Federal Court  Cour fédérale

Date: 20130430

Docket: T-586-12

Citation: 2013 FC 448

Ottawa, Ontario, April 30, 2013

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

TEVA CANADA INNOVATION

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

[1] Teva Canada Innovation (Teva) asks the Court to set aside a decision of the Patented Medicine Prices Review Board (the Board) dated February 23, 2012, wherein the Board ordered that Teva pay Her Majesty in Right of Canada the sum of $2,801,285 for having sold its Copaxone Syringe in the Canadian market at an "excessive price" between 2004 and 2010, contrary to section 83 of the *Patent Act*, RSC, 1985, c P-4.

[2] This is the second time that Teva has challenged a decision of the Board regarding a finding of excessive pricing of the Copaxone Syringe. Teva was previously successful before Justice

Hughes in quashing a decision of the Board and having it referred back for redetermination in *Teva Neuroscience GP-SENC v Canada (Attorney General)*, 2009 FC 1155. The decision currently under review was rendered by the Board as a result of that redetermination. For the reasons that follow, I find that this decision suffers from much the same problem as was found by Justice Hughes in the first decision, and accordingly, it too must be set aside.

Background

[3] Copaxone is a medicine Teva markets for use in the treatment of multiple sclerosis.

[4] Teva first introduced Copaxone in the Canadian market in 1997. At that time, Copaxone was sold in a vial format (Copaxone Vial) at $36.00 per daily dose, which was considerably lower than the Board-approved price for a competitor's drug in the same therapeutic class - Betaseron.

[5] Teva later developed an improved delivery method for Copaxone – a syringe (Copaxone Syringe). A Notice of Compliance for the Copaxone Syringe was issued by Health Canada on March 20, 2002. Teva initially sold the Copaxone Syringe, i.e. from 2002, at the same $36.00 per daily dose as Copaxone Vial.

[6] In 2002, two other competitors' medicines in the same therapeutic class as Copaxone – Avonex and Rebif – were introduced into the Canadian market at prices higher than Copaxone's.

[7] In July 2004, Teva increased the price of the Copaxone Syringe and discontinued the Copaxone Vial. The Board found that the price of the Copaxone Syringe increased 20% (i.e. to $43.20), as follows:

> 2003 – $36.00 (no increase)
> 2004 – $38.6038 (7.23% increase)
> 2005 – $40.9029 (5.96% increase)
> 2006 – $41.0145 (0.27% increase)
> 2007 – $41.1977 (0.45% increase)
> 2008 – $42.076 (2.13% increase)
> 2009 – $43.1989 (2.67% increase)
> 2010 – $43.20 (0.003% increase)
>
> ["increase" meaning increase relative to the prior, not initial year.]

[8] Notwithstanding the increases in the price of the Copaxone Syringe, the Board found that between 2002 and 2010 it was the lowest-priced medicine in its therapeutic class in Canada. The Copaxone Syringe price in Canada also remained, again according to the Board's reasons, "consistently the lowest" compared to the price charged in the seven countries listed in the Schedule to the *Patented Medicines Regulations*, SOR/94-688: France, Germany, Italy, Sweden, Switzerland, United Kingdom, and the United States.

Procedural History

[9] On May 8, 2006, the Board issued a Notice of Hearing as to whether Copaxone Syringe was being sold at an excessive price in Canada. The Board held hearings in the summer of 2007. By decision dated February 25, 2008, the Board found that the price of the Copaxone Syringe was excessive after July 1, 2004, by $2,417,223.29, and ordered that amount be paid to the Crown.

[10] Teva initiated judicial review proceedings to challenge the Board's decision. By decision dated November 12, 2009, Justice Hughes granted Teva's application on the basis that the Board had improperly limited its attention to only one of the four factors that must be considered under subsection 85(1) of the *Patent Act*, namely paragraph 85(1)(d) – "changes in the Consumer Price Index," and that "[l]ip service only was given to [the] other factors [in subsection 85(1)]." Justice Hughes returned the matter to the Board "for redetermination preferably by a different panel if sufficient members can be provided for that purpose […] [and] [i]n 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."

[11] A differently-constituted panel of the Board was struck in February 2010. The parties agreed that the evidence led before the first panel would form part of the evidentiary record. By motion, Board staff moved to supplement that record with evidence from the period 2008 to 2010. Teva opposed this motion. The Board granted the motion, which decision Teva challenged in this Court. Justice Hughes dismissed that challenge in November 2010. Both parties submitted evidence for the 2008 to 2010 period, and the Board also heard oral testimony and received additional exhibits in March 2011, and reserved its judgment.

Decision Under Review

[12] By decision dated February 23, 2012, the Board found that Copaxone Syringe was being sold at an "excessive" price, and ordered that Teva pay to the Crown $2,801,285.00.

[13] In its decision, after reviewing the background of the case and the parties' positions, the Board "turn[ed] to [its] consideration and weighing of the factors enumerated in subsection 85(1) of the *Act*" as follows.

> *Paragraph 85(1)(a) –*
> *"the prices at which the medicine has been sold in the relevant market"*

[14] The starting point of the Board's analysis was to establish what "medicine" it was to consider. Teva argued that the Board ought to consider the history of the pricing of Copaxone (both Copaxone Vial and Syringe), as it had done in the previous decision, whereas Board staff argued that the "medicine" was Copaxone Syringe. The Board agreed with the latter:

> 67. The Board regulates medicines at the DIN [Drug Identification Number] level. The entire regulatory regime is premised upon that fact. It follows, then, that the pricing history of Copaxone Vial is immaterial to our assessment of the allegation of excessive pricing of Copaxone Syringe.

The Board continued:

> 68. At introduction in 2002, the price of Copaxone was not excessive as it was sold at the same price as Copaxone Vial. This is the result of the application of the Reasonable Relationship Test. The ATP [average transaction price] was $36.00.

[15] The Board then noted how the average transaction price of Copaxone Syringe had increased in years 2003 to 2010, as excerpted above:

> 2003 – $36.00 (no increase)
> 2004 – $38.6038 (7.23% increase)
> 2005 – $40.9029 (5.96% increase)
> 2006 – $41.0145 (0.27% increase)
> 2007 – $41.1977 (0.45% increase)
> 2008 – $42.076 (2.13% increase)
> 2009 – $43.1989 (2.67% increase)

2010 – $43.20 (0.003% increase).

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

[16] The Board determined that according to the Therapeutic Class Comparison Test (TCC Test), "Copaxone Syringe [was] the lowest priced medicine in its class relative to the nearest comparators after 2004" (it being equal to Copaxone Vial between 2002 and 2004). However, the Board then proceeded to discount the importance of this factor in the following paragraph:

> 74. Teva relies upon the fact that Copaxone Syringe was the lowest priced medicine in its therapeutic class to argue that it was not excessively priced. In the Panel's view, the information that Copaxone Syringe was the lowest priced medicine is an important consideration though, in weighing this factor, it is important to state that the relevant period of time is the eight years from 2002 to 2010. Further, until 2004, the closest comparator was Copaxone Vial and would have remained as such had it not been taken off the market. It was the same price as Copaxone Syringe while both were on the market.

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

[17] With the exception of one data point, the Board staff's data agreed that Copaxone Syringe was priced lower in Canada than in other countries for the years 2004 to 2010. The Board found that this one inconsistent data point "[did] not detract from the fact that Copaxone Syringe in Canada was consistently the lowest priced medicine." However, the Board concluded its analysis of this factor which was favourable to Teva by again discounting its importance:

> 77. While the Panel has taken this factor into consideration, in our view, on the evidence before us, it is of limited application as compared to the other factors for determining whether the drug is excessively priced in Canada. This is because the evidence lead on

> this factor suffers from a degree of imprecision relative to the evidence led in respect of other factors. The comparator drugs' prices are not from Canada and as much might be affected by exogenous factors such as a different regulatory regime, different income levels, and different health and other socio-economic factors.

Paragraph 85(1)(d) –
"changes in the Consumer Price Index"

[18] Relative to this factor, the Board reasoned:

> 78. This factor requires that the Panel consider changes in the Consumer Price Index. In the normal course, Schedule 4 to the Guidelines provides for the assessment of the actual increases in the ATP of the medicine relative to allowable increases as calculated by the CPI-Adjustment Methodology. Under this approach, the benchmark price at introduction becomes the MNE [maximum non-excessive price] upon which increases in price are calculated in accordance with the allowable increases provided for by the CPI-Adjustment Methodology formula.
>
> 79. In this case, the MNE of Copaxone Syringe at the introduction was $36.00. Accordingly, it follows that on the evidence presented, the ATP increases for Copaxone exceeded the MNE. For convenience we reproduce the chart previously set out in these reasons:

YEAR	**MNE** (allowable % increase)	**ATP** (actual % increase)	**Excess ATP**
2002	36.00	36.00	0.00
2003	36.00 (0.0%)	36.00 (0.0%)	0.00
2004	37.008 (2.8%)	38.6038 (7.23%)	1.5958
2005	37.188 (0.49%)	40.9029 (5.96%)	3.7149
2006	38.1921 (2.7%)	41.0145 (0.27%)	2.8224
2007	38.232 (0.10%)	41.1977 (0.45%)	2.9657
2008	39.3752 (2.99%)	42.076 (2.13%)	2.7008
2009	40.7128 (3.4%)	43.1989 (2.67%)	2.4861
2010	41.2685 (1.36%)	43.2 (0.003%)	1.9315

> 80. The panel accepts the submission that Copaxone Syringe was excessively priced, as the price increases exceeded the permissible increases as calculated by the CPI-Adjustment Methodology. The

> Panel considers that the Board's rationale for the CPI-Adjustment Methodology is relevant to our review of paragraph 85(1)(d). It constitutes an important protection from sudden and significant price increases and it should be given considerable weight in this case. The Panel considers the following statement in the *ratio-Salbutamol HFA* decision to apply equally to this case:
>
> > 84. [The CPI-Adjustment Methodology] is intended to moderate the extent to which a patentee may increase the price of a medicine from year to year. The panel concludes that it should be given considerable weight in this case, where the price of a widely-used patented medicine was increased suddenly and significantly in 2004 in circumstances that, in the Panel's view, did not warrant such an increase.
>
> 81. Furthermore, even if the Panel were to refer to the actual Consumer Price Index during this period (see paragraph 25), the same conclusion would follow. Thus, with reference to this factor, Copaxone Syringe is excessively priced.

Conclusion

[19] In two terse paragraphs, the Board then "weighs" all of the above factors:

> 82. In the Panel's view, it is important to recognize that the determination of excessive pricing includes an analysis of both the relative price of the medicine within the market (domestic and internationally) and the price increases of the medicine relative to the introductory price. In the Panel's view, paragraph 85(1)(d) provides protection for the public which complements the limits that paragraphs 85(1)(b) and (c) place on relative pricing within the marketplace.
>
> 83. Here, the evidence establishes that following the removal of Copaxone Vial, Copaxone Syringe became the lowest priced medicine relative to its therapeutic comparators as identified by the TCC Test. However, in the period following 2004, the impact of the price increases that were imposed upon the consumer exceeded the protection that Parliament has provided. There is no evidentiary basis in this case to justify ignoring this impact on consumers that was both sudden and significant. Taking all the factors into account, the Panel concludes that Copaxone Syringe was excessively priced.

Remedies

[20] The Board reasoned that since "Copaxone Syringe became the lowest priced medicine relative to its therapeutic price comparators but also that the price increase was both sudden and significant […] the remedy must seek a balance between both of these factors."

[21] The Board concluded that the actual increase of $7.20 per unit (i.e. $36.00 to $43.20) "should be spread equally over a four year period," specifically 2004 to 2007. Using this approach, the hypothetically–"allowed" increases in price in these years were 5.0%, 4.76%, 4.55%, and 4.35%, respectively. Teva had actually increased its price by 7.23%, 5.96%, 0.27%, and 0.45% in those years, respectively. The result was that Teva's revenues in 2004 and 2005 were "excessive," in the amount of $1,029,159.00 and $1,772,126.00, respectively (totalling the final amount at issue: $2,801,285.00).

[22] The Board concluded by ordering that Teva pay its excessive revenues from 2004 and 2005 to the Crown pursuant to paragraph 83(2)(c) of the *Patent Act*.

Issues

[23] Teva raises a sole issue: "Should the Board's decision be left undisturbed or quashed?"

[24] Teva particularizes its submissions as to why the decision ought to be quashed with submissions made that the decision is unreasonable and, as a "complimentary submission, that the decision is unconstitutional."

Unreasonable Decision

(a) Undue Emphasis on CPI

[25] Teva submits that the Board "brazenly" ignored Justice Hughes' decision and once again used CPI as a "trump card" against all the other factors in subsection 85(1). It also submits that "section 83 of the Act makes [it] clear [that the *Patent Act* is ultimately concerned with excessive price levels, not any particular price *increase*]," and that the Board therefore erred by concerning itself with the price increase.

[26] Teva also draws this Court's attention to the legislative history of subsection 85(1) of the *Patent Act*, most notably a disagreement between certain Senators, who were in favour of elevating the status of CPI to a primary factor, and the Minister of Health and the House of Commons who ultimately rejected the Senate's recommendations and placed all of the factors in subsection 85(1) on an equal footing.

(b) Common Sense

[27] Teva submits that common sense, rationality, and consistency dictate that the price of a medicine that is the lowest-priced among its competitors domestically and internationally is not "excessive."

(c) Price of Betaseron

[28] Teva points to Betaseron, which is a medicine in the same therapeutic class and has always been more expensive than Copaxone, and notes that its price is Board-approved as non-excessive.

Teva submits that the Board's decision is unreasonable because it did not address this in its Decision.

(d) The "Medicine" at Issue

[29] Teva submits that the Decision is unreasonable because "[It] may make sense in other cases to do so, [but] this is not an appropriate case in which the Board should regulate mechanically "at the DIN level"."

(e) Lack of Evidence Supporting Conclusion

[30] Teva submits the Decision is unreasonable because the Board held that Copaxone's one-time price increase had an adverse impact on consumers when the evidence was that only one consumer ever complained about the price increase.

(f) Unintelligible Remedy

[31] Teva submits that the Board's remedy is, on its face, completely arbitrary. The Decision contained "*no* reasons in support of its conclusion as to why Copaxone's permitted price increase was not excessive (i.e., why implementing a 20% increase from 2004 to 2007 was acceptable) while the $2,801,285 that [Teva] was ordered to pay constituted excessive revenues."

Unconstitutional Decision

[32] Summarized, Teva's submission is this:

(i) Federal jurisdiction is defined by section 91 of the Constitution, and includes "patents of invention and discovery … [and therefore also extends to] prevent[ing] abuses of monopoly power arising form the market exclusivity created by the grant of patent;"

(ii) The regulation of pricing in a particular trade or industry, on the other hand, is outside of section 91, and falls to the provinces;

(iii) The only exceptions to the proposition at (ii) are matters of emergency or national concern;

(iv) The pharmaceutical industry is a particular trade or industry, and the regulation of its pricing is not a matter of emergency or national concern;

(v) The Board therefore has no jurisdiction to engage in pure price regulation of the pharmaceutical industry;

(vi) Teva's expert witness at the Board hearing said that Teva had engaged in "market restraint, not market abuse arising from the monopoly granted by its patent;"

(vii) Therefore, because of Teva's witness' statements, "it was incumbent upon the Board … to find and rely on evidence [of market abuse] in order to have jurisdiction to make a finding of excessive pricing," failing which it was necessarily engaging in pure regulation, for which it has no jurisdiction.

Analysis

The Medicine

[33] As noted above, Teva submits that the Board placed an unreasonable interpretation on the term "medicine" as found in the *Patent Act*, namely, by equating it with the DIN. Teva submits that the medicine flows from the patent of invention, not from the delivery mechanism. In its submission, regardless of whether the medicine is in the vial format or the syringe, and thus carries a different DIN, it is the same medicine. What hinges on the Board's interpretation is whether 1997 or 2002 is the appropriate starting point for Copaxone Syringe's pricing history under paragraph 85(1)(a).

[34] However, as the Respondent notes in its factum, Teva initially took the position in correspondence with Board staff, after being informed by the latter that it considered Copaxone Vial to be the appropriate therapeutic class comparator for Copaxone Syringe:

> "the comparison … is not appropriate… […] the differences in format of the vial and pre-filled syringe result in vastly difference administrative profiles."

[35] The Board is entitled to deference when interpreting its home statute, except regarding "questions of law of central importance to the legal system and outside the adjudicator's specialized expertise," constitutional questions, and the "exceptional other case:" *Rogers Communications Inc v Society of Composers, Authors and Music Publishers of Canada*, 2012 SCC 35 at para 16. It has not been advanced that the interpretation of the term "medicine" falls into any one of these categories, and I see nothing unreasonable with the interpretation the Board has given the term or its application in this case. Indeed, as shown above, Teva initially argued during the preliminary phases of the proceeding before the Board that Copaxone Vial should not even be used as a comparator for the purposes of subsection 85(1)(b) and (c). Logic dictates that if Copaxone Vial is not an appropriate therapeutic class comparator for the purposes of paragraphs 85(1)(b) and (c), it surely is not the *same* "medicine" for the purposes of 85(1)(a).

Interpreting and Applying Subsection 85(1) of the Act

[36] Teva submits that the Board "brazenly" ignored Justice Hughes previous decision and used CPI as the "trump card" against all other factors in subsection 85(1) of the *Patent Act*.

[37] It was clear in the first decision that the Board had considered only one of the factors in section 85(1) – CPI. In sending back the matter for redetermination, Justice Hughes provided the following direction to the Board:

> 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.
>
> [emphasis added]

[38] In the decision presently under review, as shown above, the Board sequentially laid out the subsection 85(1) factors in its analysis. Therefore, on its face, it appears as though the Board gave careful consideration to each factor, in accordance with Justice Hughes' Judgment. However, in my view, the Board's decision must be set aside because it again paid no more than lip service to the factors favouring the conclusion that the medicine was *not* excessively priced, namely paragraphs 85(1)(b) and (c), and again treated paragraph 85(1)(d), CPI, as a conclusive factor.

[39] I will first discuss the Board's discounting of the former factors, and then turn to the more fundamental legal error that underlies the Board's analysis.

[40] Regarding paragraph 85(1)(b), the medicine's price relative to "other medicines in the same therapeutic class" in Canada, as excerpted above, the Board stated:

> 74. Teva relies upon the fact that Copaxone Syringe was the lowest priced medicine in its therapeutic class to argue that it was not excessively priced. In the Panel's view, the information that Copaxone Syringe was the lowest priced medicine is an important consideration though, in weighing this factor, it is important to state that the relevant period of time is the eight years from 2002 to 2010. Further, until 2004, the closest comparator was Copaxone Vial and would have remained as such had it not been taken off the market. It was the same price as Copaxone Syringe while both were on the market.

The Board says that Copaxone Syringe being "the lowest priced medicine in its therapeutic class" was "an important consideration," but goes on to lessen that significance in stating that:

> [U]ntil 2004, the closest competitor was Copaxone Vial and would have remained as such had it not been taken off the market. It was the same price as Copaxone Syringe while both were on the market.

The Board offers no explanation why this "fact" is of any significance. Is it suggesting that the Applicant deliberately removed Copaxone Vial from the market in order to increase the price of Copaxone Syringe? If so, there is no evidence in the record to support that speculation. Or, is it suggesting that the price of Copaxone Vial would not have increased after 2004? Again, there is nothing in the record that would support that view. Frankly, I am at a loss to comprehend why this is a relevant "fact" and why the Board, because of it, apparently thought it appropriate to assign less weight to this factor; one that clearly favoured the Applicant's position. In other words, as it relates to this important factor, the decision suffers from a lack of intelligibility.

[41] Regarding paragraph 85(1)(c), the Board found that Copaxone Syringe was priced lower in Canada than in other countries for the years 2004-2010 and "was consistently the lowest price medicine." As such, this is again a factor that one would think favours the conclusion that the medicine was not being sold at an "excessive" price in Canada. However, the Board lessens the significance of this factor because "the comparator drugs' prices are not from Canada and as such might be affected by exogenous factors such as a different regulatory regime, different income levels, and different health and other socio-economic factors." The Board is certainly entitled to place less reliance on any of the factors in any given case for justifiable reasons; yet, other than this general caution which would be applicable in all cases, the Board does not point to any concrete examples of exogenous factors that lessen the impact of this factor in this particular case. Having

enacted this provision, Parliament is presumed to be aware of the difficulties in comparing the price of medicines across borders; despite this, it saw fit to include "the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada" as a factor to be considered when determining whether a drug is being sold at an "excessive" price in Canada. What the Board appears to be saying is that this factor is inherently unreliable and should be given little if not no weight. The Board appears therefore to be subverting the will of Parliament, which clearly saw this as a relevant factor to be accorded weight.

[42] In my view, the lip service paid to both paragraphs 85(1)(b) and (c) is alone sufficient to render the Board's conclusion unreasonable. This is particularly so when considered in the context of Justice Hughes' clear directions for the redetermination, which included to "provide intelligible, clear reasons as to the consideration and weight given to each factor." Nowhere in the discussion of these factors or in the Board's concluding paragraphs is there any indication as to how much weight these factors are ultimately given.

[43] However, the more fundamental legal error committed by the Board is in its interpretation of subsection 85(1) generally, which may explain why it gave decisive weight to CPI.

[44] At paragraph 82 of its decision, the Board first correctly notes that "the determination of excessive pricing includes an analysis of both the relative price of the medicine within the market (domestic and internationally) and the price increases of the medicine relative to the introductory price." However, the Board then goes on to give weight only to the CPI factor in paragraph 85(1)(d) stating: "[I]n the period following 2004, the impact of the price increases that were

imposed upon the consumer exceeded the protection that Parliament has provided" [emphasis added]. Parliament has provided no such "protection;" rather, Parliament has provided protection from "excessive" prices, stating that CPI is one factor to consider – it is not the only factor, or even the determinative factor, as this passage suggests. The Board confirms its error when it states that "paragraph 85(1)(d) provides protection for the public which complements the limits that paragraphs 85(1)(b) and (c) place on relative pricing within the marketplace [emphasis added]." Again, paragraphs 85(1)(b) and (c) place no such "limits;" nor is CPI itself a "limit." Rather, the meaning of the opening words in subsection 85(1) is straightforward and allows for only one reasonable interpretation: each of the factors listed in that provision are relevant to a singular determination, which is whether a medicine is or has been sold at a price that is "excessive."

[45] In short, the Board has fallen into exactly the error suggested by Justice Hughes – it has considered the Guidelines, and specifically those portions dealing with CPI to be binding. The Guidelines are not binding: See *Patent Act*, s 96(4). As Justice Hughes noted at para 32 of his decision: "Where the Guidelines or their application conflicts with the Act or Regulations, they cannot prevail." As was noted by Justice Rothstein, as he then was, in *ICN Pharmaceuticals, Inc v Canada (Patented Medicines Prices Review Board)*, [1996] FCJ No 112, para 6, footnote 2: "Had it treated the Guidelines as binding, the Board may well have erred."

[46] For these reasons this decision is unreasonable and must be set aside on terms identical to those issued by Justice Hughes previously.

[47] Teva asked the Court to "provide the Board with further directions in the nature of a directed verdict, specifically that the Board redetermine the matter on the basis that the allegations against [Teva] be dismissed." Just prior to these reasons issuing, Teva provided the Court with the Reasons of the Court of Appeal in *Canada (Minister of Public Safety and Emergency Preparedness) v Lebon*, 2013 FCA 55. The facts there are substantially different. Specifically, all of the factors validly considered directed only one result. This is not the present case. No verdict will be directed.

[48] The Applicant seeks costs fixed at $12,000.00, which is a reasonable sum based on the record before this Court.

[49] The Applicant submitted at the hearing that if the decision was set aside on this basis, the constitutionality argument need not be considered. I agree.

[50] However, it is appropriate to state that I was not persuaded that there is anything unconstitutional about the decision. Briefly, I note that it is not "market abuse" that the Board is required by the *Patent Act* to find, but rather "excessive price." Second, and more fundamentally, Teva has raised no argument that the excessive price provisions of the *Patent Act* are themselves *ultra vires* Parliament for failing to relate, in pith and substance, to the federal patent power. Indeed, as the Respondent points out, the general argument that the excessive prices provisions of the *Patent Act* are *ultra vires* for being purely price regulation, and thus encroaching on provincial jurisdiction, was tersely dismissed in *Manitoba Society of Seniors Inc v Canada*, 96 D.L.R. (4th) 606, 45 CPR (3d) 194 (Man CA).

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application is allowed;
2. The decision of the Board dated February 23, 2012 is quashed and returned for redetermination by a Board differently constituted than that which rendered either of the two decisions regarding this medicine, if available, in accordance with these Reasons; and
3. Teva is entitled to its costs which are fixed at $12,000.00.

"Russel W. Zinn"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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