Federal Court  Cour fédérale

Date: 20110712

Docket: T-83-10

Citation: 2011 FC 859

Ottawa, Ontario, July 12, 2011

PRESENT: The Honourable Justice Johanne Gauthier

BETWEEN:

SANOFI PASTEUR LIMITED

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

AMENDED ~~CONFIDENTIAL~~ REASONS FOR JUDGMENT AND JUDGMENT

[1] The applicant, Sanofi Pasteur Limited [Sanofi] seeks judicial review of part of the decision of the Patented Medicines Prices Review Board [the Board][1] dealing with the remedy granted with respect to the excessive prices it charged between 2002 and 2006 that is a payment in the amount of $2,512,878.74 to Her Majesty the Queen pursuant to subsection 83(2) of the *Patent Act*, RSC 1985, c P-4 [the *Act*].

[1] Original decision issued December 21, 2009, amended on March 1, 2010 and implemented by order issued March 16, 2010.

[2] The applicant raised several issues which, for reasons described below, are not founded, such as:

a. That the Board erred by imposing a penalty pursuant to subsection 83(2) of the *Act*,

b. That it fettered its discretion by relying blindly upon the Compendium of Guidelines, Policies and Procedures [the Guidelines] and past Board decisions with respect to the offsetting of excess revenues in the context of subsection 83(2) of the *Act*.

[3] It also argued that the Board had abused its power under subsection 83(2) of the *Act* by ignoring the evidence and the particular circumstances of its case and making findings that are based on pure speculation. It was agreed that these issues are to be reviewed on the reasonableness standard. After really struggling to understand the reasoning of the decision-maker, the Court concludes that the decision did not meet the transparency, intelligibility and justification criteria included in the reasonableness standard.

Background

[4] Even though most of what follows is not in dispute, I feel that it is important to put the issues raised in their proper context, including what was argued before the Board, for this is helpful and necessary to assess the intelligibility and transparency of the decision.

[5] In *Teva Neuroscience G.P.-S.E.N.C. v Canada (Attorney General)*, 2009 FC 1155 at para 2, my colleague Justice Roger Hughes briefly described the Board and its duties as follows:

> The Patented Medicines Prices Review Board (the Board) was established in 1987 and continued in 1993 under the provisions of the

> *Patent Act*, R.S.C. 1985, c. P-4 as amended in 1993 and 1996 and in particular sections 79 to 103 of that Act. It has many duties including the monitoring of prices of what are described as "medicines" if such medicines are the subject of a "patent", the reporting of such prices to Parliament and, importantly in the context of these applications, the determination as to whether such prices are "excessive" and, if so, the imposition of a variety of remedies.

[6] It is clear that Parliament's intention in creating the Board was for it to control the market power of the monopoly created by the exclusivity of a patent. The Board is given wide discretion as indicated in sections 83 and 85 of the *Act* which will be discussed later on. It publishes bulletins setting out policies, procedures and guidelines which are now consolidated in the Guidelines. The version of the Guidelines at issue in this particular judicial review is the version in effect in 2009 which is reproduced in Volume 1, Tab 10 of the Applicant's Record.[2] It has been in force since 1994 and amended several times. The Guidelines have since been amended again and a new version, including certain relevant passages, has been applied since January 1, 2010. This version was produced by consent of the parties at the hearing before me. The sections referred to by the parties are set out in Appendix "A" together with the various relevant provisions of the *Act*. It is not disputed that the Guidelines are not binding and they clearly say so.

[7] As both parties did, it is worth saying a few words about how the Board collects information and fulfills its mandate. Within 30 days of the date on which a medicine is first sold in Canada, the patentee is required to file a "Form 2" document which identifies the medicine and provides average pricing information. The Board's staff [Board Staff] uses this information and conducts price tests (considering prices for that medicine or comparable medicines in other countries as well as in

[2] Patented Medicines Prices Preview Board, *Compendium of Guidelines, Policies and Procedures* (updated to 2009), online: Patented Medicines Prices Review Board <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1034>.

Canada) to establish a price ceiling referred to as the "maximum non-excessive price" [MNE] for the particular medicine.

[8] The Board has set out two six-month reporting periods per year and within 30 days of the end of each period, the patentee is required to fill out a "Form 2" setting out average price data for the period. The average transaction price [ATP] is the total net revenue for all package sizes sold during the pricing period divided by the number of units sold. During the benchmark period, the period from the date of the first sale to the end of the six-month period, the ATP is presumed not to be excessive if it does not exceed the MNE for the medicine.

[9] According to the Guidelines, a patentee is allowed to increase the price of the medicine (the MNE will increase year-to-year) in line with increases in the consumer price index [CPI] and the Guidelines prescribe a methodology known as the CPI-Adjustment Methodology for implementing these increases.

[10] Following the benchmark period, prices are averaged on an annual basis to determine the ATP for the year. In each year following the benchmark period, the MNE for a given year is based on the previous year's ATP with allowances for a price increase in accordance with the CPI-Adjustment Methodology.[3] Provided the ATP remains at or below the MNE, the patentee will be presumed to be compliant with the *Act*.

[3] In note 5 of the Applicant's memorandum, the methodology at the time of the hearing is described as follows:

> The CPI Methodology … provided that the price of a medicine would be considered excessive if (i) the cumulative increase in the price of the medicine over any three-year period is greater than the cumulative increase in the CPI or (ii) the year to year price increase fro the medicine exceeds 1.5 times the CPI increase.

[11] According to the Guidelines, if the ATP exceeds the MNE by an amount that is too small to trigger an investigation (*de minimus* level),[4] the ATP is considered to be within the Guidelines. Schedule 5 of the Guidelines, which sets out the investigation criteria, also stipulates that "[i]n most instances where a price exceeds the maximum allowable price by an amount too small to trigger an investigation in one year, it is offset by a price below that which is permitted by the Guidelines the following year" [emphasis added]. The respondent stated that this flexibility was allowed after extensive consultation as it was felt to be an acceptable balance considering the Board's mandate to protect the public against excessive pricing versus the practical realities of overseeing about 1,200 patented medicines in Canada with limited resources. The criteria for commencing an investigation are intended to ensure that all significant cases of pricing outside the Guidelines will be subject to an investigation and "to balance the need for pricing flexibility on the part of the patentee with the [Board's] mandate of protecting consumers […]." (Guidelines (2009), Schedule 5, Annex A).

[12] Board Staff sends patentees a "review and onside letter" advising them of the compliance status of their medicines. Such form letters include statements which will be referred to in dealing with Sanofi's argument with respect to reasonable expectations (see footnote in para 33 below).

[13] Where the price appears to be outside the Guidelines, Board Staff may conduct an investigation pursuant to the Guidelines. If the investigation confirms the price exceeded the Guidelines, the matter will be referred to the chairperson of the Board who may commence a formal proceeding by issuing a Notice of Hearing.

[4] See Appendix "A".

[14] It appears that a patentee under investigation may sign a voluntary compliance undertaking [VCU] to reduce its price(s) such that it will not exceed the MNE; such VCUs may include remedial actions (paragraph 7.1 of the Guidelines). When the matter is under investigation, the VCU must be approved by the Chairperson of the Board and if a Notice of Hearing has been issued, it must be approved by the Board itself.

[15] Paragraph 7.6 of the Guidelines provides that, in most cases, the VCUs should specify a payment to Her Majesty the Queen as the means to offset the excess revenues. However, it appears that in two instances referred to during this hearing, a VCU that included the lowering of the price of a medicine for a period of time to offset the excessive revenues from previous years was approved (Applicant's Record, Vol 2, Tab 13C, 13D). This even though the price reduction had been put in place before the VCU was approved.

[16] When a hearing proceeds, Board Staff fill a prosecutorial role.

[17] As noted by Justice Anne MacTavish in *Pfizer Canada v Canada (Attorney General)*, 2009 FC 719, it is worth mentioning again that the Board's mandate is not to set prices for patented medicines in Canada, rather, its duty is to ensure that a patentee is not selling at a price which, in the opinion of the Board, is excessive. The Board is a "watchdog", to use the expression of then Minister of Consumer and Corporate Affairs Harvie Andre (see paragraph 60 in *Pfizer*) when he introduced the Bill which established the Board in 1987.

[18] Subsection 85(1) of the *Act* sets out some factors that must be considered by the Board in determining if a price is excessive. When the Board finds that, in its opinion, a price is excessive; subsection 83(1) of the *Act* empowers it to order the patentee to reduce its price thereby preventing the patentee from continuing to charge a price which the Board considers excessive. This was described as an important part of the Board's mandate when the Act was further amended in 1993 (see *Celgene Corp v Canada (Attorney General),* 2011 SCC 1 at para 27).

[19] In contrast, subsection 83(2)[5] is retrospective and allows the Board to make an order requiring the patentee or former patentee to offset ("compenser" in French) the amount of the excess revenues a patentee derived from the sale of the medicine at an excessive price.

[20] The *Act* also provides at subsection 83(4) that the Board may issue an order directing a patentee to offset ("compenser" in French) no 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 where it has been established that the said person has engaged in a policy of selling the medicine at an excessive price.

[21] The main arguments before the Board related to whether, in the particular circumstances of this case, the application of the factors set out in subsection 85(1) of the *Act* would warrant applying a CPI-Adjustment Methodology different from the one set out in the then-current Guidelines and to apply instead a methodology based, at least in part, on the Guidelines applicable prior to 1994. This included various concepts put forward by Sanofi's expert, Dr. Martyszenko, such as banking cumulative deficiencies. This expert's presentation included an opinion that Sanofi should be

entitled to a credit when the ATP was lower than the MNE, such as in 2007 and 2008 in particular, thereby offsetting any cumulative excess revenues recorded for the period between 2002 and 2006.[6] This was submitted as the second material difference between Board Staff's position and Sanofi's position on whether or not there were excess revenues at all.

[22] In its written submissions to the Board, Sanofi's brief comments dealing with the issue of remedy (Applicant's Record, Vol 9, Tab 26 at 73, section D) address the general principles and then expressly refer back to their submissions on the calculation of excessive revenues, using the methodology advocated by Dr. Martyszenko and state why this method should be adopted (see, for example, Applicant's Record, Vol 9, Tab 26 at para 286 referring to earlier paras 171-186).[7] This may explain why this application was argued before the Court by reference to the reasons (paragraphs 54-57) found in the middle of the Board's decision under the heading "Off-setting excessive revenues with sales below the MNE" as opposed to those under the heading "Remedy".

[23] In fact, in the section entitled "Remedy" (paragraph 84), the Board simply states that it requires Sanofi to:

> […] offset the excessive revenues that were earned by [Sanofi], as determined by the conclusions in this decision. The calculation of excessive revenues for the sales of Quadracel and Pentacel should be undertaken on the basis advocated by the Board Staff, but with the ATP and MNE of Quadracel and Pentacel calculated as if Ontario discounts had not occurred.
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> [Amended decision, dated March 2010]

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[5] As well as subsection 83(3).
[6] Testimony of Dr. Martyszenko, Applicant's record, Vol 8 at 2361, 2383-2384.
[7] The oral arguments on this point were also brief.

[24] The panel did not say in its reasons that payment should be made to Her Majesty the Queen. Rather, the panel requested the parties to present it with a draft order that implements the terms of the decision and that it would remain seized and willing to assist in the event of disagreement.

[25] It is important to mention, however, that the above quoted "Remedy" paragraph 84 in its original form reads as follows:

> The Panel considers that the most appropriate remedy in this case, given the stability of the customer base for Quadracel and Pentacel, is that the Respondent reduce the price at which it sells Quadracel and Pentacel (to any customers) during the term of the Respondent's current contract with the Government of Canada, to a level that offsets the excessive revenues that were earned by the Respondent, as determined by the conclusions in this decision. […]
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> [Original decision, dated December 2009]

[26] At paragraph 41 of its written submissions, the respondent indicates (and this was not disputed by Sanofi) that Sanofi subsequently submitted, and the Board staff agreed, "that paragraph 84 of the Decision should be amended to provide for a lump sum payment to Her Majesty as opposed to a price reduction. The Board accepted these submission[s] and amended paragraph 84 accordingly […]." As a result, on March 16, 2010, the Board ordered a payment of the amount mentioned above to Her Majesty in Right of Canada to be paid on or before April 15, 2010.

[27] To complete the picture, one must have in mind the main arguments put forward to the Board with respect to the remedy sought by Board Staff, i.e. disgorgement of the excess revenues made by Sanofi.

[28] First, as before me, Sanofi argued that the Board has discretion not to issue an order at all pursuant to subsection 83(2) of the *Act*. It said that the Board should exercise its discretion in this case because all excess revenues (whatever method was chosen by the Board) were effectively compensated for or offset by the lower prices set out in 2007 to the benefit of the very same customers[8] that paid the excessive prices in 2002-2006. Thus, in Sanofi's view, to order a payment or a further price reduction would amount to a penalty or a punitive order which was outside the jurisdiction of the Board pursuant to subsection 83(2) of the *Act*. In that respect, it referred to and quoted (see Applicant's Record, Vol 9, Tab 26 at 77) the following extract of the evidence given by Mr. Kreker of Public Works and Government Services Canada in an answer to a question as to whether he was aware that the Board was reviewing the prices paid in the 2002-2006 period:

> Furthermore, the 2007 pricing, because we were going competitively, would not have been impacted, or a contract would not have been impacted by the results of that particular Board. Because we fully expected the prices to drop significantly from what we were paying before, so if there was an issue of excessive pricing it would have disappeared as a result of the competition.[9]
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> [emphasis added by the applicant]

[29] Second, relying mostly on this Court decision in *Leo Pharma Inc v Canada (Attorney General)*, 2007 FC 306 [*Leo Pharma*] at paragraphs 56 and 69, Sanofi argued that "[t]o require a patentee to prove that it reduced its price for the purpose of complying with the Current Guidelines before a price reduction can be considered to address alleged excessive revenues is contrary to the *Patent Act* and the Board's mandate under it" (Applicant's record, Vol 9, Tab 26 at para 180).

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[8] Sanofi had submitted that over 99% of its vaccine sales in Canada were made to the provinces and territories (Memorandum at para 16). The Board agreed that the customer base was stable (see paragraph 84 of Decision of December 2009).

[9] Confidential Written Closing Submissions of Sanofi at 77 citing Kreker at C137. The Court does not fully understand how this evidence supports Sanofi's position given that Mr. Kreker's expectations were based on the fact that the 2007 pricing was to be set in the context of a competitive bid. It may eliminate the need for a subsection 83(1) order but is says little about the repayment of excessive revenues earned, if any, prior to 2007.

[30] This argument was apparently put forth as a complete answer to Board Staff's argument that, in the particular circumstances of this case, the factual scenario was so different in 2007 from the one in the period from 2002-2006 that the lower price paid by the customers in 2007 had nothing to do with the concept of compensation for the excessive prices paid in the previous four years or disgorgement of the revenues made, the patentee's obligations under this legislation. It certainly did not compensate these customers for the excess they paid in the past.

[31] It is not disputed that, in 2007, Sanofi, as mentioned by Mr. Kreker above, was in a competitive tender with another potential Canadian supplier (GlaxoSmithKline [GSK]) and that therefore, naturally, the price of the vaccines would be substantially lower than what it was before.

[32] In 2002-2006, Sanofi was in a monopoly situation where its main clients, the governments – like any other customer, relied on the Board's oversight to ensure that prices set in their contracts were not excessive.[10] It is not disputed that Mr. Kreker also confirmed that, in those days, the governments were essentially price-takers.

[33] Thirdly, (Sanofi did not insist much on this argument at the hearing before me) the applicant argued that, in 2007, when it reduced its prices, it acted on the legitimate expectation that it could offset its excessive revenues by reducing its price below the MNE for 2007-2008. This belief was allegedly based on some correspondence with Board Staff[11] and the two previous VCUs where, as

[10] Testimony of Mr. Kreker in Applicant's Record, Vol 5 at 1539-1540.
[11] Examples include letters from Board Staff in the Applicant's Record, Vol 1, Tab 7C – 7R; Vol 2, Tab 13A, Tab 13K, where the following passage is recited:

mentioned, the Board approved the price reduction already conceded by the patentees before – and not as a result of – entering into the VCUs. Moreover, Sanofi's expert stated that there is nothing in the *Act* that restricts the patentee's ability to offset the price through price reductions below the MNE for reasons other than compliance with the *Act* and the Guidelines (Applicant's record, Vol 8 at 2366-2368).

[34] With all this in mind, it is now worth reproducing the five paragraphs of the decision on which the parties have argued this judicial review.

> 53. The Respondent, assisted by the evidence of Mr. Martyszenko, proposed that revenues from the sale of Quadracel and Pentacel at prices that exceeded its MNE in a given year should be offset by sales during other years at prices that were below the MNEs of Quadracel and Pentacel.
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> 54. The Guidelines, implementing paragraph 85(1)(a) of the Act, allow for price averaging on an annual basis. In other words, within each calendar year, the price of the medicine in Canada is determined by price averaging that results in sales above the MNE being averaged with sales below the MNE. Patentees report average prices for the January-June and July-December periods, and these two periods are themselves averaged to determine the annual average transaction price. This gives patentees a reasonable level of flexibility without exposing purchasers, on average over the course of the year, to increases beyond those in line with annual CPI increases. The patentees of virtually all of the medicines under the Board's jurisdiction operate within these bounds.
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> 55. The Panel believes that the Board would not be fulfilling its mandate to protect consumers from excessive prices of patented medicines if it allowed patentees to average price excesses and prices below the MNE over periods of time greater than one year, and especially over periods of time chosen by the patentee. Such an approach would allow a patentee to charge excessive prices for a period of years without regulation by the Board, with the patentee

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For those drug products where the price has exceeded the Guidelines but have not become the subject of an investigation, it is the policy of the Board that companies should undertake the necessary measures in future periods to reduce any excess revenues to zero. This can be achieved by pricing a drug product below its maximum non-excessive price until such time as the excess revenues are eliminated.

> relying on lower prices in a subsequent period chosen by the patentee to avoid sanction for the excessive prices. There would be no protection for consumers during the periods that the patentee chose to charge excessive prices. The later reduction in prices cannot be presumed, or even expected, to remedy the potential harm done during the period of excessive pricing. This is true whether or not the customer base remains the same throughout the two periods, because the effect of the excessive prices on the purchasing decisions made by the customer base will likely be a matter for speculation only.
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> 56. The Respondent noted a prior occasion on which the Respondent was permitted by Board Staff to offset a small amount of excess revenue in one year by price reductions in a subsequent year. Two panels of the Board in other proceedings (regarding the medicines Nicoderm and Copaxone) have disapproved of price averaging outside of individual calendar years, and, for the reasons stated by those panels and in this decision, this Panel concurs in that disapproval.
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> 57. The Guidelines provide that Board Staff will not initiate an investigation of excessive pricing if the quantum of excess revenues is at a *de minimus* level, the excess pricing was inadvertent, and the patentee reverses the excess in the following year. This latitude is not a departure from the overall structure of the Guidelines, which is to limit price averaging to reporting periods in a calendar year. The Panel finds that this approach in the Guidelines is appropriate and was well understood by the Respondent, which approached Board Staff when it realized it was outside its bounds.
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> [emphasis added]

[35] For reasons that will be further detailed later on, the Court is not convinced that these paragraphs were intended by the Board to deal with the remedy aspect of Sanofi's argument. It seems these paragraphs sought to address Sanofi's representation that a credit should be given for the sales at prices below the MNE in 2007-2008 to determine if there were indeed excessive revenues[12] (the first issue to be dealt with by the Board under s. 83(2)). The fact that the Board's decision includes a section dealing expressly with remedies (especially the original version of

[12] Applicant's record, Vol 8 at 2371-2382.

paragraph 84) could support the view that, in fact, the Board simply did not deal with this aspect of Sanofi's arguments.[13] Obviously, this could be problematic for, in such circumstances, it may have been quite difficult for the respondent to argue that the decision meets a reasonableness standard. At best, I believe that these comments should be read keeping in mind that the Board had to deal with "the two faces of this coin".

[36] That said, both parties argued the case on the basis that the above-cited paragraphs were the reasons on which I should determine the validity of the Board's conclusion with respect to the remedy it ordered. I will therefore do so.

Analysis

A. Did the Board exceed its jurisdiction by imposing a penalty on Sanofi?

[37] By characterizing the decision to impose a price reduction or a payment as an excess of jurisdiction, Sanofi can argue that the standard of review is correctness (*Dunsmuir v New Brunswick*, 2008 SCC 9 at para 50; *Pfizer*, above, at para 51).[14]

[38] The respondent submits that the question before the Board was not a true question of jurisdiction, but rather whether, on a proper analysis of all the facts and the power granted under

[13] The fact that the same arguments were raised for two different purposes would certainly be confusing, particularly to the Board members whose expertise is directed to economic, pricing, and pharmaceutical products. This portion of the argument was towards the end of the hearing and it certainly appeared, from paragraph 83 of the decision, dealing with Board Staff's allegations of police of excessive pricing (subsection 83(4)) that the Board did not fully recall that in fact Board Staff had, toward the end of the hearing, withdrawn this allegation altogether (Applicant's record, Vol 9 at 2669).
[14] See however doubts raised in that respect in *Celgene*, above, at paras 33-34.

subsection 83(2) of the *Act*, it was appropriate for it to order that the excessive revenues be offset though one of the methods set out in that provision.

[39] In its written submissions, Sanofi indicated at paragraph 43 that Board Staff had argued that "subsection 83(2) of the *Act* did in fact grant the Board punitive powers and the ability to 'fine' a patentee for a 'past wrong'". It appears, however, from a review of the transcript[15] that the Board Staff's position about the whole provision was more nuanced than that. In effect, this comment was made only with respect to an order providing for payment to Her Majesty as opposed to an order for a reduction in price which was described as purely remedial. The respondent then clarified that it was not looking for a punitive order but rather for a remedy for a past wrong because they felt here that consumers had not been compensated for the excessive pricing. That said, it is not clear to the Court that the parties at this stage were using the word "punitive" in the same sense.[16]

[40] At the hearing before me, the respondent clearly had time to reflect further on the matter and confirmed that any order under subsection 83(2) was clearly meant to be restorative in the sense that the purpose of the order is to put the patentee in the position it would have been in but for the excessive prices. None of the options set out in paragraphs 83(2)(*a*)(*b*) and (*c*) of the *Act* are meant to be "punitive", in the sense used by Sanofi.

[41] Generally, I would agree with the respondent that there should be, in fact, only one issue here and that is, whether or not the decision to issue an order for a payment or a price reduction

[15] Applicant's record, Vol 9 at 2696-2697.
[16] This certainly confirms to the need to always look at the context in which one uses a word.

in the amount of the excessive revenues as determined by the Board in the particular circumstances of this case was reasonable or not, for under this standard of review the Court could deal with all the issues raised by the applicant.

[42] However, I understand that the distinction made by Sanofi's counsel between its first and second issues is that if, as a matter of fact, the order issued can only be described as a punitive award, and the imposition of a penalty is outside of the Board's powers, there is no reason to ask oneself the further question of whether the decision falls within a range of possible, acceptable outcomes which are defensible on the facts and the law. Simply put, for Sanofi, it is clear that the Board was bound to conclude that no order could be issued because there had already been an "offset" of the maximum amount allowed by subsection 83(2) – its excess revenues.

[43] Although the Court recognizes that, as suggested by the respondent, this may well be a clever way to circumvent the application of more deferential standard of review. I have decided to deal with it in the manner proposed by the applicant, since this is not in any way determinative of this application.[17]

[44] As mentioned and confirmed during the hearing before me, it appears that the parties have no real dispute[18] as to the meaning of subsection 83(2) of the *Act* that would impact on the determination of the questions raised in this application, for I understand that the respondent

[17] As noted by the Supreme Court of Canada in *Celgene,* above, even if parties should not be allowed to contract out of the appropriate standard of review, this is not of great importance when a decision would be upheld under the stricter standard anyway.

[18] The fact that this question of law is not in play certainly militates in favor of characterizing the question left to be determined as one of fact or at best, mixed fact and law subject to a standard of reasonableness.

maintains that if indeed the Board imposed a penalty or a punitive award then it acted outside its jurisdiction.

[45] Thus, to address this question of excess of jurisdiction, I must assess if the factual premise on which Sanofi relies has been established – that is, if Sanofi has established on a balance of probabilities that the imposition of any payment or further price reduction was or ought to be considered punitive.

[46] First, Sanofi submits that the use of the word "sanction" in paragraph 55 of the Board's reasons clearly indicates that the Board believed it had punitive powers under subsection 83(2) of the *Act* and purported to exercise such powers in this case.

[47] Although the Court recognizes that, in certain circumstances, the use of that expression may be sufficient to infer that a decision maker intended to impose a penalty (see *Thibeault v Canada (Minister of Fisheries and Oceans)* (1996), 7 Admin LR (3d) 70 (FCTD) at paras 27-35 and *Matthews v Canada (Attorney General)* (1996), 43 Admin LR (2d) 143 (FCTD) at paras 11-13, 21, aff'd [1999] FCJ No 830 (CA)) the Court must be careful to look at this wording in its proper context. In this instance, in my view, considering the general statements set out in the first part of paragraph 55, the Board is still dealing with the issue of excessive prices (first aspect of the argument put forth by Sanofi). In that context, it may well be referring to its powers generally, which do include the power to punish as was acknowledged by Sanofi who referred to subsection 83(4) of the *Act* as but one example of this. But, more importantly, this statement is followed a few lines down by a more specific reference to "the later reduction in prices cannot be presumed, or

even expected, to remedy the potential harm done […]" [my emphasis]. Would this not suggest compensation for harm done as opposed to punishment? As a whole, the convoluted wording used in this paragraph, read in context, makes it extremely difficult, if not impossible, for the Court to understand exactly the Board's intention with respect to its order under subsection 83(2) of the *Act*.

[48] Also considering that the Board had determined that the proper remedy was a price reduction (original paragraph 84) and that neither party had advocated before the Board that such an order was intended to punish, I am not willing to infer, as suggested, that the simple use of the word "sanction" is sufficient here to conclude that the Board purported to issue a punitive award.

[49] Second, Sanofi says that like in *Leo Pharma* above, whatever its intent, the simple fact that its price was reduced below the MNE for a number of units, which covered the excessive revenues established by the Board in respect of the preceding five year period, is sufficient to establish that any further order pursuant to subsection 83(2) of the *Act* ought to be penal in nature. In effect, as the Board's mandate was fulfilled, it simply ought not to have intervened.

[50] In my view, the decision of this Court in *Leo Pharma* is not particularly helpful here. In effect, in that case, Justice Blais had to determine whether the Board's finding with respect to excessive pricing was reasonable or not. In that context, he had to consider the factors set out in section 85 of the *Act* as well as the *Patented Medicine Regulations*, 1994 SOR/94-688 [the *Regulations*], particularly subsection 4(4) which clearly stated that the price to be used in calculating the average price per package of medicine, was the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods.... The Court's conclusion that

the patentee's intent in giving out free goods was irrelevant to determine if such free goods should be included in the calculation of the average price was based on the fact that through the *Regulations*, Parliament had provided very clear directives on the assessment of the average price of the medicine. If it had intended to limit the "free goods" to be included in the calculation to those distributed in the context of charitable campaigns, it would have done so.

[51] It is of interest that at paragraph 55 of its decision, the learned judge notes that in other respects, Parliament may have been rather vague in setting out the considerations that should apply thereby giving the Board more leeway to determine these issues.

[52] In the present case, the legislator could have simply provided that the patentee had to disgorge the excessive revenues it earned, leaving it to the patentee to determine when and how this should be done. Instead, in 1993, it chose to give the Board a strengthened mandate and the power to intervene with respect to offsetting/compensation to protect consumers' interests by adding, among other things, subsection 83(2) in the *Act*.

[53] The Court agrees with Sanofi, that this does not mean that in this regime, which favours voluntary compliance, a patentee cannot voluntarily take steps to offset excessive revenues earned as soon as they wish to do so. If patentees choose this route, without seeking the Board's or the chairperson of the Board's approval through a VCU, for example, they do so at their own peril since the Board, who is accountable to Parliament to fulfill its mandate, can always review their actions to ensure that they have indeed provided proper compensation.

[54] Sanofi says that this is a special case because its client base remained the same throughout. Thus, price reductions conceded to these customers should be an appropriate means of offsetting or compensating for the harm done. Although in other cases this may well be so, in the particular circumstances of this case, I cannot agree with the applicant. In effect, here, regardless of Sanofi's intention[19] and focussing only on the factual scenario, there is simply no evidence establishing that, on a balance of probabilities, this customer base actually benefited of a price reduction that properly compensated them for the amount they paid in excess had Sanofi not charged them excessive prices in 2002-2006.

[55] The Court asked the parties to provide, in writing, a list of the evidence that could be relevant to the issues before it.

[56] As mentioned earlier, although the prices in 2007 and 2008 were substantially lower than in 2006 and were below their MNE,[20] Sanofi presented no evidence that would definitely establish that, on a balance of probabilities, such reduction was in any way different – let alone substantially different – than the reductions that normally occur when a patented pharmaceutical product like theirs is put to tender in a competitive environment for the first time.[21] Mr. Kreker was quite clear that he expected a significant drop in price and this clearly had nothing to do with the excessive revenues earned by Sanofi.[22]

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[19] Be it its intention to lower its price to retain this market or its intention to offset its excessive revenues based on its alleged legitimate expectations.
[20] "Offset" or "compensate" does not necessarily mean in all cases, as suggested by Sanofi, "the averaging of excessive and non-excessive prices for a medicine so that any express revenues are reduced to zero."
[21] Until then, Sanofi was also the only licensed supplier of the vaccines in question.
[22] See also, Applicant's record, Vol 9 at 2706, paras 32-37 (confidential version).

[57] Having carefully reviewed the material provided, the Court cannot agree with Sanofi that, in the circumstances, the Board's order was or ought to be considered a punitive award.

[58] This means that there is a range of possible, acceptable outcomes which were defensible on law and the facts. I must, thus, consider if what the Board did falls in this range.

B. Did the Board exceed its jurisdiction by abusing its discretion?

[59] Sanofi argues that the Board ordered it to offset its excessive revenues based on pure speculation and conjecture and while ignoring the evidence. It says that it never meaningfully considered the circumstances of the case before it. Thus, it is fair to reframe this question simply as whether or not the decision made was reasonable. In effect, both parties agree that however one frames the question it involves a question of fact or mixed fact and law which must be reviewed on the standard of reasonableness. Considering the decisions of this Court in *Hoechst Marion Roussel Canada Inc v Canada (Attorney General)*, 2005 FC 1552 and in *Leo Pharma*, above, where the Court reviewed the nature of the review mechanisms available, the relative expertise of the Board, the purpose of the *Act* in the context of mixed questions of fact and law, I cannot but agree with the parties that this standard should also apply to pure questions of fact (*Dunsmuir*, above, at para 57).

[60] This leaves the issue of the fettering of discretion as Sanofi argues that the Board blindly followed its Guidelines and past Board decisions. Although in *Thamotharem v Canada (Minister of Citizenship and Immigration)*, 2007 FCA 198 at para 33 the Federal Court of Appeal applied a correctness standard to determine whether the application of a particular guideline was an unlawful

fettering of discretion, in the more recent case of *Waycobah First Nation v Canada (Attorney General)*, 2010 FC 1188 at para 23,[23] the Court applied the reasonableness standard to this question of law, which is not of central importance to the legal system and is not outside the specialized area of the administrative decision-maker.

[61] In the present case, I am far from convinced that the question before me is truly one of law and in any event I would have concluded that I should apply the standard of reasonableness considering that Sanofi's real concern is not that the Board felt compelled to apply the Guidelines and follow its previous decisions, but rather that its approach in determining whether to apply them was deficient.

[62] In effect, the Court agrees with the Respondent that the Board clearly appreciated that the Guidelines were not binding on it as it rejected some arguments by Board Staff and made significant findings that departed from the Guidelines, based on its consideration of the particular facts of the case. The Board mentions at the end of paragraph 57, that it finds the approach taken in the Guidelines appropriate and in paragraph 56 that it concurs with the reasoning of the two panels in the Nicoderm and Copaxone proceedings as opposed to simply their conclusions.

[63] The real problem if the Board was truly directing itself to the issue of compensation under subsection 83(2) of the *Act* in these paragraphs (53 to 57), is to determine how the Guidelines and the cited Board decisions deal with the particular issue facing the Board. Also, once this is done, whether it is a reasonable answer in this particular case.

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[23] See *Smith v Alliance Pipeline Ltd*, 2011 SCC 7, at para 37.

[64] For example, in paragraphs 56 and 57 did the Board mean to say that any remedial action taken by a patentee under investigation, outside of a VCU and without a prior Board order, should be disregarded and considered inappropriate to compensate or offset excessive revenues, whatever the circumstances?

[65] If this were so, considering my comments in para 53 above, it would likely not be an acceptable outcome justifiable on the law.

[66] On the other hand, were these paragraphs simply intended to deal with Sanofi's argument that its position with respect to compensation and offsetting, was in line with the Board's past practice (including for example, the VCUs in the Forteo and Aromacin proceedings),[24] and to address its argument that they genuinely had a legitimate expectation that the method they chose to offset their excessive revenues was acceptable (based on the general wording of the Guidelines and correspondence with Board Staff)?

[67] Considering the parameters of the doctrine of legitimate expectations (see *Canada (Attorney General) v Mavi*, 2011 SCC 30 at para 68) it may well be open to the Board to find that the previous VCUs and the fact that the Board had already issued two decisions contradicting Sanofi's interpretation of these VCUs, combined with the Guidelines (as understood by Sanofi) cannot constitute clear, unambiguous and unqualified representations on which Sanofi could base its legitimate expectation.

[68] What did the Board mean when it said that "the later reduction in prices cannot be presumed, or even expected, to remedy the potential harm done […] this is true whether or not the customer base remained the same throughout the two periods […]"? Could this really be intended to deal with this particular case when one considers that in its original paragraph 84, the Board decided that it was appropriate to remedy the harm done in this case through a price reduction because the customer base remained essentially the same?

[69] When it notes, in the last two sentences of para 55, "because the effect of excessive prices on the purchasing decisions made by the customer base will likely be a matter for speculation only", was the Board making a finding based on the evidence it heard or was it making a general statement? If the former, was this conclusion reached because of the lack of credibility of a particular witness or was it because the probative value of the evidence produced was simply insufficient?

[70] The standard of review applicable here requires that the Court inquires into the justification, transparency and intelligibility of the decision.

[71] In *Vancouver International Airport Authority v Public Service Alliance of Canada*, 2010 FCA 158 [*Vancouver*] recently followed in *Holmes v Canada (Minister of Public Safety and Emergency Preparedness)*, 2011 FC 112 at paragraph 43, the Federal Court of Appeal revisited the issue of adequacy of reasons setting out some very fundamental purposes this obligation seeks to achieve. It is worth reproducing paragraph 16 of *Vancouver*, above:

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[24] Applicant's Record, Vol 2, Tabs 13C and 13D. In Forteo, the patentee was permitted to offset excessive revenues from July 2004 to December 2006 with reduced prices in 2007. At the end of 2007 it still had excessive revenues owing and

Where, as here, an administrative decision-maker, acting under a procedural duty to receive and consider full submissions, is adjudicating on a matter of significance, what sort of reasons must it give? From the above authorities, and bearing in mind a number of fundamental principles in the administrative law context, the adequacy of the decision-maker's reasons in situations such as this must be evaluated with four fundamental purposes in mind:

(a) *The substantive purpose*. At least in a minimal way, the substance of the decision must be understood, along with why the administrative decision-maker ruled in the way that it did.

(b) *The procedural purpose*. The parties must be able to decide whether or not to invoke their rights to have the decision reviewed by a supervising court. This is an aspect of procedural fairness in administrative law. If the bases underlying the decision are withheld, a party cannot assess whether the bases give rise to a ground for review.

(c) *The accountability purpose*. There must be enough information about the decision and its bases so that the supervising court can assess, meaningfully, whether the decision-maker met minimum standards of legality. This role of supervising courts is an important aspect of the rule of law and must be respected: *Crevier v. Attorney General of Quebec*, [1981] 2 S.C.R. 220; *Dunsmuir, supra* at paragraphs 27 to 31. In cases where the standard of review is reasonableness, the supervising court must assess "whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law": *Dunsmuir, supra* at paragraph 47. If the supervising court has been prevented from assessing this because too little information has been provided, the reasons are inadequate: see, *e.g., Canadian Association of Broadcasters, supra* at paragraph 11.

(d) *The "justification, transparency and intelligibility" purpose*: *Dunsmuir, supra* at paragraph 47. This purpose overlaps, to some extent, with the substantive purpose. Justification and intelligibility are present when a basis for a decision has been given, and the basis is understandable, with some discernable rationality and logic. Transparency speaks to the ability of observers to scrutinize and understand what an administrative decision-maker has decided and why. In this case, this would include the parties to the proceeding, the employees whose positions were in issue, and employees, employers, unions and businesses that may face similar issues in the future. Transparency, though, is not just limited to observers who

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was required to make a payment. In Aromasin, the 2001 excessive revenues were offset with price reductions in 2002.

> have a specific interest in the decision. The broader public also has an interest in transparency: in this case, the Board is a public institution of government and part of our democratic governance structure.

[72] The Court also sets out a number of important principles established in prior authorities that must be kept in mind when determining whether these fundamental purposes are met. The first principle is that extraneous material can be relevant to understand why a decision-maker ruled the way he or she did. Second, "[t]he adequacy of reasons is not measured by the pound". Thirdly, a judge ruling on adequacy of reasons must not be allowed to frustrate Parliament's intention to remit decisions to specialized administrative tribunals and "should make allowance for the 'day-to-day realities' of administrative tribunals". Finally, judges should practice judicial restraint and ensure only that legal minimums are met (see paragraph 17).

[73] Having read and re-read the relevant portions this decision a number of times, the Court simply cannot decipher on what basis the Board discarded, in the unique circumstances of this case, Sanofi's argument that it had, either totally, if not at least in part, compensated for its excessive revenues. The respondent insisted at the hearing before me, that in the particular circumstances, considering that Sanofi was engaged in a competitive bidding process, the decision made sense. However, nowhere does the Board refer to this circumstance which was at the core of Board Staff's position. Where does it fit in the reasons expressed in paragraphs 53-57? Was it even considered?

[74] The Court is simply not in a position to exercise its duty to review the legality of the Board's decision and to determine if it was within the range of possible and acceptable outcomes. The decision does not meet the applicable standard. It is not reasonable because of its lack of

transparency, intelligibility and justification. It must be set aside and the matter remitted for reconsideration.

[75] The parties have agreed that the costs in this matter should be fixed at $12,000.00 (inclusive of disbursements and GST).

[76] Since the Board's order of March 16, 2010 is now a nullity, the payment made by Sanofi in the amount of $2,512,878.74 to the Consolidated Revenue Fund should be returned promptly to the Applicant together with appropriate interest. The Respondent is requested to give prompt attention to this matter.

POSTSCRIPT

[1] These Reasons for Judgment are un-redacted from confidential Reasons for Judgment which were issued on July 8, 2011.

[2] The Court canvassed counsel for the parties whether they had concerns if the reasons were issued to the public without redactions and they confirmed they had none.

JUDGMENT

THIS COURT'S JUDGMENT is that this application is allowed with costs to the applicant fixed in the amount of $12,000.00 which is inclusive of all fees, disbursements and GST. The order dated March 16, 2010 is declared null and void and the respondent is requested to give prompt attention to the matter of the return to the applicant of the sum of $2,512,878.74 together with appropriate interest.

"Johanne Gauthier"

Judge

APPENDIX "A"

***Patent Act*, RSC 1985, c P-4**

Excessive Prices	Prix excessifs
Order re excessive prices 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.	Ordonnance relative aux prix excessifs 83. (1) Lorsqu'il estime que le breveté vend sur un marché canadien le médicament à un prix qu'il juge être excessif, le Conseil peut, par ordonnance, lui enjoindre de baisser le prix de vente maximal du médicament dans ce marché au niveau précisé dans l'ordonnance et de façon qu'il ne puisse pas être excessif.
Idem (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:	Idem (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 :
(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.

Idem
(3) Subject to subsection (4), where the Board finds that a former patentee of an invention pertaining to a medicine had, 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 former 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 former patentee from the sale of the medicine at an excessive price:

Idem
(3) Sous réserve du paragraphe (4), lorsqu'il estime que l'ancien breveté a vendu, alors qu'il était titulaire du brevet, le médicament 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 à l'ancien breveté la vente du médicament au prix excessif :

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

a) baisser, dans un marché canadien, le prix de vente de tout autre médicament lié à une invention dont il est titulaire du brevet dans la mesure et pour la période prévue par l'ordonnance;

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

b) payer à Sa Majesté du chef du Canada le montant précisé dans l'ordonnance.

Where policy to sell at excessive price
(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

Cas de politique de vente à prix excessif
(4) S'il estime que le breveté ou l'ancien breveté s'est livré à une politique de vente du médicament à un prix excessif, compte tenu de l'envergure et de la durée des ventes à un tel prix, le Conseil peut, par ordonnance, au lieu de celles qu'il peut prendre en application, selon le cas, des paragraphes (2) ou (3), lui enjoindre de prendre l'une ou plusieurs des mesures visées par ce paragraphe de façon à réduire suffisamment les recettes pour compenser, selon lui, au plus le double de l'excédent procuré par la vente au prix excessif.

patentee or former patentee from the sale of the medicine at an excessive price.

Excess revenues
(5) In estimating the amount of excess revenues under subsection (2), (3) or (4), the Board shall not consider any revenues derived by a patentee or former patentee before December 20, 1991 or any revenues derived by a former patentee after the former patentee ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

Excédent
(5) Aux fins des paragraphes (2), (3) ou (4), il n'est pas tenu compte, dans le calcul de l'excédent, des recettes antérieures au 20 décembre 1991 ni, dans le cas de l'ancien breveté, des recettes faites après qu'il a cessé d'avoir droit aux avantages du brevet ou d'exercer les droits du titulaire.

Right to hearing
(6) Before the Board makes an order under this section, it shall provide the patentee or former patentee with a reasonable opportunity to be heard.

Droit à l'audition
(6) Avant de prendre une ordonnance en vertu du présent article, le Conseil doit donner au breveté ou à l'ancien breveté la possibilité de présenter ses observations.

Limitation period
(7) No order may be made under this section in respect of a former patentee who, more than three years before the day on which the proceedings in the matter commenced, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

Prescription
(7) Le présent article ne permet pas de prendre une ordonnance à l'encontre des anciens brevetés qui, plus de trois ans avant le début des procédures, ont cessé d'avoir droit aux avantages du brevet ou d'exercer les droits du titulaire.

[…]

[…]

Factors to be considered
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:

Facteurs de fixation du prix
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 :

(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

b) le prix de vente de médicaments de la

in the same therapeutic class have been sold in the relevant market;

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.

Additional factors
(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:

Facteurs complémentaires
(2) Si, après avoir tenu compte de ces facteurs, il est incapable de décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil peut tenir compte des facteurs suivants :

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

a) les coûts de réalisation et de mise en marché;

(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.

b) tous les autres facteurs précisés par les règlements d'application du présent paragraphe ou qu'il estime pertinents.

Research costs
(3) 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

Coûts de recherche
(3) Pour l'application de l'article 83, le Conseil ne tient compte, dans les coûts de recherche, que de la part canadienne des coûts mondiaux directement liée à la recherche qui a abouti soit à l'invention du médicament, soit à sa mise au point et à sa mise en marché, calculée proportionnellement au rapport entre les ventes canadiennes du médicament par le breveté et le total des ventes mondiales.

sales by the patentee in Canada of that medicine to total world sales.

Patented Medicines Prices Preview Board, *Compendium of Guidelines, Policies and Procedures* (updated to 2009), online: Patented Medicines Prices Review Board <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1034>.

7. Voluntary Compliance Undertakings (VCUs)

7.1 A patentee may make a VCU to adjust its price and to take other remedial action as may be appropriate at any time.

7.2 It is the policy of the Board that only the Chairperson or the Board itself may approve a VCU.

7.3 The Chairperson is authorized to approve a VCU in lieu of issuing a Notice of Hearing if satisfied that it meets the objectives of the Act and conforms to the policies of the Board which may b established from time to time. If the undertaking is made after the issuance of a Notice of Hearing, it may only be approved by the Hearing Panel of the Board as a basis for terminating or adjourning the proceeding following an opportunity for submissions by all parties.

7.4 The Chairperson is not authorized to negotiate the terms of a VCU with a patentee. In deciding whether to accept a VCU, the Chairperson will be guided by section 83 of the Act and the policy of the Board that the price should be adjusted to conform to the Guidelines and that the patentee offset any excess revenues received since the price first exceeded the Guidelines.

7.5 The proposed VCU should include a statement as to the maximum price the patentee proposes to charge for the drug product, and the relevant dates, to be consistent with the Guidelines and policies of the Board, and where appropriate, the means by which it proposes to, offset the excess revenues it received during the period the price was outside the Guidelines.

7.6 In most cases, the VCU should specify a payment to Her Majesty in Right of Canada as the means to offset excess revenues.

7.7 The proposal of a VCU does not constitute an admission by the patentee that the price of the drug product is or was excessive.

7.8 The Board will report publicly on all VCUs accepted by the Chairperson or the Board. The information reported will ordinarily include the names of the drug product and the patentee and such other information as it considers appropriate. This information will be included in the PMPRB´s Annual Report and may also be published in the NEWSletter, on the PMPRB Web site or other publications. Privileged or confidential information will not be included in the report except to the extent that such information has been made public in a proceeding.

8. Remedial Orders

8.1 If the Chairperson is of the view that the investigation has revealed that the price exceeded the Guidelines or otherwise may be or has been excessive, the Chairperson may commence a formal proceeding by issuing a Notice of Hearing and establishing a Hearing Panel of the Board for that proceeding.

8.2 The determination by the Board of the appropriate remedy, if any, in any case will be made by the Board in light of the evidence available to it.

8.3 Where the Board finds, following a public hearing, that the price of a patented drug product is excessive, it may make an order pursuant to subsection 83(1) requiring the patentee to reduce the price of the drug product to a level the Board considers not to be excessive.

8.4 In addition, the Board may order the price to be further reduced, pursuant to subsection 83(2), for a specified period of time to offset any excess revenues received by the patentee. The Board will take into consideration any submissions as to why it may be inappropriate to order such a reduction given the facts of the case.

8.5 In the alternative, or in addition to a price reduction order, the Board may order a price reduction with respect to one other patented medicine being sold by the patentee.

8.6 In the case of a former patentee, the Board may order, pursuant to subsection 83(3), a reduction in the price of another patented medicine to offset the excess revenues received by the former patentee.

8.7 If the above remedies are not considered appropriate, or if there are no medicines with respect to which the Board may make an order, the Board may order the payment by the patentee to Her Majesty in Right of Canada under subsection 83(2), or by the former patentee, under subsection 83(3), as the case may be, of an amount equal to the excess revenues.

8.8 If the Board finds that there has been a policy of selling the drug product at an excessive price, for example if the patentee has failed to comply with a previous price reduction order, the Board may, pursuant to subsection 83(4), order further price reductions or monetary payments to recover twice the excess revenues received by the patentee.

8.9 All orders by the Board, under section 83, will be registered with the Federal Court of Canada pursuant to section 99, and may be enforced thereafter, in the discretion of the Board, as an order of the Federal Court.

8.10 Evidence that a patentee has failed to comply with an order of the Board under section 83 respecting price will be brought to the attention of the Chairperson who may decide to issue a Notice of Hearing.

8.11 If the Board finds that a patentee has failed to comply with an order of the Board respecting price under section 83 it may issue a further order including an order to recover double the excess revenues if it finds that there has been a policy of selling at an excessive price.

8.12 At any time, in lieu of or in addition to the Board´s own proceeding, the Board will refer any evidence that the patentee intentionally failed to comply with an order respecting price to the Attorney-General of Canada for proceedings under subsection 76(1) or contempt of court as may be appropriate.

Schedule 5 – Criteria for Commencing an Investigation

The PMPRB's Compliance and Enforcement Policy provides that the Board may establish criteria for identifying cases for investigation from time to time. The criteria, which are subject to change, may include the amount by which a price exceeds the Guidelines and the amount of excess revenues along with other factors.

The criteria balance the need for pricing flexibility on the part of patentees with the PMPRB's mandate of protecting consumers by ensuring that the prices of patented drug products are not excessive. The Board publishes its criteria for commencing an investigation to improve transparency and to provide patentees with greater certainty as to their responsibilities in the regulatory process.

A price is considered to be within the Guidelines unless it meets the criteria for commencing an investigation. The criteria represent the standards the Board applies in order to allocate its resources to investigations as efficiently as possible. Their existence should not be construed as indicating that the Board accepts any deviation from the Guidelines. The Board is satisfied that its criteria assure all significant cases of pricing outside the Guidelines will be subject to an investigation. In most instances where a price exceeds the maximum allowable price by an amount too small to trigger an investigation in one year, it is offset by a price below that which is permitted by the Guidelines the following year. The Board expects the prices of all patented medicines to be within the Guidelines and evidence of persistent pricing outside the Guidelines, even by a small amount, may be used as a criterion for commencing an investigation.

Should the price of a patented drug product, or its cumulative excess revenues ever meet the criteria, an investigation will be initiated in conformity with the Compliance and Enforcement Policy. If the investigation confirms that the price exceeds the Guidelines, the patentee may choose to voluntarily adjust its price and offset the excess revenues through a Voluntary Compliance Undertaking (VCU).

Patentees will be advised of cumulative excess revenues for each of their DIN´s as part of the compliance reports they receive from the PMPRB. Excess revenues below the amount specified in the criteria can be reduced voluntarily by the patentees in subsequent years by pricing below the maximum non-excessive price. However, cumulative excess revenues cannot fall below zero.

Criteria for Commencing an Investigation
Board Staff will commence an investigation into the price of a patented drug

product when any of the following criteria are met:

New Drug Products

1. The introductory price is 5% or more above the maximum non-excessive price;
2. Excess revenues in the introductory period are $25,000 or more; or
3. Complaints with significant evidence.

Existing Drug Products

1. A price is 5% or more above the maximum non-excessive price and there are cumulative excess revenues of $25,000 or more over the life of the patent after January 1, 1992;
2. Cumulative excess revenues are $50,000 or more over the life of the patent after January 1, 1992; or
3. Complaints with significant evidence.

Patented Medicines Prices Preview Board, *Compendium of Guidelines, Policies and Procedures* (current version), online: Patented Medicines Prices Review Board <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1206&mp=73>.

C.12 Review of Prices of Existing Patented Drug Products

C.12.1 The price of an existing patented drug product will be presumed to be excessive if the National Average Transaction Price exceeds the National Non-Excessive Average Price as determined by the lower of:

- The change in the CPI as per the CPI-Adjustment Methodology (see Schedule 9); or
- The result of the Highest International Price Comparison test (see Schedule 6).

C.12.2 If the National Average Transaction Price exceeds the National Non-Excessive Average Price by an amount which triggers the investigation criteria (see Schedule 11), Board Staff shall review the Market-Specific Average Transaction prices. Board Staff shall also review the prices in these markets, if a complaint is the trigger for the commencement of an investigation.

- The price in each of three classes of customer (hospital, wholesaler, pharmacy) and in each province/territory will be presumed to be excessive if the Market-Specific Average Transaction Price exceeds the Market-Specific Non-Excessive Average Price as determined by the change in the CPI as per the CPI-Adjustment Methodology (see Schedule 9).
- In addition, the price in each of two classes of customer (hospital and pharmacy) and in each province/territory will be presumed to be excessive if the Market-Specific Average Transaction Price exceeds the Market-Specific Non-Excessive Average Price as determined by the Highest International Price Comparison test (see Schedule 6).

C.12.3 In the event that the actual change in the CPI is less than the forecast CPI and an apparent excessive price arises solely due to the patentee's reliance on the forecast CPI, the price will not be presumed to be excessive. The patentee is expected to comply with the actual CPI in all subsequent reporting periods, and the application of the CPI-Adjustment Methodology for the forecasted year will be based on the actual change in the CPI for that year. The result for patentees that took price increases based on the forecast inflation will be that the actual change in the CPI for the forecasted year will be used to calculate the next year's National and Market-Specific Non-Excessive Average Prices.

C.12.4 In addition, when a patentee can demonstrate that an increase in the National Average Transaction Price is due solely to a sales-mix shift and none of the Market-Specific Average Transaction Prices for each class of customer and in each province/territory exceed their respective Market-Specific Non-Excessive Average Prices as determined by the CPI-Adjustment Methodology, the National Average Transaction Price will not be presumed to be excessive.

C.12.5 When the National Average Transaction Price or a Market-Specific Average Transaction Price of a drug product increases from a previous year due to the reduction or end of a benefit(s) and the patentee provides evidence to demonstrate that the price increase was due solely to the reduction or termination of the benefit(s), it may be appropriate to adjust the Non-Excessive Average Prices (national and market-specific) through the DIP Methodology, as described in Schedule 10.

C.12.6 The Board recognizes that there may be cost of making and marketing arguments, whereby it may be appropriate to adjust the Non-Excessive Average Price(s) of a patented drug product (e.g., once a Notice of Compliance has been obtained and the drug product was first sold on a compassionate basis as an Investigational New Drug, through a Clinical Trial Application or under the Special Access Programme).

C.12.7 The PMPRB may review the price of any existing patented drug product in any market in Canada (e.g., by class of customer in a province/territory).

Investigations

C.13 Introduction

C.13.1 When the price of a patented drug product appears to exceed the Guidelines but not by an amount that triggers the investigation criteria (Schedule 11), the patentee will be notified and the patented drug product will be reported on the PMPRB's Web site as "Does Not Trigger Investigation". The patentee will be expected to reduce its National Average Transaction Price and Market-Specific Average Transaction Prices and to offset any excess revenues that may have accrued (see Schedule 13), but no immediate action will be taken by Board Staff.

C.13.2 When the National Average Transaction Price of a patented drug product appears to exceed the National Non-Excessive Average Price and the circumstances are within the criteria established by the Board (Schedule 11), the patentee will be notified of the commencement of an investigation and the patented drug product will be reported on the PMPRB's Web site as "Under Investigation."

C.13.3 The examination will include an analysis of the pricing history of the patented drug product from introduction for both the National Average Transaction Price and Market-Specific Average Transaction Prices (i.e., for each class of customer (hospital, pharmacy, wholesaler) and each province/territory).

C.13.4 The International Therapeutic Class Comparison (ITCC) test compares the price of the patented drug product with the publicly available ex-factory prices in the comparator countries listed in the Regulations of comparable drug products identified in the domestic price test (i.e., the RR or TCC test). The ITCC test will only be conducted on a case-by-case basis if it appears it might provide information in the context of an investigation into apparent excessive prices. It will not be used as a primary price test. This test is described in Schedule 7.

C.13.5 The period of time available to the patentee to respond to Board Staff following a notification that an investigation has been commenced is ordinarily brief. For example, if the patentee should have known that a price would appear excessive based on its own filings (e.g., where the price increased by more than would be permitted under the CPI-Adjustment Methodology), the period of time may be as short as seven calendar days. A longer period of time, 30 calendar days, may be available if it is reasonable to believe that the patentee might have been unaware that the National Average Transaction Price or Market-Specific Average Transaction Prices may appear to be excessive (e.g., if HDAP has recommended the use of different drug products for comparison purposes or dosage regimens from those which were proposed by, and may have been reasonably anticipated by, the patentee).

C.13.6 There are three possible outcomes to an investigation:

- The National Average Transaction Price and/or Market-Specific Average Transaction Prices do not appear to be excessive; or
- The National Average Transaction Price and/or Market-Specific Average Transaction Prices appear to be excessive and the patentee submits an acceptable Voluntary Compliance Undertaking (VCU); or
- The National Average Transaction Price and/or Market-Specific Average Transaction Prices appear to be excessive and the patentee does not submit an acceptable VCU in which case Board Staff will refer the matter to the Chairperson and recommend the issuance of a Notice of Hearing.

Schedule 13 – Offset of Excess Revenues

Approaches to offset excess revenues

1.1 Subject to section 1.3.1 below, if the investigation criteria have not been triggered, patentees will be given the opportunity to take a voluntary price reduction to offset excess revenues.

1.2 Once the investigation criteria have been triggered, patentees will only be permitted to offset cumulative excess revenues pursuant to the specific terms of an approved VCU or a Board Order.

Timeframes to offset excess revenues

1.3 Patentees are expected to offset excess revenues in a timely manner. The following parameters will generally be applied in the determination of repayment terms.

1.3.1 Excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six month reporting periods (3 years) will be expected to be offset through a VCU. Failing this, Board Staff will refer the matter to the Chairperson.

1.3.2 In the context of a VCU, and subject to the specific terms of the VCU, patentees will generally be allowed:

- 30 days following the Board's acceptance of the VCU to make payment; or
- Until the end of the following reporting period to offset excess revenues through a price reduction. Any excess revenues remaining at the end of the specified period would be due in payment.

FEDERAL COURT

SOLICITORS OF RECORD

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