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Toronto, Ontario, November 12, 2009

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

TEVA NEUROSCIENCE G.P.-S.E.N.C.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

[1] These consolidated proceedings relate to two applications for judicial review sought by Teva Neuroscience G.P.-S.E.N.C. of decisions made by the Patented Medicines Prices Review Board in the first of which it was determined by the Board that Teva had priced its medicine,

Copaxone, excessively and, in the second of which, that a payment to the Crown of $2,417,223.29 be made as a result of that determination. For the reasons that follow, I find that the applications are allowed and the decisions are to be sent back for redetermination.

[2] 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.

[3] The Applicant Teva Neuroscience G.P.-S.E.N.C. (Teva) distributes in Canada a medicine under the name Copaxone which is useful in the treatment of multiple sclerosis. That medicine as it was first introduced was packaged in a vial. It subsequently was packaged in a pre-filled syringe. It is the medicine as packaged in a syringe that is the particular subject of these proceedings. There is no dispute between the parties that such Copaxone is a "medicine" within the relevant provisions of the *Patent Act* and that such medicine is the subject of a "patent" within such provisions. In this case it is Canadian Patent 2,191,088 which has an application filing date in Canada of May 23, 1995, and was granted and issued September 28, 2004. There is no dispute between the parties that, for purposes of the Board's decisions and this Court's review of the matter, Copaxone is of the same therapeutic class (as that term is used in s. 85(1) of the *Patent Act*) as competitive medicines distributed by others in the Canadian market, namely Betaseron, Avonex and two versions of Rebif.

[4] In 1997 Teva introduced Copaxone into Canada. It was in vial form. There was one competitor medicine on the market, Betaseron. Teva approached the Board for a preliminary view as to categorization and pricing of its drug. Since Teva had only a pending patent application at the time, the Board took the position that it did not yet have jurisdiction to consider such matters. Nonetheless the Board expressed the view that, since the price of Copaxone was below that of Betaseron ($36.00 per day for Copaxone vs. $44.51 per day for Betaseron), the pricing of Copaxone was, in all probability, not excessive. It is important to note that the price of Betaseron had been previously approved by the Board as being not excessive.

[5] Between 1997 and 2002 Teva made a number of changes to Copaxone, in particular it introduced packaging in the form of a syringe which on March 20, 2002 was granted a separate Notice of Compliance by Health Canada. The syringe form was introduced in the market in Canada on May 15, 2002. The 2,191,088 patent was granted on September 28, 2004. The Board's decision dated February 28, 2008 at paragraph 6 misstates that the patent was directed to the syringe, it is in fact directed to the medicinal composition itself, however, that is immaterial since the parties have not disputed that the patent was sufficient so as to bring Copaxone within the jurisdiction of the Board.

[6] Once the patent issued, Teva was requested by the Board to file information related to pricing both for the earlier vial as well as syringe form of Copaxone. It is important to note that at the time the Board was of the opinion that it could only make such a request after the relevant patent had issued, however since the 2007 decision of this Court in *Shire Biochem Inc. v. Canada*

(Attorney General), 2007 FC 1316, 63 C.P.R. (4th), 342, it has been determined that such a request could be made earlier, that is, once the patent was laid open to the public.

[7] A few months prior to the time the patent issued, that is, on or about July 27, 2004, Teva implemented a 20% price increase for the Copaxone syringe product, raising it from $36.00 to $43.20 per day. While this was still the lowest price for medicines in its category, the Board warned Teva that such an increase may be considered excessive. Once the patent issued discussions ensued in earnest between Teva and the Board. Nothing was resolved. The Board issued a Notice of Hearing on May 8, 2006, evidence was submitted, arguments made and an oral hearing was held. The result was the two decisions by the Board which are the subject of these consolidated judicial reviews.

[8] The first decision of the Board dated February 25, 2008 was a determination that Copaxone had been sold at an excessive price on and after July 1, 2004 and that the only price increases permitted were those related to the Consumer Price Index (CPI) in accordance with the Board's Guidelines. A formula was provided in the decision respecting permitted increases. The Board recommended that negotiations be conducted as to the amount of excess revenues that were to be paid to the Crown by Teva as a result of its findings that the price was excessive. The Board further determined that Teva had not engaged in a policy of selling the medicine at an excessive price therefore no Order in that regard under section 83(4) of the *Patent Act* would be made. No review is sought in respect of this latter determination.

[9] The second decision of the Board dated May 12, 2008 is a consequence of the first decision since no agreement had been reached. This second decision fixed the amount to be paid by Teva to the Crown in the amount of $2,417,223.29.

[10] Teva has sought judicial review of these two decisions.

Issues

[11] While Teva simply states that the issue is whether these decisions should be left undisturbed or should they be quashed, a number of issues in that regard have been raised which I have placed in the following order:

- Issue #1 - Was the decision that Copaxone was priced "excessively" unreasonable?
- Issue #2 - Were the Board's reasons adequate?
- Issue #3 - Did the Board have jurisdiction to make the section 83 Order that it did?
- Issue #4 - Did the Board have jurisdiction to make the Order for payment that it did?

[12] Before considering these issues directly I will discuss the origin and nature of the Board in the context of this proceeding, consider the standard of review, consider the Guidelines of the Board, provide a chronology of events, consider the Board's decisions and, present the theory of the case as asserted by Counsel for each party. I thank Counsel for the clear and direct manner in which this case was presented and their assistance in answering questions throughout the hearing.

The Origin and Nature of the Board

[13] Under the *Constitution Act, 1867*, section 91(22), "Patents of Invention and Discovery" is an area of jurisdiction assigned to the Parliament of Canada. The *Patent Act*, R.S.C. 1985, c. P.5, enacted in respect thereof affords rights to persons to be granted a patent in respect of inventions directed to a new and useful art, process, machine, manufacture or composition of matter or improvements to the same. That *Act* provides for exemptions to things that can be patented, for instance section 27(8) exempts any mere scientific principle or abstract theorem. Judicial interpretation has excluded living creatures such as mice from patentable subject matter (*Harvard College v. Canada (Commissioner of Patents)*, [2004] 4 S.C.R. 45).

[14] For a considerable period of time, medicines were exempted by the *Patent Act* so that no patent could be granted for a "medicine." Certain forms of clever claims drafting such as "Swiss Claims" were devised by patent practitioners to overcome this exemption in part. Gradually Canada's patent laws were changed so as to permit "process dependent" claims to medicines and, eventually, to claims directed to medicines themselves. Still, medicines were treated specially under patent legislation. Until 1993, the Commissioner of Patents (not the patent owner) could grant compulsory licences in respect of patents directed to medicines to third parties who wanted to make, use or sell patented medicines in Canada. Almost everyone who applied got such a licence. Thus, unlike a patent directed for instance to a ferris wheel, patents directed to medicines were the subject of special restrictions.

[15] In 1993, substantial amendments were made to the *Patent Act*, compulsory licenses were abolished and the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 were put in

their place. However prior to that, during the era of the compulsory licences, Parliament established, in 1987, the Patented Medicines Prices Review Board with a mandate to monitor, report upon and regulate the prices at which patented medicines were sold in Canada.

[16] Section 83(1) of the *Patent Act supra* provides for a finding by the Board that a patented medicine is being sold in Canada "*… at a price that, in the Board's opinion, is excessive …*"

Excessive Prices	***Prix Excessifs***
Order re excessive prices	***Ordonnance relative aux prix excessifs***
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.*	***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.*

[17] Section 83(3) stipulates the consequences that the Board may impose when a finding that the price was "excessive" is made, they include the payment of a specified amount to the Crown:

Idem	***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	*(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*

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:	*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.*

Standard of Review

[18] The parties are agreed that, when it comes to whether or not the Board acted within its Constitutional jurisdiction the standard to be applied is correctness, otherwise the standard to be applied is that of reasonableness as set out in *Dunsmuir v. New Brunswick*, [2008] 1 S.C.R. 190, especially paragraph 47 which directs the Court to consider whether the decision under review is justified, transparent and intelligible and falls within the range of defendable possible, acceptable outcomes:

> *Reasonableness is a deferential standard animated by the principle that underlies the development of the two previous standards of reasonableness: certain questions that come before administrative tribunals do not lend themselves to one specific, particular result. Instead, they may give rise to a number of possible, reasonable conclusions. Tribunals have a margin of appreciation within the range of acceptable and rational solutions. A court conducting a review for reasonableness inquires into the qualities that make a decision reasonable, referring both to the process of articulating the reasons and to outcomes. In judicial review, reasonableness is concerned mostly with the existence of justification, transparency and intelligibility within the decision-making process. But it is also concerned with whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law.*

[19] As set out at paragraph 58 of the same decision, correctness applies to Constitutional questions regarding division of powers:

> *For example, correctness review has been found to apply to constitutional questions regarding the division of powers between Parliament and the provinces in the Constitution Act, 1867*: *Westcoast Energy Inc. v. Canada (National Energy Board), [1998] 1 S.C.R. 322. Such questions, as well as other constitutional issues, are necessarily subject to correctness review because of the unique role of s. 96 courts as interpreters of the Constitution*: *Nova Scotia (Workers Compensation Board) v. Martin, [2003] 2 S.C.R. 504, 2003 SCC 54; Mullan, Administrative Law, at p. 60.*

[20] While deference is to be afforded to an adjudicator whose decision is under review, where that decision falls outside the range of acceptable outcomes, it must be set aside, as the Supreme Court wrote at paragraph 72 of *Dunsmuir*:

> *While we are required to give deference to the determination of the adjudicator, considering the decision in the preliminary ruling as a whole, we are unable to accept that it reaches the standard of reasonableness. The reasoning process of the adjudicator was deeply flawed. It relied on and led to a construction of the statute that fell outside the range of admissible statutory interpretations.*

Guidelines of the Board

[21] The Board has prepared, apparently with consultation with relevant stakeholders, a detailed set of Guidelines, Compendium of Guidelines, Policies and Procedures, first published in 1994. These Guidelines are periodically revised. I was provided with the October 2003 version which version is said to be relevant to this consideration of the Board's decisions. The *Patent Act* section 96(4) provides that the Board may issue such Guidelines but clearly specifies that they are not binding:

Guidelines	***Directives***
(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.	*(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.*

[22] Further, section 96(6) of the *Patent Act*, provides that the *Statutory Instruments Act* does not apply to such Guidelines:

Non-application of Statutory Instruments Act	***Non-application de la Loi sur les textes réglementaires***
(6) The Statutory Instruments Act does not apply to guidelines issued under subsection (4). *1993, c. 2, s. 7.*	*(6) La Loi sur les textes réglementaires ne s'applique pas à ces directives.* *1993, ch. 2, art. 7.*

[23] The Guidelines are described in their Introduction as follows:

> ***Introduction***
>
> *This Compendium is a consolidation of the Guidelines, policies and procedures of the Patented Medicine Prices Review Board previously published in Bulletins 1 through 13. It is divided into three chapters:*
> - *Excessive Price Guidelines*
> - *Compliance and Enforcement Policy; and*
> - *Scientific Review Procedures*
>
> *One of the PMPRB's primary objectives is to ensure that patentees are aware of the policies, procedures and Guidelines under which staff review the prices of patented drug products, and proceed when a price appears to be excessive. This Compendium has been issued to promote awareness and facilitate compliance. Should there be any inconsistency, its contents supersede and replace all the directives previously published in Bulletins 1 through 13 inclusively.*

[24] The purpose of the Guidelines is set out in Chapter 1, section 1. Specifically section 1.3 states that the Guidelines are not rigid and not binding:

> ***1. Purpose***
>
> *1.1 Subsection 85(1) of the Act stipulates those factors that the Board, during the course of a public hearing, must take into consideration when determining whether a medicine is being sold or has been sold at an excessive price. These factors are:*
>
> - *the prices at which the medicine has been sold in the relevant market;*
> - *the prices of other medicines in the same therapeutic class;*
> - *the prices of the medicine and of the other medicines in other countries;*
> - *changes in the Consumer Price Index; and*
> - *such other factors as may be specified by regulations*
>
> *1.2 If after considering the above factors, the Board is unable to determine if a price is excessive, it may consider the costs of making and marketing the medicine as well as other factors*

> *which can be specified by regulations or that the Board considers relevant in the circumstances.*
>
> *1.3 The Board's Excessive Price Guidelines are issued pursuant to section 96 of the Act. They are not a rigid set of decision-making rules and are not binding on the Board or on any patentee. They are intended to provide patentees with parameters and information that will aid them in establishing, in advance, prices that may be presumed not to be excessive.*

[25] Justice Rothstein (as he then was as a Judge of this Court) wrote, in respect of the Guidelines, in *ICN Pharmaceuticals, Inc. v. Canada (Patented Medicines Prices Review Board)* (1996), 69 C.P.R. (3d) 129, [1996] F.C.J. No. 1112, at paragraph 6:

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

and at footnote 2 referred to in paragraph 6 Rothstein J. wrote:

> *2 Had it treated the Guidelines as binding, the Board may well have erred. Subsection 96(4) of the Patent Act provides that the Board may issue guidelines, but that such guidelines are not binding on the Board.*

[26] Among many things covered in the Guidelines is the approach of the Board to the question of "excessive" pricing. A number of "tests" are set out in section 6:

> ***6. Excessive Price Tests***
>
> *6.1* *The PMPRB, in consultation with interested parties, has developed various tests to determine whether the price of a drug product is within the Guidelines.*
>
> *6.2* *The* Reasonable Relationship *Test considers the association between the strength and the price of the same medicine in the same or comparable dosage forms. The Reasonable Relationship Test is described in Schedule 1.*
>
> *6.3* *The* Therapeutic Class Comparison *Test compares the price of the DIN under review with the prices of DINs that are clinically equivalent and are sold in the same markets at prices that the Board considers not to be excessive. This test is described in Schedule 2.*
>
> *6.4* *The* International Price Comparison Test *compares the average transaction price of the DIN under review with the publicly available ex-factory prices of the same medicine sold in countries listed in the Regulations. This test is described in Schedule 3.*
>
> *6.5* *The measurement of change in the Consumer Price Index (CPI) over a specified period is used to compare the average transaction price of a drug product with the CPI-adjusted price of the product. The calculation of the CPI-adjusted price is described in Schedule 4.*
>
> *6.6* *The application of these tests in the PMPRB's review of the average price of a drug product is explained in the following sections.*

[27] It is important to note that the Board, in its Guidelines, has set out at least two circumstances in respect of which regardless as to other circumstances, it will presume that a price is excessive. The first is set out in section 7.1 of the Guidelines, and states that if the price in Canada exceeds that of all other countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland,

United Kingdom, United States) then the price is presumed to be excessive (that is not the circumstance here):

> *7.1 The price of a new or existing patented drug product will be presumed to be excessive if it exceeds the prices of the same medicine sold in all countries listed in the Regulations. These prices will be determined using the International Price Comparison Test described in Schedule 3.*

[28] The second is stated in section 9.1 where the price is presumed to be excessive if the price change exceeds the "benchmark price" by more than the cumulative CPI increase during the "pricing period" under review.

> *9.1 In addition to the Guideline applicable to all patented drug products detailed in Section 7, the price of an existing DIN will be presumed to be excessive if it exceeds the benchmark price of the DIN adjusted for the cumulative change in the Consumer Price Index (CPI) from the benchmark period to the pricing period under review (CPI-adjusted price). Schedule 4 provides detailed definitions and examples of the PMPRB's CPI-adjustment methodology.*

[29] Thus the Guidelines stipulate that a presumption applies if a price increase over what is considered a benchmark price exceeds the cumulative CPI increase during what is considered to be the pricing period.

[30] In considering the nature and effect of these Guidelines it is important to start with sections 96(4) and (6) of the *Patent Act* which clearly provide that the Guidelines are not binding, which enjoinder is repeated in section 1.3 of the Guidelines themselves. The Guidelines constitute what Professor Sullivan calls "soft law" in her text *"Sullivan on the Construction of Statutes"* 5th ed., Lexis Nexis, 2008 at pages 621-630. She cites a decision of the Federal Court of Appeal, *Canada v. Thamotharem*, [2007] F.C.J. No. 734 in which Evans JA writes at paragraph 56:

> *56 Through the use of "soft law" an agency can communicate prospectively its thinking on an issue to agency members and staff, as well as to the public at large and to the agency's "stakeholders" in particular. Because "soft law" instruments may be put in place relatively easily and adjusted in the light of day-to-day experience, they may be preferable to formal rules requiring external approval and, possibly, drafting appropriate for legislation. Indeed, an administrative agency does not require an express grant of statutory authority in order to issue guidelines and policies to structure the exercise of its discretion or the interpretation of its enabling legislation:* Ainsley Financial Corp. v. Ontario (Securities Commission) *(1994), 121 D.L.R. (4th) 79 (Ont. C.A.) at 83 ("*Ainsley*").*

[31] Expressing a need for caution in dealing with guidelines, Professor Sullivan cites the decision of the Alberta Court of Appeal in *Miller, McClelland Ltd. v. Barrhead Savings & Credit Union Ltd.*, [1995] A.J. No. 167 at paragraphs 8-10:

> *8 The Registry Information Guide published by the Attorney General, directs that the birth certificate name be used in registering securities. However, while we agree that administrative interpretations are useful in interpreting the intent of legislation, they cannot be applied to establish mandatory requirements beyond the purview of the legislation itself.*
>
> *9 The Guide is not registered as a Regulation and was not published in the Alberta Gazette, so the presumption of notice and knowledge does not apply.*
>
> *10 Though the language used in the Guide is directive, in the absence of some cross reference or delegation in the regulations, those directives have no binding legal effect. As Coté, J.A. said in Case Power & Equipment v. Price Waterhouse Limited, September 29, 1994 (in dissent, but the majority did not disagree on this point):*
>
> > *The law is not set by private or government manuals telling the public how to search. Such manuals have no force of law. And their counsel is one of caution. They doubtless give good advice, but even when they touch on law and not computers, they reflect the law; they do not make it. To rely on them is to argue in circles or even backwards.*

[32] These Guidelines as published by the Board are useful both for the Board and for the public and may legitimately be referred to by the Board in the course of making its decisions. However, these Guidelines are not law nor do they have the force of law, at best they are "soft law". Primary attention must be paid to the *Patent Act* and any relevant *Regulations*. Where the Guidelines or their applications conflicts with the Act or Regulations, they cannot prevail.

Chronology of Relevant Events

[33] The following events, in chronological order, are relevant to consideration of the issues:

> May 3, 1995
>
> Application for the '088 patent is deemed to have been filed in Canada.
>
> Sometime prior to 1997
>
> Betaseron, a competitive product is introduced in Canada at a price of $44.51 per daily dose which price has been approved by the Board as being "not-excessive" and in respect of which a Voluntary Compliance Undertaking (VCU) was provided to the Board.
>
> September 1997
>
> Teva introduces Copaxone in the Canadian market at a price of $36.00 per daily dose. This Copaxone is provided in a vial format.
>
> November 1997
>
> The Board provides Teva with an advisory opinion that the price of $36.00 per daily dose was in all probability not excessive. At the time the Board believed that it could only provide actual rulings once the patent had issued. Case law in 2007, *supra*, has held that the Board could do so earlier once a patent application had been published (here at the end of 1997 but the belief at the time was nothing could be done then).

May 15, 2002

Teva introduces Copaxone in a syringe format. The price remained the same $36.00 per daily dose.

July 1, 2004

Teva increases the price of the daily dose of Copaxone in syringe format from $36.00 to $43.20, an increase of 20%. It was, nonetheless, still the lowest priced medicine in its therapeutic class.

September 28, 2004

The ’088 patent issues.

July 2004 to May 2006

Negotiations take place between the Board and Teva as to the 20% price increase; the Board taking the position that the increase was “excessive”.

May 8, 2006

The Board issues a Notice of Hearing and proceedings commence.

January 25, 2008

Board issues its decision that Teva’s price increase was excessive.

May 12, 2008

Board requires Teva to pay the Crown $2,417,223.29.

From July 2004 to January 2008

Teva does not make any further price increases, the price remains at $43.20 per daily dose.

[34] Reference is frequently made to the Consumer Price Index (CPI) and it changes from year to year. It was agreed that the CPI as put in evidence before the Board is accurate, part of which is as follows:

Year	All Items 2002=100	Change from previous year %
1988	71.2	3.9
1989	74.8	5.1
1990	78.4	4.8
1991	82.8	5.6
1992	84.0	1.4
1993	85.6	1.9
1994	85.7	0.1
1995	87.6	2.2
1996	88.9	1.5
1997	90.4	1.7
1998	91.3	1.0
1999	92.9	1.8
2000	95.4	2.7
2001	97.8	2.5
2002	100.0	2.2
2003	102.8	2.8
2004	104.7	1.8
2005	107.0	2.2
2006	109.1	2.0
2007	111.5	2.2

(1997 to 2004 inclusive = 15.9%)

Decisions of the Board

The February 25, 2008 Decision

[35] By its February 25, 2008 decision the Board found, as stated in paragraph 57 that the magnitude of the price increase (20% in July, 2004), and its one-time impact on consumers, resulted in the medicine being sold at an excessive price on and after July 1, 2004. It said:

> *In light of all the factors enumerated in section 85 of the Act, we have concluded that the magnitude of the price increase, and its one-time impact on consumers, resulted in the medicine being sold at an excessive price on and after July 1, 2004.*

[36] The Board begins its reasons with a recitation of a number of factual findings, among which are:

> Para 5: Teva's Copaxone price of $36.00 as initially sold in vial form was below that of its only competition Betaseron which sold at an approved price of $44.51 per day, thus the Copaxone price was in all probability, non-excessive.
>
> Para 6: Between 1997 and 2002 Teva made significant change to Copaxone's mode of delivery, including a change from vial to syringe.
>
> Para 8: Teva advised the Board that between July 1, 2004 it had implemented a 20% price increase from $36.00 to $43.20, still the lowest priced medicine in its therapeutic class.
>
> Para 9: The Board advised Teva that the introductory price of the syringe, $36.00 was within the Guidelines but that the increased price of $43.20 was excessive under the Guidelines.
>
> Para 38: The introductory price of the Copaxone syringe as of May 2002 at $36.00 is the "benchmark" price. It is the same price as the earlier vial. Both the vial and syringe contain the same active ingredient at comparable dosages. The "benchmark year" to be used is 1997, the year that the vial was introduced, for purposes of calculating CPI increases from 1997 to 2004.
>
> Para 40: Copaxone has always been the lowest priced drug in its therapeutic class. When Copaxone was introduced, the only competitive drug, Betaseron was priced 25% higher. The Betaseron price had been approved by the Board. The other drugs in the same therapeutic class later introduced all at prices significantly higher than Copaxone.
>
> Para 49: Improvements made by Teva respecting Copaxone may not have improved its therapeutic value but they significantly benefited users.
>
> Para 50: No objective evidence as to the costs of improving the delivery mechanics of Copaxone, particularly those attributable to Canada, was provided by Teva.

> Para 52: The Board was satisfied that Teva incurred substantial costs, which can be attributed to its Canadian operation. An increased price was justified.
>
> Para 57 (a): The CPI increased by 15.9% from 1997 to July 1, 2004.

[37] The Board explained the methodology by which it arrived at its decision in its reasons as follows:

> Para 34: This is the first case that the Board was called upon to deal with the meaning and effect of section 85 (1)(d) of the *Act* and its CPI methodology as set out in its Guidelines.
>
> Para 35: The Panel's decision is discretionary and must be based on all factors enumerated in subsection 85 (1) of the *Act*, and, if a judgment cannot be made regard must be given to subsection 85 (2) of the *Act*.
>
> Para 38: A benchmark price of $36.00 would be established and a benchmark year of 1997.
>
> Para 39: CPI methodology as set out in the Guidelines is the central issue, equal weight does not need to be given to all factors in subsection 85 (1), the Board may assign different weight to each factor.
> Para 40: The only issue is the permissible increase to the price of Copaxone in 2004 and whether it must be strictly limited in accordance with the CPI methodology in the Guidelines.
>
> Para 41: The CPI (Guidelines) methodology refines the language of section 85 (1)(d) of the *Act*, it remains with the Board to determine how the CPI factor applies in this case.
>
> Para 42: Patentee market power is presumed, the Board does not need to find an abuse of market power.
>
> Para 43: The Board is not instructed to consideration of price levels, it may consider price increases as well. In considering price increases, the Board will start with the CPI Guidelines but have regard to other factors in subsection 85 (1).
>
> Para 44: The only relevant issue is the one time price increase in 2004.

Para 45: The Board allocated greater weight to the CPI factor in subsection 85(1)(d) but acknowledges that factors in 85(1) (b) and (c) must be recognized.

Para 46: The Panel recognizes that prices may be so low compared to the price of competitive medicines that it *"flies in the face of common sense"* to conclude that a price increase is excessive merely because it exceeds the CPI. Teva may increase its price in excess of the Guidelines subject to certain limitations.

Paras 47 & 48: I repeat this paragraph as written because it is puzzling:

> *In the alternative, even were the Panel's conclusion based upon subsection 85 (1) factors for some reason found not to be conclusive, having considered the evidence and submissions, and weighing all of the factors outlined in paragraphs 85 (1)(a), (b), (c) and (d), the Panel would nevertheless conclude that it is unable to determine whether the medicine is being or has been sold in Canada at an excessive price and would invoke paragraph 85(2)(a) of the Act.*

It is not clear whether the Panel is saying that it is unable to reach a conclusion having regard to the factors set out in subsection 85 (1) therefore must go to subsection 85 (2) or whether it is considering subsection 85 (2) simply as an alternative.

The Panel appears to be cognizant that this is the first time that the Board is required to address excessive pricing issues based on paragraph 85(2)(a) factors and that the Guidelines provide no guidance on this issue.

Paras 48 to 50: The Panel points out that there was little objective data as to actual costs, although it was prepared to conclude that substantial investments were made, a portion of which can be attributed to Canada.

Paras 51 to 53: The Board considers that Teva is justified in increasing its price. While it is unclear, it appears that a 20% increase was not considered unreasonable. I repeat paragraph 53.

> *In coming to this conclusion, the Panel has taken note of the fact, as previously stated, that the only increase in the medicine's price since its introduction in*

> *Canada was the 20% increase in July, 2004. It remains the lowest-priced medicine in its therapeutic class in Canada, and one of the lowest-priced medicines in its class among the comparator countries referred to in the Regulations under the Act. The Panel emphasizes in particular that there were, at the time of the price increase, four products in the therapeutic class. No inference can be drawn, therefore, that there were as any lack of real price choice for MS therapy medicines of this sort.*

Para 54: The Panel appears to be reacting to administrative pressure to adhere strictly to the Guidelines for administrative convenience. It says that this decision is of restricted precedential value.

Paras 55 & 56: The Panel deals with and dismisses arguments made by Teva's counsel as to the precedential value of Parliamentary debates and the use of Guidelines.

Para 57: the Panel concludes that:

> *"…the only price increase to be permitted for reasons of increases in the CPI or for any other reasons are a)* a phased increase equal to CPI increases from 1997 to 2004, and b) the increases shall be phased over 2004, 2005 and 2006.

Thus the Panel concluded that the one time 20% increase in 2004 was excessive and that phased increases representing in total the 15.9% CPI increase from 1997 to 2004 were the only permissible increases.

The May 12, 2008 Decision

[38] The second decision of the Board under review is that dated May 12, 2008. This decision follows upon the first and fixes the quantum of money that Teva is to pay the Crown at $2,417,223.29.

[39] This decision is not arranged by numbered paragraphs. The bulk of the reasoning is directed to Teva's argument that it did not raise prices in the years 2005 and 2006 and that the CPI increases in those years should be included with the CPI increases in the years 1997 to 2004. The Panel of the Board did not accept this argument and concluded in the last two paragraphs of its reasons:

> *The Guidelines provide for the calculation of the average transaction price at which a medicine is sold on an annual basis. The Guidelines do not permit a patentee to charge excessive revenues in one or several years and then offset those revenues of its own accord by reducing (or not increasing) the price of the medicine in subsequent years. Indeed, such an approach would seriously impair, if not defeat, the Board´s mandate. While the Guidelines permit price-averaging within a calendar year, the Panel believes that this is the reasonable time limit on price-averaging. Beyond such averaging, excessive revenues (other than de minimus revenues that do not warrant an investigation by Board Staff) should only be capable of being offset by compliance with an order of the Board. The Panel considers these terms in the Guidelines to be an appropriate implementation of the terms of the Act, and that the Order is reflective of this.*
>
> *Accordingly, the Panel concludes that, in implementing the Decision, the terms of the Order should require the offsetting of the cumulative excessive revenues received by the Respondent in 2004 and 2005 by a payment to the Crown in the amount of $2,417,223.29. This amount will represent the excess revenues received by the Respondent for the period from the introduction of Copaxone in Canada to the end of 2007.*

[40] The reasons do not set out how this sum of $2,417,223.29 was calculated. Teva, at paragraph 45 of its Memorandum of Fact and Law, sets out an extensive chart indicating that, if revenues from December 2002 to December 2007 were calculated, the accumulated "excess" revenue would be a negative amount, -$348,135.81. In oral argument, Teva's counsel submitted that, even if one were to accept that the years 2005, 2006 and 2007 could not be taken into account, the amount payable would amount to $658,644.00 and not $2,417,223.29.

[41] Respondent's counsel offered two possible explanations as to how the Board arrived at the sum of $2,417,223.29. One was with reference to paragraph 57 of the Board's reasons in the first decision which directed that staged increases could be contemplated in the years 2004, 2005 and 2006. The other explanation was with reference to Teva's written submissions to the Board found at Volume 13, Tab CC, of the Record, paragraphs 24 and 25 where Teva submitted that a calculation should be based on three-year increases in the CPI having regard to a benchmark price in the three years prior and 1.5 times the CPI for each year.

[42] The point is that nowhere did the Board clearly set out in its reasons how it arrived at its figure of $2,417,223.29. Counsel for each party were uncertain and this Court remain puzzled as to how the figure was calculated.

The Parties' Theory of the Case

[43] Teva's theory is that its product has always been the lowest priced product in its class, even with the 20% price increase. It has only increased its price once in the years 1997 to 2007 and the increase is below the CPI increase in that overall period. It argues that the Board looked only to its Guidelines and only in respect to the CPI. It failed to give proper consideration to all of the factors enumerated in section 85(1) of the *Patent Act* and based its findings only on subsection 85(1)(d), the CPI increases. Even at that, the calculation of the amount of $2,417,223.29 is puzzling and, in any event, wrong.

[44] The Respondent argues that the Board took a nuanced approach, it considered CPI increases not just from 2002 when the syringe format was introduced, but, in an exercise of its discretion,

went back to 1997 when the vial format was introduced so as to permit CPI increases totalling 15.9 %. Respondent's Counsel says that while the calculation of the sum of $2,414.223.29 in unclear, it is within the Board's discretion.

<u>Issue #1</u> – Was the decision that Copaxone was priced "excessively" unreasonable?

[45] Sections 83(1) and (2) of the *Patent Act* stipulate that the Board may provide remedies in a situation where the price of a patented medicine:

> *"… in the Board's opinion is excessive"*

[46] Section 85(1) of the *Patent Act* provides that the Board shall take into consideration five factors to the extent that information on the factors is available to the Board:

> *(a) the prices at which the medicine has been sold in the relevant market;*
> *(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;*
> *(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;*
> *(d) changes in the Consumer Price Index; and*
> *(e) such other factors as may be specified in any regulations made for the purposes of this subsection*

[47] Factor (e) is irrelevant as there is no other factor set out in any regulation. There is no doubt in reviewing the Record that information was available to the Board in respect of each of the factors a), b), c) and d), thus the Board was required to give consideration to each of those factors. Section 85(1) does not provide for equal weight to be given to each factor, nor does it provide any formula by which the weight to be given to each factor is to be determined. The point is that <u>each</u> 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. I refer to the reasoning of Justice Rothstein in *ICN Pharmaceuticals* cited earlier.

[48] I am therefore troubled by the Board's Guidelines, in particular section 9.1 earlier referred to, which provides that if price increases exceed the cumulative CPI increase in the relevant period, there is a presumption that the price is "excessive". Such a presumption effectively ignores the other factors a), b) and c) of section 85(1).

[49] I appreciate that the Guidelines themselves state that they are not necessarily binding. The *Patent Act,* as discussed earlier, clearly states that they are not binding. However a review of the reasons of the Board in its February 25, 2008 decision leads to a clear and inevitable conclusion that the Board focused only on the CPI essentially to the exclusion of the other factors set out in section 85(1). Lip service only was given to these other factors. For example, paragraph 34:

> *34. This is the first case that the Board has been called upon to rule on an issue that relates to the meaning and effect of paragraph 85(1)(d) and the CPI-Adjustment Methodology as set out in Schedule 4 of the Guidelines. The Panel is fortunate to have had able and exhaustive submissions from all counsel on this important matter. We turn now to the key propositions advanced by the parties.*

[50] This is the introductory paragraph to the conclusions of the Board. This paragraph indicates that the only real focus of its reasoning is section 85(1)(d), the CPI.

[51] At the next paragraph, paragraph 35, the Board acknowledges that it must consider the other factors in section 85(1) and, if they are unable to make a judgment, then proceed to section 85(2):

> *35. It is agreed that the Panel's decision is discretionary as to whether or not the price of the medicine is excessive. However, such a determination must be based on all factors enumerated in subsection 85(1) and further that if, after taking into consideration all of those factors, we are unable to make a judgement, then we may consider the factors enumerated in subsection (2).*

[52] So far, so good, but the Board never provides in its reasons any serious analysis of factors 85(1) a), b) or c) nor does it say clearly whether it was "unable to make a judgment" and whether that was the basis upon which it proceeded to section 85(2).

[53] Paragraph 37 of the Board's reasons again demonstrates a focus only on the CPI Methodology factor:

> *37. Having considered the testimony as well as the written communications between the parties, the Panel is satisfied that Board Staff did not mislead the Respondent or misrepresent the manner in which the Guidelines are routinely applied in categorizing drug products, establishing benchmark prices for drugs, or in applying the Guidelines' CPI Methodology to increases in drug prices following introduction.*

[54] Paragraph 39 of the reasons clearly shows that the Board was focusing on the CPI as the "central issue". The Board acknowledges the other factors and states that they are not to be given "equal weight", however, when considering some of these factors in paragraph 40 of its reasons the Board states that the "only issue" is whether it must be "strictly limited" by "CPI Methodology":

> *39. The CPI Methodology contained in the Guidelines is the central issue in this case. The Panel agrees with the Respondent that its discretion cannot be restricted or curtailed by the provisions of the current CPI methodology if the Panel determines that there are factors, within the ambit of section 85, which support a departure from that*

> *methodology. However, in making any determination as to excessive pricing, the Panel wishes to emphasize that it does not agree with the Respondent's assertion that subsection 85(1) requires equal weight to be given to each of subparagraphs (a), (b), (c) and (d); rather, while each must be considered by the Board, the weight to be assigned to each is a matter within the Board's sole discretion.*
>
> *40. The unique situation is that Copaxone, in both forms of delivery, has always been the lowest priced drug in its therapeutic class. When introduced, there was only one other drug in the class, Betaseron, and its price was found by the Board to be non-excessive when the Board approved a VCU, establishing the Betaseron price at a level approximately 25% higher than the introductory price of Copaxone. Later, three other drugs in the same therapeutic class came into the market – Avonex and two versions of Rebif – and all carry prices significantly higher than Copaxone. The only issue, therefore, is the permissible increase to the price of Copaxone in 2004, and whether it must be strictly limited in accordance with the terms of the current CPI Methodology in the Guidelines.*

[55] At paragraph 41 of its reasons the Board seems to be providing justification for giving overwhelming importance to factor 85(1)(d), the CPI measurement:

> *41. For the most part, the Guidelines deal with matters of definition and process and the ways in which the comparison measurements mandated by paragraphs 85(1)(a), (b) and (c) should be carried out to avoid a presumption that a given price is excessive. For these purposes, as counsel for the Respondent freely admits, they are helpful in assisting patentees in establishing non-excessive introductory prices. The CPI methodology, in contrast, qualifies and refines the language of paragraphs 85(1)(d) by defining precisely how patentees must, in all cases, apply the CPI measurement factor in dealing with price increases following the establishment of the medicine's benchmark price. Whether this is tantamount to legislation by an administrative tribunal improperly purporting to exercise legislative powers that are within the exclusive jurisdiction of Parliament, as argued by the Respondent, is not necessary for us to decide. However, as the Act stipulates, the Guidelines are not binding on the*

> *Board in its adjudicative role, and it remains for this Panel to determine whether, on the unique facts of this particular case, how the CPI factor should be applied in determining whether the price increase in dispute was justified.*

[56] At paragraph 43 the Board affirms that it is fixated on section 85(1)(d):

> *43. The Respondent argues that since subsection 85(1) of the Act refers solely to excessive prices, we should concern ourselves only with a given medicine's price level. The Panel does not agree. The reference in paragraph 85(1)(d) clearly enables the Board to take into account the quantum of incremental increases in prices based on their relationship to CPI level changes. The Panel's determination of whether or not a price increase is excessive will of necessity start from the factor in paragraph 85(1)(d) concerning the relevant CPI Index in accordance with the Guidelines, but ultimately be based on the Panel's assessment of its relationship, if any, to other factors in subsection 85(1).*

[57] At paragraphs 44, 45, 46 the Board provides its conclusions in respect of section 85(1). It remarks at paragraph 46 that a low price may lead to a conclusion that it "… *flies in the face of common sense*" to conclude that a price is excessive. That seems to be precisely the case here, Copaxone has always been priced significantly lower than competitive products, yet no serious consideration was given by the Board to this factor. The Board returns to its position that the CPI should be the only factor given serious consideration:

> *44. The only relevant issue remaining is whether the one-time increase in 2004 justifies a conclusion that the "medicine is being or has been sold at an excessive price", within the meaning of and in accordance with all the factors listed section 85 of the Act.*
>
> *45. The Board confirms its comments made above whereby it allocates the greatest weight to the CPI factor in paragraph 85(1)(d) in situations concerning increases in prices of existing medicines. The Board agrees however, that fact situations involving price increases similar to the circumstances of Copaxone in this matter cross a threshold where the CPI factor should not be the sole determinant of*

> *whether a price increase is excessive. In other words, the Board is prepared to recognize that the factors in paragraphs 85(1)(b) and (c) should apply to situations involving an increase in the price of a medicine that was and remains the lowest in a group of medicines of its therapeutic class in order to moderate the determination of excessiveness of price based on the Guidelines' CPI methodology.*
>
> *46. The Panel is prepared to adopt this interpretation of the Act because it is of the view that at some point the price of a medicine relative to that of the other medicines in its class, which are the measures referred to in paragraphs 85(1)(b) and (c), can be so low that it flies in the face of common sense to conclude that the medicine is excessively priced merely because the increase exceeds the CPI. The Panel recognizes that the determination of the point at which price differentials between medicines will impact on issues of price increases is not easy to formulate. In all the circumstances, the Panel considers that a reasonable threshold for the application of paragraphs 85(1)(b) and (c) factors is crossed in the situation presented by Copaxone, when after an increase in the price of a medicine it remains the lowest priced in a group of medicines in its therapeutic class. In these exceptional circumstances, the Panel is prepared to conclude that the patentee may increase the price of its medicine in an amount in excess of the Guidelines, subject to certain limitations described below.*

[58] It must be concluded from an analysis of these reasons that the Board, in reality, was focusing only on the CPI factor in section 85(1)(d) and that no proper weighing of any kind was given to factors a), b) and c). It may be that the Board was unable to reach a conclusion under section 85(1), if that is the case, it did not say so. Instead, at paragraph 47 of its reasons the Board said *"as an alternative"* it was considering section 85(2), but why? Could it not conclude as to excessiveness based on section 85(1)? If so it didn't say so.

> *47. In the alternative, even were the Panel's conclusion based upon subsection 85 (1) factors for some reason found not to be conclusive, having considered the evidence and submissions, and weighing all of the factors outlined in*

> *paragraphs 85(1)(a), (b), (c) and (d), the Panel would nevertheless conclude that it is unable to determine whether the medicine is being or has been sold in Canada at an excessive price and would invoke paragraph 85(2)(a) of the Act.*

[59] In turning to section 85(2) the Board acknowledges that this decision marks the first time that it is to consider section 85(2)(a) factors. At paragraph 48:

> *48. The Panel is cognizant that this is the first time that the Board is required to address excessive pricing issues based on paragraph 85(2)(a) factors and that the Guidelines provide no guidance on this issue.*

[60] In the balance of paragraph 48 of its reasons and at paragraphs 49 and 50 the Board addresses the question of costs. It recognizes that Teva introduced improvements over the period 1997 to 2002 which "significantly benefited users." However, Teva provided no objective evidence as to the actual costs. The Board wrote at paragraph 50:

> *50. The Respondent did not provide any objective data on the costs incurred in making the improvements to the delivery mechanisms of Copaxone. Nor did it attempt to attribute these costs to Canada, as opposed to those incurred in other countries where its affiliates carry on business. Instead, it relies upon the obvious conclusions that such improvements in the delivery mechanisms involve very substantial investments in research and manufacturing and that it is reasonable to attribute a portion of those costs to Canada where the medicine is sold.*

[61] At paragraphs 51 and 52 the Board again relies upon the CPI as its basis for establishing increases that it believes to be acceptable:

> *51. Because the increase in prices that Panel is considering herein are in the realm of the magnitude of CPI increases that Teva could have taken after 1997, but chose not to*

> *implement, there is less concern about the need to demonstrate a direct relationship between the costs incurred to improve the delivery mechanisms and the increase in the price of Copaxone. To some extent, it is generally recognized that yearly increases in prices up to the CPI are intended to reflect the increasing cost of medicines. Not having increased its price, there is no issue of the Respondent taking these costs twice.*
>
> *52. While the Panel would have preferred to have more concrete evidence as to the precise expenditures incurred by the Respondent, for these purposes the Panel is satisfied that substantial costs were incurred which should properly be attributed to the Canadian operations of Teva. In the circumstances the improvement initiatives undertaken involved sufficient additional costs to Teva Canada to justify an increased price in the medicine that is not considered excessive.*

[62] At paragraph 56 the Board affirms its view as to the importance of the Guidelines:

> *Thus, while the statute makes it abundantly clear that the Guidelines are not binding on the Board, we wish to affirm that they are, and will remain, of utmost importance in the continued fair and impartial administration of the Act by the Board's expert and dedicated Staff.*

[63] In its conclusion at paragraph 57 said to be based on "all the factors" enumerated in section 85 (without saying whether 85(1) or 85(2)) the Board said that the only permitted increases were those related to the CPI or for any other (unstated) reasons:

> *We therefore direct that the only price increase to be permitted for reasons of increases in the CPI or for any other reasons are as follows …*

[64] It must be concluded, therefore, that the Board acted unreasonably and outside the mandate it was given under sections 85(1) and 85(2) of the *Patent Act*. The Board, in reality focused only on section 85(1)(d), the CPI factor, and failed to give proper, if any consideration to factors 85(1)(a), (b) or (c). The Board considered section 85(2) but did not say why, was it unable to make a

conclusion under section 85(1)? If so, it did not say that. Again under section 85(2) the Board focused only on the CPI. The Board simply did not do what sections 85(1)(a), (b), (c) and (d) and 85(2) require. The decision is unreasonable.

Issue # 2 – Were the Board's reasons adequate?

[65] The foregoing discussion makes it clear that the Board's reasons were inadequate. They fail to demonstrate clearly what consideration was given, if any, to factors 85(1)(a), (b) and (c) of the *Patent Act*. They fail to state why consideration was given to section 85(2).

[66] As stated in *Dunsmuir*, paragraph 54, previously referred to, reasons should be sufficiently transparent and intelligible. Here they are not. It is best that the Board reconsider the matter and provide transparent and intelligible reasons.

[67] Similarly, the Board's decision of May 12, 2008 in which it fixed a sum of $2,417,223.29 is unintelligible in that no basis for arriving at that figure is provided in the Board's reasons. Counsel for both Teva and the Respondent were not able to provide any clear and cogent explanation as to how that figure was arrived at given the evidence and submissions that the Board had. The matter must be returned for reconsideration if, after reconsidering the question of excessive pricing, the matter still needs to be addressed.

<u>Issue #3</u> - Did the Board have jurisdiction to make the section 83 Order that it did?

[68] The Respondent argues that the Board took a nuanced approach, it considered CPI increases not just from 2002 when the syringe format was introduced, but in an exercise of its discretion, went back to 1997 when the vial format was introduced so as to permit a CPI increase as large as 15.9%. The calculation of $2,414,223.29 though unclear, is within the discretion of the Board.

[69] The constitutionality of the Board was challenged in the Manitoba Courts in *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) (Q.B.) affirmed 1992, 96 D.L.R. (4th) 606 (Man. C.A.). In the Manitoba Queen's Bench, Dureault J. reviewed the history of the relevant patent legislation and of the Board up to that time (1991) and concluded at page 492:

> *I conclude that in pith and substance the impugned amendments pertain to the field of patents of invention. As the legislation re-establishes exclusivity for patented medicines to an extent not enjoyed since 1931, Parliament also provided for a mechanism to deal with price abuse that may incidentally occur as a result of these monopolies it created. The Board is only empowered to deal with the excessive prices of medicines patented under the new regime. It is not a scheme of general supervision of all patented pharmaceutical inventions. It clearly deals with the potential abuse flowing incidentally from the newly created patent exclusivity. Any firm not wishing to submit to the Board's authority can do so by renouncing its right to obtain a patent. Thus, the legislation is targeted to patent and patent abuse.*

[70] The Manitoba Court of Appeal, in a brief decision, affirmed the decision of Queen's Bench, stating at page 608:

> *In our opinion there can be only one answer to the question in this case. The impugned legislation is in pith and substance in relation to matters within Parliament's exclusive legislative jurisdiction over*

> *patents. The fact that the legislation may have an effect upon matters within provincial jurisdiction (in this case, property and civil rights) is then of no consequence.*

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

[72] It is noted that the Attorneys General of the provinces and territories were served with a Notice of Constitutional Question in these proceedings but none have chosen to appear or otherwise make submissions.

[73] In the present case Teva's Counsel conceded that the constitutional issue need not be considered if the Court concludes that the Board's decision was unreasonable. The constitutional issue would only need to be considered if the Board acted outside its jurisdiction.

[74] I have concluded that the Board's decision as to excessive pricing must be set aside not because the Board went beyond its jurisdiction but rather that it failed to exercise properly the jurisdiction mandated to the Board. The question of constitutionality does not, therefore arise.

Issue #4 - Did the Board have jurisdiction to make the Order for payment that it did?

[75] This matter has already been substantially addressed in these reasons. The Board does, under section 83(3)(b) have jurisdiction to make an Order for payment to Her Majesty. There has been no argument raised by Counsel that such a provision is unconstitutional. The decision has been set aside for two reasons. The first is that the decision upon which this decision is based, namely that the prices were excessive, has been set aside. The second is that the basis for arriving at the figure stipulated is unintelligible.

Conclusion

[76] Both the decisions of February 25, 2008 and May 12, 2008 will be set aside. The matter will be returned to the Board for redetermination preferably by a different panel if sufficient members can be provided for that purpose. In redetermining the matter the Board must consider all factors in section 85(1) and provide intelligible, clear reasons as to the consideration and weight given to each factor. If the Board is unable to reach a conclusion having regard to all factors under section 85(1) it must say so and then consider section 85(2) and provide intelligible, clear reasoning as to its consideration. The Board should not simply give lip service to these matters and arrive at the same result. The Board should give a thorough reconsideration of the matter without considering that it is in any way bound to arrive at the same result.

Costs

[77] Teva is entitled to its costs. I would prefer to award a lump sum. The parties should confer with a view to agreeing as to that sum. I will therefore defer as to the quantum of costs and request that the parties provide, within two weeks, their submissions as to quantum.

JUDGMENT

FOR THE REASONS provided herein:

THIS COURT ADJUDGES that:

1. The two applications are allowed;

2. The decisions of the Board dated February 28, 2008 and May 12, 2009 are quashed and returned for redetermination by a differently constituted Board, if available, in accordance with these reasons;

3. Teva is entitled to its costs. Counsel should within two weeks from the date of this decision provide brief written submissions as to a lump sum quantum of costs.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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