris"

REASONS FOR DECISION

(Motion to Issue Subpoenas)

Decided by the panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**PMPRB**" or the "**Board**") seized with this proceeding on the basis of the written record.

1. Board Staff brought a motion late Friday, January 20, 2017 asking the Panel to issue subpoenas requiring Mr. Eric Lun and Mr. John Haslam to produce certain documents related to Product Listing Agreements ("**PLAs**") negotiated between Alexion and various provincial drug plans concerning Soliris.

2. The BC Minister of Health consents to the issuance of the subpoena to Mr. Lun in respect of the documents in his possession, subject to having the opportunity to make submissions that the documents be redacted for confidentiality reasons before being placed on the public record.

3. Alexion objects to the issuance of the subpoenas on two main grounds. First, Alexion argues that the documents requested are irrelevant. Second, Alexion argues that Board Staff's request is abusive, ill-timed, and will cause unnecessary delay and costs.

4. In its Reply, Board Staff agreed with Alexion that "in the ordinary course information regarding the existence of PLA agreements should not be relevant" but noted that they are specifically referred to in the witness statement of Mr. Haslam. Board Staff offered to withdraw its motion in respect of Mr. Haslam if Alexion confirms that it is not relying on the PLAs or the amended Forms 2s that it filed claiming rebates based on the PLAs. Alexion has not provided that confirmation.

5. In making its decision, the Panel has fully considered the written representations of Board Staff and Alexion, the BC Minister's consent, and the oral submissions made by the Parties during the hearing on January 23, 2017.

6. The Panel does not accept Board Staff's assertion that its motion could not have been brought earlier and at a time that did not disrupt the conduct of this proceeding, which it has. Nevertheless, the Panel has jurisdiction under section 96(1) of the *Patent Act* and Rule 24 of the PMPRB *Rules of Practice and Procedure*[1] (the "**Rules**") to issue the requested subpoenas, and concludes that it should do so if the documents requested by Board Staff are relevant to the issues in this proceeding, and their production is consistent with the fair and expeditious conduct of this proceeding (see section 97(1) of the *Patent Act* and Rule 5(2) of the Rules).

7. The Panel concludes that the documents requested to be produced for inspection are relevant to the issues in the proceeding, and that their production furthers the fair and expeditious resolution of the proceeding. The PLAs are specifically discussed in the witness statements of both Mr. Lun and Mr. Haslam. Correspondence about the PLAs is included in Exhibit 1 and was discussed with Mr. Richard Lemay during his examination-in-chief. If the PLAs are going to be the subject of testimony, it is important that the Panel have an accurate and complete picture.

8. The Panel therefore grants Board Staff's motion, in part, as follows:

i. A subpoena will issue today requiring Mr. Lun to produce for inspection the agreements referred to in paragraph 28 of his witness statement that are

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[1] SOR/2012-247.

in the possession of the BC Minister of Health, as well as the correspondence relevant to the negotiations referred to in that same paragraph that are in possession of the BC Minister of Health, on or before January 27, 2017. In the circumstances, Mr. Lun's testimony will be adjourned to the week of February 20, 2017;

ii. A subpoena will issue today requiring Mr. Haslam to produce for inspection the agreements referred to in paragraphs 32 to 37 of Mr. Haslam's witness statement, as well as the correspondence relevant to the negotiations referred to in those same paragraphs, on or before January 31, 2017; and

iii. At the same time as the documents are produced, counsel, including counsel for the BC Minister of Health, shall make any confidentiality claims in respect of the documents in writing, and provide proposed redacted versions of the documents that can be placed on the public record without delay.

9. In order to ensure that this hearing continues as fairly and as expeditiously as possible, the Panel makes the following direction applicable to the remainder of this week:

i. Mr. Malcolm Ruby is to complete his cross-examination of Mr. Lemay, without prejudice to Mr. Ruby's ability to reserve any questions he may have for Mr. Lemay about the documents we have ordered be produced for inspection until after those documents have been received and reviewed. We note that by their very nature, most, if not all, of the documents are already in Alexion's possession. Mr Lemay will remain in cross-examination and may be recalled to answer those questions if Mr. Ruby so desires on a date set by agreement of counsel or, if counsel cannot agree, as directed by the Panel. Any reply questions of Mr. Lemay by Board Staff will also be reserved to that time;

ii. As noted above, Mr. Lun's testimony will be adjourned to the week of February 20, 2017, to allow all parties the opportunity to review the documents that he produces for inspection prior to his examination taking place. Counsel shall work together to agree on a date for Mr. Lun's examination during that week; and

iii. We will proceed with the evidence of both Dr. Richard Schwindt and Dr. Sumanth Addanki this week, after Mr. Ruby completes his cross-examination of Mr. Lemay on all matters he wishes to cross-examine on, excluding the documents we have ordered be produced for inspection.

Dated at Ottawa, this 24th day of January, 2017.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members:

Dr. Mitchell Levine
Ms. Carolyn Kobernick

TAB 8

August 20, 2008

Decision: PMPRB-07-D1-PENLAC
- **Motion for Production; and**
- **Leave to File Reply Evidence**

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

AND IN THE MATTER OF sanofi-aventis Canada Inc. (the "Respondent") and the medicine "Penlac Nail Lacquer"

Board Order

This is the decision of the Penlac hearing panel (the "Panel") on a motion brought by Board Staff for the production of documents in this proceeding and for leave to file reply evidence in relation thereto (the "Motion").

The Panel, having heard the parties on the Motion and having decided to grant a variation on the relief sought on the Motion, hereby orders that:

Production of Documents

1. The Respondent shall produce to Board Staff such data and protocols used in the production of the studies referred in these proceedings as Trials 312 and 313 (the "Data") as are in the possession, power or control of the Respondent, and in this regard, the Respondent shall use its best efforts to obtain the Data from any affiliated or related entities or other persons that the Respondent might reasonably expect to have the Data in their possession, power or control.

2. The Respondent shall file an affidavit in this proceeding with respect to the Data that are in its possession, power or control, and with respect to its efforts to obtain the Data in accordance with paragraph 1 hereof.

Reply Evidence

3. Board Staff shall have leave to file Reply Evidence pertaining to the Data.

4. The Respondent shall have the right to file evidence that responds to any evidence that might be filed by Board Staff in accordance with paragraph 3.

Schedule

5. The events discussed in this Order shall be completed according to the following schedule:

i)	Production of the Data by the Respondent:	September 26, 2008
ii)	Respondent's Affidavit in accordance with paragraph 2:	September 26, 2008
iii)	Reply Evidence:	October 20, 2008
iv)	Responding Evidence:	November 17, 2008
v)	Hearing:	December 8, 2008

Board Members: Dr. Brien G. Benoit
Mary Catherine Lindberg
Anne La Forest

Board Counsel: Gordon Cameron

Appearances

For Board Staff: Kirsten Crain, Counsel

For the Respondent:
Martin Mason, Counsel
Graham Ragan, Counsel

Original signed by

Sylvie Dupont
Secretary of the Board

TAB 9

THE *PATENT ACT*

The Patented Medicine Prices Review Board

IN THE MATTER OF ratiopharm Inc. and the medicine ratio-Salbutamol HFA

SUBPOENA

TO: GlaxoSmithKline Inc.

You are hereby summoned and required, pursuant to subsection 96(1) of the *Patent Act*, to produce to the Patented Medicine Prices Review Board, on or before September 8, 2009, in respect of all sales of the medicine ratio-Salbutamol HFA to ratiopharm Inc. in Canada since 2001, annual and monthly breakdowns of prices charged and quantities sold by GlaxoSmithKline Inc.

DATED this 14th day of August 2009

Original signed by

The Patented Medicine Prices Review Board

Sylvie Dupont
Secretary of the Board