Federal Court  Cour fédérale

Date: 20190612

Docket: T-1596-17

Citation: 2019 FC 734

Ottawa, Ontario, June 12, 2019

PRESENT: Mr. Justice Gleeson

BETWEEN:

ALEXION PHARMACEUTICALS INC.

Applicant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

and

THE MINISTER OF HEALTH FOR THE PROVINCE OF BRITISH COLUMBIA

Intervenor

PUBLIC JUDGMENT AND REASONS

(Identical to the Confidential Judgment and Reasons issued on May 23, 2019)

I. Overview

[1] The applicant, Alexion Pharmaceuticals Inc. [Alexion], developed, manufactures, and markets the drug Soliris. It is used to treat two rare and life-threatening blood-related disorders and was initially approved by Health Canada in January 2009.

[2] In September 2017, a panel of the Patented Medicine Prices Review Board [Panel] concluded that the price of Soliris in Canada exceeded the lowest price in seven comparator countries. On this basis, the Panel found the price to be "excessive" under sections 83 and 85(1) of the *Patent Act*, RSC 1985, c P-4 [Act]; ordered Alexion to lower the price of the drug; and ordered a payment to the federal Crown to offset past excess revenues resulting from the excessive pricing.

[3] Alexion now seeks judicial review of that decision under subsection 18(1) of the *Federal Courts Act*, RSC 1985, c F-7. Alexion submits that the Panel erred by departing from longstanding tests for assessing excessive pricing, that the Panel's decision is inconsistent with the plain language of the *Patent Act* and *Patented Medicines Regulations*, SOR/94-688 [Regulations], and that the decision is not supported by adequate reasons.

[4] The British Columbia Minister of Health, who appeared before the Panel, sought to intervene in this application. The parties did not oppose this request, and an order granting intervenor status issued. The British Columbia Minister of Health made both written and oral submissions.

[5] The respondent and the intervenor submit that the decision was reasonable and that the Panel committed no error warranting the Court's intervention on judicial review.

[6] For the reasons that follow, the application is dismissed.

II. Legislation, Regulations, and Guidelines

[7] The price of patented medicines in Canada is regulated under the *Patent Act*.

[8] Sections 79 to 103 of the Act set out a comprehensive scheme for the regulation of the price of patented medicines.

[9] The Act establishes the Patented Medicine Prices Review Board [Board] and confers upon it responsibility for monitoring and regulating the prices of patented medicines. The Board also has the authority to determine if a patented medicine is being sold at an excessive price. Where a panel of the Board is of the opinion that a patented pharmaceutical is being sold at an excessive price, it may direct measures to address the excessive pricing and offset excess revenues (*Patent Act*, ss 83, 91).

[10] To assist the Board in carrying out its mandate, the Regulations set out the information and documentation that patentees are required to provide to the Board (*Patent Act*, s 101). The Act also provides for the Board to issue guidelines with respect to any matter within its jurisdiction. Guidelines are not binding on the Board or any patentee (*Patent Act*, s 96(4)).

[11] The Act provides for the appointment of staff to assist the Board in the administration of the excessive pricing scheme (*Patent Act*, s 94(1)). Where the Chairperson determines that a hearing is warranted, he or she appoints a panel of Board members that presides over an oral hearing, where the patentee is provided an opportunity to be heard (*Patent Act*, ss 83(6), 93(2)). The panel is charged with making statutory determinations and issuing appropriate remedial orders. In accordance with the *Patented Medicine Prices Review Board Rules of Practice and Procedure*, SOR/2012-247 [Rules], Board staff, which operates independently of the panel, is tasked with presenting the case to the panel (Rules, ss 1, 15). Patentees are represented by their own counsel (Rules, s 13). Notice of the hearing must be given to the Minister of Industry and the provincial ministers of health, who are entitled to appear and make representations to the panel (*Patent Act*, s 86(2)).

[12] The Board has the authority to determine whether a price is excessive and to direct the patentee to sell the medicine at a price that the Board considers not to be excessive. In addition to ordering reductions in price, the Board is also empowered to order payment to the federal Crown for the purposes of offsetting excess revenues (*Patent Act*, ss 83(1), (2)(c)).

[13] In determining whether a price is excessive, the Board is required under subsection 85(1) to take into account a number of factors to the extent the information is available:

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	**85 (1)** Pour décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil tient compte des facteurs suivants, dans la mesure où des renseignements sur ces facteurs lui sont disponibles :

is available to the Board:	
(a) the prices at which the medicine has been sold in the relevant market;	**a)** le prix de vente du médicament sur un tel marché;
(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;	**b)** le prix de vente de médicaments de la même catégorie thérapeutique sur un tel marché;
(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;	**c)** le prix de vente du médicament et d'autres médicaments de la même catégorie thérapeutique à l'étranger;
(d) changes in the Consumer Price Index; and	**d)** les variations de l'indice des prix à la consommation;
(e) such other factors as may be specified in any regulations made for the purposes of this subsection.	**e)** tous les autres facteurs précisés par les règlements d'application du présent paragraphe.

[14] If the Board is unable to determine if a price is excessive after having considered the factors identified in subsection 85(1), it may also consider the costs of making and marketing the pharmaceutical and any other factors it considers relevant (*Patent Act*, s 85(2)).

[15] The Board's guidelines are intended to assist Board staff and patentees in complying with their duties and obligations under the Act and the Regulations (*Compendium of Policies, Guidelines and Procedures* (Patented Medicine Prices Review Board Canada, updated February 2017, online: <www.pmprb-cepmb.gc.ca> [Guidelines]). The Guidelines provide the patentee with guidance on how price information will be reviewed and in what circumstances Board staff will recommend that an excessive pricing hearing be held. In the conduct of an excessive price

hearing, a panel may consider the Guidelines; however, the Guidelines do not address the application of the factors identified at section 85 of the Act, and, as noted above, they are not binding on either patentees or the Board:

96 (4) Subject to subsection (5), the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any patentee.	**96 (4)** Sous réserve du paragraphe (5), le Conseil peut formuler des directives — sans que lui ou les brevetés ne soient liés par celles-ci — sur toutes questions relevant de sa compétence.

[16] In furtherance of the objectives of the legislation, sections 80 to 82 of the Act and sections 3 to 5 of the Regulations impose reporting obligations on patentees with respect to the pricing and costs of medicines and authorize the Board to compel production of information and documents. All patentees must provide information to the Board on a variety of matters, including the identity of the patented medicine sold or intended to be sold in Canada; the average transaction price for sales in Canada; and the ex-factory prices for the medicine in Canada and in the seven comparator countries listed in the schedule to the Regulations (*Patent Act*, s 80(1); Regulations, s 4). It is this information that is assessed by Board staff to identify instances of excessive pricing and upon which a recommendation is made to the Chairperson on whether an excessive pricing hearing is warranted (Guidelines, C.13.6).

III. Background – Soliris and its Pricing History

[17] Soliris is the first and only treatment for two rare and life-threatening blood disorders, paroxysmal nocturnal hemoglobinuria [PNH] and atypical hemolytic uremic syndrome [aHUS].

[18] Alexion obtained approval from Health Canada to market Soliris for the treatment of PNH in January 2009. In May 2009, the Human Drug Advisory Panel recommended that Soliris be classified as a Category 2 new drug product or "breakthrough drug" on the basis that it "provides significant therapeutic improvements over supportive therapies for the management of patients with PNH."

[19] Soliris was first sold in Canada in June 2009. Its package price for a 300 mg vial was $6,742 and its unit price, 10 mg/ml, was $224.7333. This price was based on a Median International Price Comparison [MIPC test], which in turn reflected the guidance in the Guidelines. The Guidelines provided that the maximum price for a breakthrough drug on introduction was to be based upon the median international price arrived at based on pricing in seven comparator countries (*Compendium of Policies, Guidelines and Procedures* (Patented Medicine Prices Review Board Canada, October 2003); *Compendium of Policies, Guidelines and Procedures* (Patented Medicine Prices Review Board Canada, January 2010)). The respondent notes that the annual cost of Soliris per patient is $520,000 to $700,000, making it one of the most expensive medicines in Canada.

[20] The Canadian Expert Drug Advisory Committee, a body that recommends drugs for inclusion in publicly funded drug plans based on the clinical therapeutic value of a drug in relation to its cost, recommended that Soliris not be listed for the treatment of either PNH or aHUS due to its cost and potential impact on healthcare system sustainability. However, a number of provinces undertook joint listing negotiations with Alexion, and Soliris was listed for treatment of PNH in four provinces and for aHUS in two.

[21] In June 2010, Board staff began an investigation into the introductory price of Soliris as it had determined that the price exceeded the maximum allowable price between July and December 2009 and had generated excess revenues in the amount of $78,322.71. In response, Alexion did not lower the price of Soliris but instead provided further information relating to the price of the drug in the seven comparator countries. On the basis of this further information, Board staff determined that the price of Soliris no longer triggered its investigation criteria and that the cumulative excess revenue between July and December 2009 was $16,946.37, not the originally calculated amount of $78,322.71. Alexion subsequently offset the excess revenue.

[22] The price of Soliris was found to be within the Guidelines in 2010 and 2011; however, in August 2012, Alexion was advised that the price had exceeded the High International Price Comparison [HIPC test]. Again Alexion did not reduce the price but rather advised Board staff that appreciation in the Canadian dollar created the appearance of a higher price than that in the comparator countries when in fact the price of Soliris in Canada had been constant.

[23] Board staff acknowledged this to be the case but advised Alexion that this did not justify a deviation from the Guidelines. In February 2013, Board staff told Alexion that its filings had triggered the Board's investigation criteria in 2012 and requested that Alexion lower its price by the end of the year. Alexion met with Board staff in December 2012 and December 2013 to discuss the exchange rate issue but did not lower the price of Soliris.

[24] In January 2014, Alexion filed amended data for 2011 to 2013 to include rebates paid to the provinces under Product Listing Agreements [PLAs]. Board staff requested more information

on the rebates. Alexion declined, citing confidentiality concerns, but offered to meet with Board staff to show them the agreements. The meeting did not take place. In April 2014, Board staff advised Alexion that it would not accept the data revisions relating to the PLAs and asked Alexion to refile its data removing the rebates. Board staff also invited Alexion to undertake to voluntarily reduce the price of Soliris by approximately 5% and to pay $4,097,670.81 in excess revenues to the federal Crown. Alexion refiled its data removing the rebates but did not lower the price of Soliris.

[25] In January 2015, Board staff filed a Statement of Allegations alleging that the price of Soliris was excessive between 2012 and 2014 and sought an order that would require Alexion to reduce the price to one not exceeding the international highest price among comparator countries. The Board subsequently issued a Notice of Hearing. The Minister of Health for British Columbia appeared before the Panel on its own behalf and on behalf of the Ministers of Health for Manitoba, Ontario, and Newfoundland and Labrador.

[26] The Panel was confronted with a series of interlocutory motions seeking particulars, alleging conflicts of interest and bias on the part of individuals involved in the proceeding, and seeking to strike certain evidence. Alexion sought judicial review of one of these interlocutory decisions (Court Docket T-1855-15), which was initially set to be heard with this application. However, Alexion discontinued that application on August 29, 2018.

[27] In May 2016, Board staff brought a motion seeking, among other things, an order allowing it to file amended allegations. The amended allegations sought an order requiring

Alexion to reduce the price of Soliris to a price not exceeding the Lowest International Price Comparison [LIPC test] instead of the HIPC test initially relied upon. The motion to amend the Statement of Allegations was granted, and the hearing adjourned for several months to allow Alexion to respond to the amendment.

[28] The hearing was conducted intermittently between January and April 2017, and the Panel's decision was rendered on September 20, 2017.

IV. The Decision Under Review

[29] The Panel reviewed the uses of Soliris and the history of the excessive price proceedings. The Panel accepted the evidence of four fact witnesses. It also heard from a series of witnesses proffered by Board staff and Alexion. The Panel noted that the expert evidence was not particularly helpful as much of it did not focus on the core issue of whether the price of Soliris was excessive.

[30] The Panel identified two issues: (1) is or was the price of Soliris excessive under sections 83 and 85 of the Act, and (2) if so, what order should the Panel make?

[31] The Panel found the LIPC test was the correct benchmark for determining whether the price of Soliris was excessive. It found that, when making a determination under section 85, the Panel must consider its consumer protection mandate identified in *Celgene Corporation v Canada (Attorney General)*, 2011 SCC 1 [*Celgene*], noting "specifically, the Board's role in ensuring that all Canadians are able to obtain patented medicines at 'reasonable prices' and that

prices of patented medicines do not rise to ‘unacceptable levels.’” It found Alexion’s conduct was irrelevant to whether the price of Soliris was excessive.

[32] The Panel found that the Guidelines, which adopt the MIPC test, were of assistance when applying the factors in section 85 but noted they are advisory only and are not binding. The Panel then concluded the Guidelines should be applied with one modification: the LIPC test was the appropriate benchmark in this case. While it acknowledged that stakeholders rely on the Guidelines, the Panel found it had to deviate from them as they did not result in a reasonable implementation of the factors in subsection 85(1). It rejected various arguments of Alexion and BIOTECanada, an intervenor on behalf of the biotechnology industry that it was not open to the Panel to deviate from the Guidelines.

[33] The Panel then explained its approach to subsection 85(1). It noted the *Patent Act* does not define “excessive” nor provide tests or a methodology for determining whether a price is excessive. This showed Parliament contemplated that different tests and approaches may be appropriate in different situations, giving the Board discretion to determine what is appropriate in each case. The Panel found it had discretion to determine the relevance and weight of each factor, but it had to provide sufficient reasons for its determinations and limit itself to the subsection 85(1) factors.

[34] Considering paragraph 85(1)(a), the Panel rejected the contextual analysis put forward by Board staff and the Ministers, instead looking to the information filed by Alexion, which showed the price of Soliris had consistently been $224.7333 per unit.

[35] The Panel found that paragraph 85(1)(b) was not applicable as there were no other medicines in the same therapeutic class.

[36] Turning to paragraph 85(1)(c), the Panel explained that, since there were no other medications in the same therapeutic class, it could only consider the price of Soliris in other countries. It noted the price of Soliris had been under scrutiny in other countries. It explained the question was whether the relevant sections of the Guidelines, including the MIPC and HIPC tests, were an appropriate implementation of the Act's requirement that the Board consider the international prices of Soliris. The Panel acknowledged that it was limited to comparing the price to publicly available ex-factory prices in the comparator countries specified in the Regulations and noted that no evidence regarding rebates or discounts in the comparator countries was filed. Using the ex-factory prices allowed the Panel to conduct an apples-to-apples comparison as the Canadian price of $224.7333 did not include any discounts or rebates. The Panel noted that this external referencing pricing [ERP] method was consistent with Parliament's will, as Parliament was presumed to be aware of the difficulties in comparing prices across borders but still required it, and was fair and reasonable.

[37] The Panel acknowledged that the ERP comparison may fail to properly consider different supply and demand factors across countries; however, most developed countries used such a method. It found the ERP method was appropriate; however, in this case, the LIPC test should be applied rather than the HIPC test as the LIPC test would more accurately implement the Act. The Panel noted that even the lowest price for Soliris in comparator countries had been under attack for being unreasonable and that the evidence showed patented medicines were generally more

expensive internationally, especially in the United States [US]. It commented that one would expect the price of Soliris in Canada to be lower than the US price, which it was not.

[38] The Panel noted its mandate included ensuring that "all Canadians are able to obtain patented medicines at reasonable prices." It found the reasonable price for Soliris in Canada was one that did not exceed the lowest international price [LIP] in the comparator countries. It noted that the LIP was in the United Kingdom [UK] and that Alexion was presumably "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." The Panel stated it could "see no justification why Canadians should not have the benefit of the lowest price being paid in any of the comparator countries." As Soliris had been priced above the lowest price in the comparator countries since its first sale, the Panel concluded its price was, and since 2009 had been, excessive under sections 83 and 85 of the Act.

[39] The Panel then addressed arguments regarding the use of foreign exchange rates to compare the prices of Soliris. Alexion had argued the only reason for its non-compliance was exchange rate fluctuations, which were outside its control. The Panel noted fluctuating exchange rates were explicitly contemplated in the Guidelines, and Alexion knew they were a consideration. While they were outside Alexion's control, that was not relevant to the analysis under subsection 85(1). The Panel noted Alexion had chosen not to comply with the Guidelines to address the fluctuations. Instead, it had sought to negotiate a resolution with Board staff with full knowledge of its non-compliance with the Guidelines. Alexion was aware of the risk that a

panel would conclude the Guidelines' treatment of the fluctuations was an appropriate implementation of paragraph 85(1)(c).

[40] The Panel rejected Alexion's argument that it should not convert international prices into Canadian dollars under paragraph 85(1)(c), finding it had to do so. It found that conversion using the market exchange rates in the Guidelines, rather than purchase price parity rates, was appropriate.

[41] The Panel agreed with Alexion that Board staff had failed to clearly explain its calculations of excess revenues and to establish that the data it relied on was an appropriate source of foreign price verification. However, none of the disputed sources would alter the fact that Soliris would fail the LIPC test. Any concerns Alexion may have had with the information relied on by Board staff were completely resolved by the requirement that the parties only use the information provided by Alexion when calculating excess revenues. The Panel found no breach of procedural fairness, as Board staff had complied with its disclosure obligations and Alexion had been given sufficient time to review and respond to the Board's allegations.

[42] Turning to paragraph 85(1)(d), the Panel found the methodology in the Guidelines was appropriate except that, going forward, a price increase based on the Consumer Price Index [CPI] could not exceed the LIPC test. The Panel noted the evidence of one expert, Mr. Soriano, that the price of Soliris in "real dollars" had decreased due to inflation. However, it found that Mr. Soriano's evidence was not based on an appropriate comparison, as his calculations disregarded the effect of inflation in comparator countries. The Panel rejected Mr. Soriano's analysis of

additional revenues Alexion could have realized had it increased its price by the CPI factor each year as the Act did not guarantee a yearly CPI increase.

[43] The Panel also rejected the approach of converting the nominal price of Canadian Soliris and international Soliris to its "real price" by applying CPI adjustments and then comparing the CPI-adjusted price. This was inconsistent with the wording of paragraph 85(1)(d) and conflated the factors in paragraphs 85(1)(c) and (d).

[44] The Panel concluded that paragraph 85(1)(d) only required it to consider changes in the CPI. It noted the price of Soliris had not changed despite a positive rate of inflation; however, the UK price had not changed either, despite inflation, and the UK had a higher CPI factor than Canada.

[45] The Panel found that paragraph 85(1)(e) was not applicable as no regulations had been passed pursuant to that section. It then concluded that the price of Soliris in Canada had been, since its introduction, excessive.

[46] In addressing the excess revenue question, the Panel found it had the discretion to calculate excess revenues under subsection 83(2) on a different basis than the price of Soliris going forward under subsection 83(1). It ordered Alexion to reduce the price of Soliris to no higher than the price in the lowest priced comparator country. However, it ordered Alexion to pay for past excess revenues based on the HIPC test, finding this remedy would be appropriate,

fair, and consistent with the Panel's mandate given that Board staff had applied the HIPC test to Soliris until 2015.

[47] The Panel held that the rebates Alexion provided to the provinces and others did not justify a reduction or an offset of excess revenues. It also rejected the argument that the cost of administering the drug through infusion should be taken into account as Alexion had failed to show those costs were in fact covered by it or the amount of costs covered. Finally, the Panel found that the failure to take into account inflation did not justify any offset of excess revenues as such an approach incorrectly assumed Alexion would have been permitted to take yearly CPI increases.

[48] The Panel concluded that the provisions of the Guidelines dealing with permitted offsets were appropriate. It rejected Alexion's arguments based on the law of expropriation, the *North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can TS 1994 No 2 (entered into force 1 January 1994), and the *Canadian Bill of Rights*, SC 1960, c 44, to the effect that the Panel could not interpret the *Patent Act* as allowing it to make an order based on methodology not in the Guidelines.

[49] The Panel emphasized that the Guidelines did not address remedies for excessive pricing and did not limit the Panel's available remedies.

[50] In a short subsequent decision, the Panel ordered Alexion to pay to Her Majesty the Queen in Right of Canada the amount of $4,245,329.60 on or before December 8, 2017.

V. Issues

[51] The applicant has identified the following issues:

A. Was the Panel's adoption of the LIPC test inconsistent with the *Patent Act* and therefore unreasonable?

B. Was the Panel's refusal to give weight to CPI changes unreasonable?

C. Was the Panel's refusal to consider provincial rebates unreasonable?

D. Was it unreasonable for the Panel to order past "excess revenues" to be forfeited based on the HIPC test after conceding there was insufficient evidence on which to establish liability based on that test?

VI. Standard of Review

[52] A specialized tribunal's decisions, including its interpretation and application of its home statute, will, subject to limited exceptions, be reviewed against a standard of reasonableness (*Dunsmuir v New Brunswick*, 2008 SCC 9 at para 54–62 [*Dunsmuir*]). The parties agree that none of the exceptions identified in *Dunsmuir* arise here and that the Board is entitled to deference (*Celgene* at para 34).

[53] In conducting a reasonableness review, a reviewing court is required to consider whether the decision-making process reflects the elements of "justification, transparency and intelligibility" and whether the decision "falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and the law" (*Dunsmuir* at para 47). It is not the

court's role to finely parse a decision for error. However, a reviewing court may intervene where the "decision is demonstrably unreasonable, even where the ultimate findings might be capable of being supported by the record" (*Whyte v British Colombia (Superintendent of Motor Vehicles)*, 2013 BCCA 454 at para 11).

VII. Analysis

A. *Was the Panel's adoption of the LIPC test inconsistent with the Patent Act and therefore unreasonable?*

[54] Alexion submits that the Panel was required to consider and reach a determination on the question of excessive pricing by considering only the factors set out at subsection 85(1) of the Act. Of the factors identified at subsection 85(1), it was agreed by the parties and the Panel that only three factors were applicable: (1) the prices at which the medicine has been sold in the relevant market; (2) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada; and (3) changes in the CPI (*Patent Act*, ss 85(1)(a), (c), (d)). Alexion submits that in conducting the international price comparison, the Panel was limited to a consideration of the prices contained in Alexion's filings of the price of Soliris in the seven comparator countries identified in the Regulations. Alexion further notes that during the relevant period, the Guidelines provided that a presumption of excessive pricing would only arise where the Canadian price exceeded the MIPC on introduction or the HIPC thereafter.

[55] Alexion argues that, in adopting and applying the LIPC test to conclude that the price of Soliris was excessive, the Panel erred by: (1) adopting a test that was inconsistent with the Act

and the Regulations; (2) failing to give due consideration to the Guidelines; and (3) generating reasons that fail the transparency, intelligibility, and justification standard. I will address each of these alleged errors.

(1) Did the Panel err by adopting a test that was inconsistent with the Act and the Regulations?

[56] Alexion argues that the LIPC test is plainly inconsistent with the language of the Act and the Board's statutory mandate. In advancing this argument, Alexion relies on the ordinary dictionary meaning of "excessive"—something that "exceeds 'what is usual, proper necessary or normal'"—to submit that the LIPC, a price that is lower than every single comparator except one, cannot, on the basis of common sense or logic, be considered excessive.

[57] Alexion argues that Parliament did not intend that the Board routinely intervene on the pricing of patented medicines. It submits, relying on *Pfizer Canada Inc v Canada (Attorney General)*, 2009 FC 719 [*Pfizer*], that Parliament did not establish a general price control regime, which would intrude on provincial jurisdiction, but rather implemented a regime to avoid excessive or unreasonable pricing that may result from abuse of the patent monopoly.

[58] Alexion further submits that the LIPC test is inconsistent with the apparent intent of the Regulations, which identify seven comparator countries. The LIPC test does not provide a comparative basis upon which to conclude a price is excessive and does not control for idiosyncratic factors unique to the low-price country.

[59] In adopting the LIPC test, the Panel noted that the Act does not define an "excessive" price. On this basis, it concluded that Parliament had contemplated different tests and approaches for different patented medicines and that the Panel had broad discretion in determining the question. This conclusion is not inconsistent with the Act; it reflects the discretion provided to the Board in section 83 of the Act to form an opinion on excessive pricing after considering the factors set out at section 85. This authority was also recognized by Justice Pierre Blais in *Leo Pharma Inc v Canada (Attorney General)*, 2007 FC 306 at paragraph 18 [*Leo Pharma*]:

> [18]…Section 85 of the Act lists a series of factors to be considered by the Board, but does not specify how these factors should be used or weighed by the Board, nor does it specify the circumstances in which the price will be considered excessive. As the Board noted in its decision: "performing a comparison does not dictate a conclusion that must result from the comparison".
>
> [Emphasis added]

[60] In forming an opinion as to whether a medicine is selling at an excessive price, a panel is not required to apply any defined test. In other words, there is no correct test. While Alexion does not take issue with this, it does argue that there is an *incorrect* test. I disagree. Alexion cites no authority to support its position. To find that the LIPC test is simply not available to a panel would, in effect, specify some circumstances in which the price of a drug would or would not be considered excessive. Such a result would be contrary to the broad discretion that the *Patent Act* extends to this expert tribunal and that is recognized in this Court's jurisprudence.

[61] In considering the question of whether the price of a drug is "excessive," a panel is required to consider drug pricing on a case-by-case basis and to consider the statutorily prescribed factors in light of the circumstances of the drug before it. Just as the Act and

Regulations cannot be read as excluding a particular result, they cannot be read as excluding a particular test.

[62] The adoption of the LIPC test is not, on its face, inconsistent with the Act and the Regulations. Further, in selecting a particular test, a panel is not setting the price of a drug, which would intrude on provincial jurisdiction. Rather, it is determining which benchmark is appropriate in the context of a particular drug. In the absence of a legislated test this, in my view, is precisely what Parliament intended the Board to do.

(2) Did the Panel fail to give due consideration to the Guidelines?

[63] Alexion argues that the Panel's departure from the Guidelines on the issue of the benchmark test was a reviewable error. Citing prior Board decisions, Alexion argues that although the Guidelines are not binding, they are an important means of ensuring fairness, consistency, and predictability. Alexion submits that the MIPC and HIPC benchmark tests set out in the Guidelines were relied on in establishing the introductory price for Soliris and that the Panel was required to give those tests due consideration in interpreting and applying the Act.

[64] Alexion states that departing from established guidelines in the absence of substantial and compelling reasons is a factor of significance when assessing whether an exercise of discretion was unreasonable (*Baker v Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817 at para 72). Alexion argues the Panel's finding that the LIPC test was the appropriate benchmark for determining whether the price of Soliris was excessive was a significant departure from Guidelines, which renders the Panel's exercise of discretion unreasonable. I disagree.

[65] It is clear that the Guidelines are not binding (*Patent Act*, s 96(4)). While the Panel is required to adopt a rationale, approach, or methodology when considering the section 85 factors, that approach "may be ad hoc or may be derived from the Board's Guidelines" (*ICN Pharmaceuticals Inc v Canada (Patented Medicine Prices Review Board)* (1996), 119 FTR 114 at para 6).

[66] The Panel acknowledged that the Guidelines measured pricing against the MIPC test on the introduction of Soliris and that they applied the HIPC test or the CPI test on a going-forward basis. It addressed key principles relating to the Guidelines and their application as set out in prior Board decisions: (1) the Guidelines are advisory in nature, but a panel must give them "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"; (2) the certainty and consistency promoted by the Guidelines need to be balanced against the requirement to remain flexible and adopt fact-specific solutions when addressing excessive pricing questions; (3) a panel must be satisfied that the Guidelines appropriately implement the Act, as they will not be presumed to do so; and (4) the evidence, the submissions received, and the panel's own expertise may be considered in assessing whether the Guidelines may be appropriately applied (*In the matter of the Patent Act RSC 1985, c P-4, as amended and in the matter of Leo Pharma Inc (the "Respondent") and the medicine "Dovobet"* (19 April 2006), PMPRB-04-D2-DOVOBET, online: <http://www.pmprb-cepmb.gc.ca>; *In the matter of the Patent Act RSC 1985, c P-4, as amended and in the matter of Shire BioChem Inc (the "Respondent") and the medicine "Adderall XR"* (10 April 2008), PMPRB-06-D3-ADDERALL XR, online: <http://www.pmprb-cepmb.gc.ca>). The Panel further noted that guidelines cannot fetter a tribunal's discretion nor can they prevail over the Act and

the Regulations (*Teva Neuroscience GP-SENC v Canada (Attorney General)*, 2009 FC 1155 at para 32 [*Teva Neuroscience*]; *Canada (Attorney General) v Sandoz Canada Inc*, 2015 FCA 249 at para 75 [*Sandoz*]).

[67] The Panel addressed the arguments made in support of the position that it was not open to the Panel to deviate from the benchmark tests in the Guidelines. It found that Alexion "was given a full and fair opportunity to respond to the amendments" seeking to apply the LIPC test and concluded that the application of the Guidelines by Board staff to determine an initial price for Soliris did not estopp the Panel from adopting a different benchmark in an excessive price hearing.

[68] The Panel also detailed its reasons for concluding the LIPC test was the appropriate benchmark against which to determine the question of "excessive" pricing for Soliris as part of its section 85 analysis. Alexion takes issue with the reasonableness of the Panel's section 85 analysis and these arguments are addressed below. I am, however, satisfied that in considering the benchmark against which to assess the issue of excessive pricing, the Panel gave due consideration to the Guidelines and provided substantial and compelling reasons in support of its decision to depart from the Guidelines. The Panel did not err in this respect.

(3) Generating reasons that fail the transparency, intelligibility, and justification standard

[69] Alexion takes issue with the Panel's reasons for applying the LIPC test to Soliris and submits that neither fact nor precedent support the Panel's conclusions that:

a) the price of Soliris in the UK (the lowest of the comparator countries) had been "under attack for being unreasonable";

b) there was a rational connection between the price of Soliris in the US and the adoption of the LIPC test;

c) the Canadian price was higher than the US price in 2016; and

d) the Board's mandate extended beyond the prevention of price abuse by patentees to include ensuring patented medicines can be obtained by Canadians at reasonable prices.

[70] Alexion argues that in finding the price of Soliris in the UK "has been under attack for being unreasonable" and that "permitting Alexion to sell at a price [in Canada] up to the UK price is generous to Alexion," the Panel relied on and unreasonably interpreted guidance issued in 2015 by the UK National Institute for Health and Care Excellence relating to the use of Soliris in the treatment of aHUS [NICE Report]. Alexion submits the authors of the NICE Report did not find the price was unreasonable. Instead, the authors found they "had not been presented with enough justification for the high cost per patient of [Soliris] or for the overall cost of [Soliris] with reference to what could be expected to be reasonable in the context." Alexion further submits that it was unreasonable for the Panel to place any weight on the NICE Report as the Panel did not engage in any analysis of the basis for the report's findings or the validity and applicability of those findings to the Canadian context. Alexion notes that the NICE Report was limited to a consideration of the use of Soliris in the treatment of aHUS only and that there was no basis to conclude the NICE Report's statements would have been made in the context of the treatment of PNH.

[71] In concluding that the reasonableness of the price of Soliris was under attack in the UK, the Panel recognized that the NICE Report was limited to a consideration of the price of Soliris

in the treatment of aHUS only. The Panel also acknowledged that it was unable to comment on whether or not the price of Soliris in the UK context was excessive. It is also evident upon a review of the NICE Report as a whole that the cost of Soliris was of concern to the authors, that the cost had not been justified, and that the cost of Soliris was "materially higher than the overall cost of other highly specialised technologies."

[72] There was also evidence before the Panel to the effect that a price in one comparator jurisdiction can provide a reasonable perspective on costs and rate of return in another. This evidence is consistent with the Panel's conclusion that the NICE Report "suggests" that allowing Soliris to be sold in Canada at a price up to the UK price "is generous to Alexion."

[73] The Panel is owed deference on a reasonableness review. The fact that there may be alternative reasonable interpretations to be given to evidence does not, in itself, render a finding unreasonable (*Newfoundland and Labrador Nurses' Union v Newfoundland and Labrador (Treasury Board)*, 2011 SCC 62 at paras 15, 17). I am unable to conclude that the Panel unreasonably interpreted the NICE Report or came to an unreasonable conclusion on pricing as a result.

[74] Similarly, Alexion's submissions to the effect that the Panel unreasonably concluded that its willingness to supply the US market at a lower price than Canada indicated the Canadian price was "excessive" and justified the adoption of the LIPC test are not persuasive. The Panel relied on evidence, including the testimony of three experts, to the effect that pharmaceuticals have generally been priced lower in Canada than in the United States. Based on this evidence,

the Panel noted that "one would expect the price of Soliris in Canada to have been lower than the price in the US, which it was not." The Panel then cited the expert evidence of Drs. Addanki and Schwindt to the effect that the willingness of Alexion to supply the US market at a lower price than the Canadian price indicated the Canadian price may be excessive. The Panel agreed with the experts on this point, a conclusion that was reasonably available it.

[75] Alexion points to the Panel's factual error in finding that the price for Soliris in Canada remained 20% higher than in the US in early 2016 when in fact it was 20% lower. The error is not disputed; Dr. Addanki's expert evidence, upon which the Panel relied, is clear the price of Soliris in the US did exceed the Canadian price beginning in late 2014, towards the end of the period reviewed. However, Dr. Addanki's evidence also indicated that, on average, expensive medicines are 220% more expensive in the US than in Canada and that even at the 20% maximum differential he observed in early 2016, he was of the view that the price of Soliris in Canada was higher than he would have expected.

[76] Modest or inconsequential errors that do not impact upon the overall result do not warrant a court's intervention on judicial review (*Zhan v Canada (Minister of Citizenship and Immigration)*, 2010 FC 822 at para 50). The Panel's error in this matter was not consequential and does not undermine the reasonableness of the Panel's overall findings.

[77] Alexion also submits that the Panel misread the Supreme Court of Canada's decision in *Celgene* in broadly interpreting the Board's mandate as ensuring reasonable drug prices for Canadians. In Alexion's view, the Board's mandate is much narrower: the prevention of price

abuse. It is submitted that in adopting a broad and erroneous interpretation of the Board's mandate, the Panel relied on factors that were irrelevant to its subsection 85(1) analysis and gave no weight to other factors that should have informed its analysis. I disagree.

[78] In making reference to the Board's consumer protection role, the Panel acknowledged its mandate as expressed in *Celgene*. In doing so, it did not limit itself to a consideration of a passage from *Hansard*, as alleged. Rather, it recognized that in conducting its section 85 analysis, it was required to consider "the Board's role in ensuring that all Canadians are able to obtain patented medicines at 'reasonable prices' and that prices of patented medicines do not rise to 'unacceptable levels,'" citing paragraphs 27 and 28 of *Celgene*. The consumer protection aspect of the Board's mandate has long been recognized, and this aspect of the Board's function is not, in my opinion, inconsistent or incompatible with the objective of preventing price abuse by patentees.

[79] Alexion seeks to draw a distinction between "non-excessive" pricing and "reasonable" pricing. These concepts are not necessarily mutually exclusive. "Reasonable" is defined in the Merriam-Webster dictionary as "being in accordance with reason…not extreme or excessive…moderate, fair" (*Merriam-Webster Dictionary*, sub verbo "reasonable" (online: <www.merriam-webster.com>). Upon a reading of the Panel's decision as a whole, it is evident that the Panel understood that the issue before it was "[i]s or was the price of Soliris excessive within the meaning of sections 83 and 85 of the Patent Act." Having clearly set out its role, the Panel did not err in using the terms "reasonable price" and "non-excessive price" interchangeably.

[80] I agree with Alexion's submissions to the effect that the *Patent Act* does not empower the Board to set a pharmaceutical price at whatever level it considers reasonable. A panel is tasked with ensuring that a price is not excessive. Alexion points to the Panel's statement to the effect that it could see no justification as to why Canadians should not have the benefit of the lowest price paid for Soliris in any of the comparator countries to argue the Panel ignored its primary purpose of preventing price abuse.

[81] I do not share Alexion's interpretation of the Panel's statement. The statement is made in the context of the Panel's comparator countries analysis, after having considered and addressed the price comparison evidence and having concluded that the LIPC test was the appropriate excessive pricing benchmark in this case. The Board did not seek to determine a reasonable price for Soliris; instead, it sought and established a non-excessive price benchmarked against the comparator countries. Having done so, it then observed that the evidence had failed to disclose any justification for a higher price in Canada and noted the impact of the high cost of Soliris on provincial budgets. These observations do not undermine the reasonableness of the Panel's conclusion that the LIPC test is the appropriate excessive pricing benchmark in this case.

[82] I am also not persuaded that the Panel erred in noting Dr. Schwindt's evidence to the effect that the price charged in one comparator country can allow one to conclude that the patentee is covering costs and earning a normal rate of return. In Alexion's view, the Panel essentially considered the costs of making and marketing Soliris under subsection 85(2) of the Act, when the Panel had stated it would not have regard to that factor. I disagree. This appears to

be a common sense conclusion that falls well short of a consideration of the costs of making and marketing medicine as contemplated at subsection 85(2).

[83] Alexion further argues that the Panel erred in concluding that its conduct was irrelevant to the Panel's excessive price determination under subsection 85(1). Alexion states that, having taken the position that Alexion's conduct was irrelevant, the Panel also failed to give any weight to relevant factors relating to its conduct. This included but was not limited to the fact that the price of Soliris had not been increased in Canada since introduction and, after inflation, had in fact decreased in cost by approximately 10%. The Panel's alleged failure to give weight to the fact that Alexion did not increase the price of Soliris to keep pace with inflation is addressed below.

[84] In concluding Alexion's conduct was irrelevant to its excessive pricing analysis, the Panel relied on the Federal Court of Appeal's decision in *Sandoz*. In that case, the Court held that a panel reasonably concluded that the purpose of sections 79 to 103 of the *Patent Act* was to protect consumers from excessive pricing and that the mischief might arise in circumstances without the patent owner itself charging excessive prices (*Sandoz* at paras 65, 67).

[85] Alexion argues that price abuse or "mischief" by definition requires a consideration of the patentee's conduct. Alexion seeks to distinguish *Sandoz* and invites the Court to conclude that the Panel erred in failing to give any weight to Alexion's conduct. The facts of *Sandoz* are distinguishable from those that were before the Panel in this case; however, this does not render unreasonable the Panel's conclusion that patentee conduct was of little assistance in answering

the excessive pricing question. The principle reflected in paragraphs 65 through 67 of *Sandoz*—it was reasonable for the Board to consider the mischief of excessive pricing by focusing on the persons in need of protection from such mischief rather than the patentee—was considered and applied by the Panel to the unique facts before it: a breakthrough drug with no alternative treatment available in the marketplace. The Panel's conclusion that Alexion's conduct in these circumstances was irrelevant to the determination of the excessive pricing question was reasonably available to it. It is trite to note that neither Alexion's disagreement with the Panel's interpretation of *Sandoz* nor the identification of an alternative reasonable interpretation renders the Panel's approach unreasonable.

B. *Was the Panel's refusal to give weight to CPI changes unreasonable?*

[86] Paragraph 85(1)(d) of the Act requires a panel to consider changes in the CPI. Alexion submits that the Panel erred by subsuming any consideration of CPI changes within its consideration of the LIPC test. In doing so, Alexion argues the Panel failed to give any independent weight to the fact that the price of Soliris in Canada had never increased, that in "real dollars" the price in Canada had decreased, and that the compliance issues that did arise were solely the result of exchange rate fluctuations. I disagree.

[87] A panel is required to consider the factors identified in subsection 85(1) where information relevant to the factors is before it. There is no requirement that a panel weigh the factors in any particular manner. However, "each factor must be given some reasonable consideration, no factor can be ignored, nor can any one factor be given such dominance such that others are essentially irrelevant" (*Teva Neuroscience* at para 47 [emphasis in original]).

[88] In addressing paragraph 85(1)(d), the Panel acknowledged Alexion's position as it related to the CPI, noted that the price of Soliris had not changed since introduction, and referred to expert evidence to the effect that in "real dollars" the price had decreased due to inflation. The Panel engaged with the expert evidence, noted deficiencies in the analytical approach adopted by the experts, and concluded on this basis that the evidence was unhelpful. The Panel undertook a serious analysis of the CPI factor.

[89] Alexion argues that the Panel conflated the international price comparison analysis under paragraph 85(1)(c) and the CPI analysis under paragraph 85(1)(d) when it referenced the absence of price changes in the UK during the same period despite a positive rate of inflation in that jurisdiction. Again, I disagree. The Panel understood that the 85(1)(c) and 85(1)(d) factors were distinct. It understood that the 85(1)(d) factor was to be considered in respect of Canadian prices, not prices in the comparator countries. The Panel's reference to pricing in another jurisdiction, a reference that responded to expert evidence placed before it, does not support the view that the CPI analysis was subsumed into the price comparator analysis or that mere lip service was paid to paragraph 85(1)(d).

C. *Was the Panel's refusal to consider provincial rebates unreasonable?*

[90] Relying on *Leo Pharma*, Alexion submits that, in finding the price of Soliris "excessive" and ordering Alexion to pay excess revenues, the Panel unreasonably refused to consider payments by Alexion to the provinces under PLAs between 2011 and 2013.

[91] In *Leo Pharma,* the Panel was asked to consider the applicant's free medicine distribution program in assessing the average transaction price for the medicine. Subsection 4(4) of the Regulations addresses the calculation of the average price of patented medicine and as currently drafted states:

(4) For the purposes of subparagraph (1)(f)(i),	**(4)** Pour l'application de sous-alinéa (1)f)(i),
(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 benefits of a like nature and after deduction of the federal sales tax shall be used.	**a)** le prix après déduction des réductions accordées à titre de promotion ou sous forme de rabais, escomptes, remboursements, biens ou services gratuits, cadeaux ou autres avantages semblables et après déduction de la taxe de vente fédérale doit être utilisé pour le calcul du prix moyen par emballage dans lequel le médicament était vendu.

[92] The Panel in *Leo Pharma* declined to consider the impact of the free distribution program, finding it was not a genuine compassionate program but had been pursued following the commencement of a pricing investigation for the purpose of artificially reducing the drug's average transaction price. On judicial review, the Court noted that although the Guidelines made reference to a "compassionate release program," the Regulations themselves made no reference to the purpose of a free distribution program. The Court found that there was a sufficient basis for the Panel to reasonably conclude that the free distribution program was not a genuine compassionate use program. However, Justice Blais held that the Regulations made no reference to a patentee's intent in this regard and provided clear direction on the calculation of average price. He concluded that the Regulations were drafted to provide patentees with an incentive to distribute free medicines by allowing them to include free distribution and rebate programs in the

average price calculation, regardless of the intent of any such program. The Panel's refusal to consider the free distribution was held to be unreasonable (*Leo Pharma* at paras 55–57).

[93] In addressing whether rebates paid by Alexion under the PLAs were to be taken into account in determining the average transaction price in this matter, the Panel acknowledged *Leo Pharma*. However, relying on *Pfizer*, the Panel interpreted the *Leo Pharma* direction "as referring to rebates given to customers," not to third parties or strangers to the sales transaction.

[94] In *Pfizer*, Justice Anne Mactavish found the Board had acted outside its jurisdiction in requiring patentees to report rebates (including rebates or payments to third parties), discounts, free services, gifts, and other similar benefits in calculating the average price of patented medicines. Justice Mactavish noted the Board's role was constitutionally limited to "determin[ing] whether, taking certain specified factors into account, a patentee is selling patented medicines to its customers at an 'excessive price'" (*Pfizer* at para 11). She noted, in reviewing the legislative history of the 1993 amendments to the *Patent Act*, that federal jurisdiction was limited to the regulation of "factory-gate" prices. She described "factory-gate" prices as being generally understood in the industry as the price between the patentee and the first purchaser of the patented medicine, commonly a wholesaler (*Pfizer* at paras 61–62).

[95] Although some provinces had negotiated agreements with patentees, Justice Mactavish also concluded that the provinces were not "customers," as the Board itself defined them as "third parties" (*Pfizer* at para 82). She further noted that the decision in *Leo Pharma* did not consider whether the obligation to report rebates extended to "rebates or payments to third

parties" (*Pfizer* at para 57). She concluded that the provinces were not customers of the patentee and that payments made under PLAs were not rebates pursuant to subsection 4(4) of the Regulations, as the circumstances did not involve the return of funds actually paid to the patentee (*Pfizer* at paras 86–89).

[96] Alexion submits that *Pfizer* does not prevent the Board from taking into account third party discounts that are voluntarily reported to the Board and that adopting this interpretation is consistent with *Leo Pharma*. I disagree.

[97] As was noted by Justice Mactavish in *Pfizer*, *Leo Pharma* does not consider whether the obligation to account for payments, discounts, or rebates extends to payments made to third parties (*Pfizer* at para 57). The Panel's interpretation of *Leo Pharma* and its conclusion that *Leo Pharma* did not apply to the facts before it was neither inconsistent with that decision nor unreasonable.

[98] Section 80 of the Act requires a patentee to provide information and documents as specified in the Regulations respecting the price at which a medicine is sold in Canada. The Regulations require the reporting of and regulate the "factory-gate" price at which the medicine was sold to "each class of customer in each province and territory." Although paragraph 4(4)(a) of the Regulations speaks to the actual price after discounts, rebates, etc., the price contemplated in the Regulations is the price to a customer.

[99] It was open to the Panel to conclude, as it did, that provinces that have received payments from a patentee pursuant to a PLA are not customers for the reasons set out by Justice Mactavish in *Pfizer*. On this basis, it was reasonable for the Panel to conclude that discount payments to the provinces were not to be taken into account in determining the average transaction price.

[100] Alexion further argues that even if the Panel reasonably concluded that it could not consider discounts to the provinces in determining the price of Soliris under subsection 85(1), the Panel was required to take these payments into account in calculating excess revenues under subsection 83(2) of the Act.

[101] The Panel declined to consider discount payments to the provinces for the purposes of offsetting any excess revenues, relying on its reasons for excluding these discounts in determining the price of Soliris.

[102] Subsection 83(2) of the Act states the following:

83 (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	**83 (2)** Sous réserve du paragraphe (4), lorsqu'il estime que le breveté a vendu, alors qu'il était titulaire du brevet, le médicament sur un marché canadien à un prix qu'il juge avoir été excessif, le Conseil peut, par ordonnance, lui enjoindre de prendre l'une ou plusieurs des mesures suivantes pour compenser, selon lui, l'excédent qu'aurait procuré au breveté la vente du médicament au prix excessif :

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;	**a)** baisser, dans un marché canadien, le prix de vente du médicament dans la mesure et pour la période prévue par l'ordonnance;
(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	**b)** baisser, dans un marché canadien, le prix de vente de tout autre médicament lié à une invention brevetée du titulaire dans la mesure et pour la période prévue par l'ordonnance;
(c) pay to Her Majesty in right of Canada an amount specified in the order.	**c)** payer à Sa Majesté du chef du Canada le montant précisé dans l'ordonnance.

[103] Paragraph 83(2)(c) allows a panel to order payment to the federal Crown of excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price. The excessive price is the average transaction price, a number that was not in dispute. Having reasonably concluded that discounts to the provinces were not to be considered in determining the price of Soliris, the Panel did not err in excluding these discounts in assessing the quantum of the excess revenue order under subsection 83(2).

D. *Did the Panel unreasonably adopt the HIPC test in making the excess revenue order?*

[104] Alexion argues that the Panel unreasonably based its order to forfeit excess revenues on the HIPC test. Alexion relies on the Panel's finding that the evidence was insufficient to establish liability under the HIPC test. Alexion argues that due to the evidentiary uncertainty highlighted

by the Panel, the Panel was not in a position to calculate an excess revenue amount that related to the excess revenues estimated to have been derived by the patentee.

[105] I am not convinced. Subsection 83(2) provides significant discretion to a panel. It need not issue an excessive revenue payment or take any other steps to offset excess revenues. However, when it does so, the panel must take account of the estimated amount of excess revenues. In this sense, I agree with Alexion that a panel cannot issue an order in any amount. Subsection 83(2) is not intended to impose a penalty or sanction.

[106] However, in estimating excess revenues, nothing in logic or law prevents the panel from adopting a more conservative test than it might otherwise be entitled to pursue where warranted by the facts and the circumstances. This is exactly what the Panel did in this case. In adopting the HIPC test for the purposes of calculating the excessive pricing order, the Panel recognized that the LIPC test was not proposed as an appropriate benchmark until 2015 and that Board staff had consistently applied the HIPC test in accordance with the Guidelines. The Panel sought to be fair and equitable in dealing with Alexion. This was neither unfair nor unreasonable.

VIII. Conclusion

[107] For the above reasons, I find the decision is reasonable in all respects, and the application is dismissed. The respondent shall have its costs. The intervenor has not sought costs, and none are awarded.

JUDGMENT IN T-1596-17

THIS COURT'S JUDGMENT is that:

1. The application is dismissed; and

2. The respondent shall have its costs. No costs to the intervenor.

"Patrick Gleeson"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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