Federal Court  Cour fédérale

Date: 20171109

Docket: T-83-17

Citation: 2017 FC 1023

Ottawa, Ontario, November 9, 2017

PRESENT: The Honourable Mr. Justice Phelan

BETWEEN:

GALDERMA CANADA INC

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

I. Introduction

[1] This is the judicial review of a decision by the Patented Medicine Prices Review Board Panel [Board] in which the Board found that it had jurisdiction over a medicine (Differin) which was no longer the subject of its own patent. As a consequence, Galderma Canada Inc [Galderma] was required to file pricing information in respect of Differin [also Differin 0.1 or the 0.1 Patents].

II. Facts

A. *Background*

[2] The parties largely agree to the facts. Galderma is an affiliate of a Swiss pharmaceutical company and manufactures and markets drugs almost entirely for dermatological conditions.

[3] Galderma had patents for Differin – an acne medicine containing 0.1% adapalene. The patents were Canadian Patent Nos. 1,266,646 [the 646 Patent] and 1,312,075 [the 075 Patent]. The two patents expired in March 2007 and December 2009 respectively.

[4] As had been required by the Board, Galderma provided sales and price information for Differin from January 1996 until December 2009 – the period of the 0.1 Patents.

[5] In May 2009, Galderma obtained Canadian Patent No. 2,478,237 [the 237 Patent or the 0.3 Patent] which expired March 14, 2016. The 237 Patent covered the drug Differin XP containing 0.3% of the active ingredient adapalene [Differin XP or Differin 0.3].

[6] The parties agree that Differin 0.1 and Differin 0.3 are different medicines with separate and distinct formulations and uses.

[7] Galderma filed the necessary information with the Board in respect of Differin XP until its patent expired.

[8] Seven years after the 0.1 Patents expired, the Board staff brought an application alleging that Galderma had failed to provide the Board with information regarding the medicines Differin 0.1 and Differin XP (as well as other medicines not relevant to this matter) on the basis that the 237 Patent pertains to those medicines. As the 237 Patent was already listed with the Board for Differin XP, there was no issue that Galderma had to file in respect of Differin XP.

[9] The parties agreed that the question of whether the invention claimed and described in the 237 Patent "pertained" to Differin 0.1 was the substantial issue before the Board and the reasonableness of the Board's decision is the substantial issue in this judicial review.

[10] The relevant provisions of the *Patent Act*, RSC 1985, c P-4, which engage the Board's jurisdiction are as follows:

79 (2) For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.	**79 (2)** Pour l'application du paragraphe (1) et des articles 80 à 101, une invention est liée à un médicament si elle est destinée à des médicaments ou à la préparation ou la production de médicaments, ou susceptible d'être utilisée à de telles fins.
…	[…]
80 (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting	**80 (1)** Le breveté est tenu de fournir au Conseil, conformément aux règlements, les renseignements et documents sur les points suivants :

(a) the identity of the medicine;	**a)** l'identification du médicament en cause;
(b) the price at which the medicine is being or has been sold in any market in Canada and elsewhere;	**b)** le prix de vente — antérieur ou actuel — du médicament sur les marchés canadien et étranger;
(c) the costs of making and marketing the medicine, where that information is available to the patentee in Canada or is within the knowledge or control of the patentee;	**c)** les coûts de réalisation et de mise en marché du médicament s'il dispose de ces derniers renseignements au Canada ou s'il en a connaissance ou le contrôle;
(d) the factors referred to in section 85; and	**d)** les facteurs énumérés à l'article 85;
(e) any other related matters.	**e)** tout autre point afférent précisé par règlement.
(Court's underlining)	(La Cour souligne)

[11] It is common ground that a three-part test is applied to determine whether the Board has jurisdiction over a medicine sold in Canada:

1. Is the party a patentee of an invention?
2. Does the invention pertain to a medicine?
3. Is the medicine being sold in Canada?

Only the 2nd part of the test – whether the invention claimed and described in the 237 Patent pertained to Differin 0.1 – was in issue in relation to the 237 Patent.

B. *Board Decision*

[12] The mandate and function of the Board, and the history of pricing control for patent medicines, is set out in detail in *ICN Pharmaceuticals, Inc v Canada (Staff of the Patented Medicine Prices Review Board)* (1996), [1997] 1 FC 32, 138 DLR (4th) 71 (CA) [*ICN*], and need not be repeated here.

[13] In summary, the Board was established in 1987 to provide Canadians protection from excessively priced patented medicine. The Board is governed by the *Patent Act*, at sections 79-103, and the *Patented Medicines Regulations*, SOR/94-688. Section 79(2) of the *Patent Act* sets out the Board's jurisdiction. When a medicine falls under the Board's jurisdiction, section 80 of the *Patent Act* requires the patentee to disclose information to the Board, such as the cost to make the medicine and the price it sells at.

[14] Section 79(2) requirements are important as not all medications fall within the Board's jurisdiction. Prior jurisprudence has established that as a federal board, the Board can only oust the provincial jurisdiction over property if there is a patented invention that pertains to medicine sold in Canada.

[15] If the jurisdictional requirements are met, the Board takes steps to ensure Canadians are protected from excessive medical costs. For example, the Board can cap a medication's maximum sale price. In addition, if the Board finds a medication was sold at excessive prices, it has the power to order the excessive revenue paid back to Canada. This consumer protection

purpose means Board decisions are provided deference. It only takes the "merest slender thread" to meet the s 79(2) requirements (*ICN* at para 46), although the scope of those words has not been given greater definition. Whatever the adjectives, there must be a thread between the medicine in issue and the patent at issue. That thread must be found by proper analysis and the application of proper legal principles.

[16] The Board, on December 19, 2016, concluded that the 237 Patent covering Differin 0.3 pertained to Differin 0.1 and ordered that Galderma file the prescribed information for the period January 1, 2010 to March 14, 2016.

[17] The Board referred to prior jurisprudence putting particular emphasis on the *ICN* decision and its teachings that the word "pertains" be given a broad meaning, that the connection between the invention and the medicine can be one of the "merest slender thread," and that the Board should not go beyond "the face of the patent" (such as engaging in claims construction) in determining the connection between the invention and the medicine.

[18] The Board first defined the issue as whether the invention in the 237 Patent pertains to Differin 0.1, though later narrowed the issue to whether "the 237 Patent is or can be used for the medicine Differin."

[19] In examining the 237 Patent, the Board noted that the abstract only refers to 0.3% adapalene but nowhere did the patent say it exclusively pertains to 0.3% adapalene. The Board

referred to some parts of the patent but did not refer to or examine the claims, even for purposes of determining on its face to what the 237 Patent was directed.

[20] The Board found that both Differin and Differin XP had only adapalene as the active ingredient, that the 237 Patent provides for the use of adapalene to treat dermatological disorders, and that Differin is a medicine that uses adapalene to treat such disorders.

[21] The Board concluded that the 237 Patent was capable of being used for Differin, and therefore the 237 Patent pertains to Differin.

[22] As part of the Applicant's challenge to the correctness of the Board's decision, the Applicant raises an issue of procedural fairness. The Applicant argues that the Board decided a point which was never argued by either party and therefore argues that there was a breach of procedural fairness.

[23] In oral submissions, the Applicant pointed to the Board's conclusion in the decision at paragraph 54 that the 237 Patent pertains exclusively to 0.3% adapalene. In its written submissions, the Applicant referred in particular to paragraph 57 of the decision dealing with the Board's view that "the decision of whether a patent pertains to a medicine is a discretionary one."

[24] To put the offending sentence in context, the whole of paragraph 57 is set forth below:

> The decision of whether a patent pertains to a medicine is a discretionary one. This is not to say that the discretion of this Panel

> is unfettered but the analysis of "pertains to" requires a holistic evaluation of various factors outlined above. Of particular significance to the issues in this case, the Panel notes that:
>
> i. In ascertaining whether there is a connection between the invention and the medicine, the Panel should not go beyond the face of the patent (such as by engaging in patent or claims construction, or infringement analysis). The 237 patent is entitled "Use of Adapalene for the Treatment of Dermatological Disorders" and it is not clear from the face of the patent that it applies exclusively to 0.3% adapalene;
>
> ii. Adapalene is the only active ingredient in Differin and Differin XP;
>
> iii. The 237 patent provides for the use of adapalene to treat dermatological disorders and Differin is a medicine that uses adapalene to treat dermatological disorders; and
>
> iv. The 237 patent pertains to Differin XP which is a medicine that uses adapalene to treat dermatological disorders.
>
> [Emphasis in original]

III. Issues

[25] The Applicant has raised two issues:

1. that the Board breached procedural fairness by deciding this matter, in part, on points not argued by either party; and
2. that the Board committed legal errors in arriving at its conclusion.

IV. Standard of Review

[26] The Applicant contends that the standard of review is correctness in respect to both issues. In respect of the Board's decision, the Applicant argues that the issue is a jurisdictional one, particularly as it deals with definitions like "invention" and "patent" in the *Patent Act* –

legislation which is of central importance to the legal system and outside the specialized area of the Board's expertise.

[27] It is now well established that the standard of review for matters of natural justice or procedural fairness is correctness (*Dunsmuir v New Brunswick*, 2008 SCC 9, [2008] 1 SCR 190 [*Dunsmuir*]).

[28] With respect to the Board's decision, generally where the Board is dealing with its mandate – in this case whether an invention "pertains" to a patent – the Board is engaged in a consideration of mixed law and fact. It has been held in such cases as *ICN*, *Celgene Corp v Canada (Attorney General)*, 2011 SCC 1, [2011] 1 SCR 3, and *Canada (Attorney General) v Sandoz Canada Inc*, 2015 FCA 249, 390 DLR (4th) 691, that the reasonableness standard applies.

[29] However, where the Board interprets general terms in the *Patent Act* or where it interprets or applies principles of more general patent law, the Board must be correct for the reasons advanced by the Applicant. This is particularly so where its analysis or conclusions touch upon constitutional issues or engage principles laid down by the Federal Court of Appeal in *ICN* at para 55:

> That there must be a rational connection or nexus between the invention outlined in a patent and the medicine which is being sold in Canada cannot be doubted. Without such a statutory requirement the constitutional authority of Parliament to enact price control legislation would be in issue. The competence of Parliament to enact legislation which seeks to regulate the prices of goods, which legislation would otherwise intrude upon the legislative competence of the provinces to enact legislation affecting property

> and civil rights, arises from Parliament's jurisdiction to legislate with respect to patents: see *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485 (Man. Q.B.); affd (1992), 96 D.L.R. (4th) 606 (Man. C.A.). The question this Court must address is what is the rational connection required, and, in particular, whether the nexus is to be established without going beyond the face of the '264 and '265 patents. In my opinion, the answer lies in the meaning or scope to be attributed to the word pertaining found in subsection 83(1) of the Act, and its extended meaning set out in subsection 79(2).
>
> [Emphasis in original]

V. Analysis

A. *Procedural Fairness*

[30] The Applicant did not argue in Court the issue raised in its Memorandum regarding the failure to appoint an advisory counsel. Given the nature of the argument made in Court, I take the appointment issue to have been abandoned – perhaps wisely.

[31] On the issue of deciding a matter on grounds not argued by the parties, the Applicant cites no authorities for the proposition that this is a breach of procedural fairness.

[32] In my view, the remedy for this point is to show in judicial review that the points relied on by the decision makers were either incorrect or unreasonable, as the case may be.

[33] To hold that a decision maker must decide matters only on the points raised by the parties would unduly handcuff a decision maker, and run contrary to the obligation to decide a matter on the law and facts, as he or she knows them to be. As the Supreme Court has noted, a decision is

assessed on the basis of the reasons a tribunal offered or could have offered on the record before it (*Dunsmuir* at para 48; *Alberta (Information and Privacy Commissioner) v Alberta Teachers' Association*, 2011 SCC 61 at paras 52-53, [2011] 3 SCR 654).

[34] While there may be instances where to decide a matter on a point not argued, or to not offer an opportunity for parties to address such a point would be unfair, this is not one of those rare situations. In this case, there was no such obligation and therefore no unfairness.

B. *Review of Decision*

[35] In reviewing the Board's decision on the applicable standard of review, the Court must conclude that there are a number of problems with the decision which individually and cumulatively are sufficiently serious as to warrant that the decision be quashed.

[36] The central question the Board had to address was whether the invention in the 237 Patent pertains to Differin 0.1. The Board is entitled to deference on the scope of "pertains" so long as it asks the right question, and does not so stretch the application of "pertains" such that it strays into constitutionally impermissible grounds to regulate drug prices which are not sufficiently connected to a federal field of jurisdiction (i.e. patents).

[37] Throughout the Board's decision it appeared to use the words "patent" and "invention" interchangeably. This would not be an issue if it was clear that the Board had in mind that its focus was on the invention in the patent and merely used the two words interchangeably as a form of short hand.

[38] However, in this case, I cannot find that these references were merely a form of short hand. The Board did not address the invention itself.

[39] Section 2 of the *Patent Act* defines an "invention" and a "patent" as follows:

invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;(*invention*)	***invention*** Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité. (*invention*)
…	[…]
patent means letters patent for an invention; (*brevet*)	***brevet*** Lettres patentes couvrant une invention. (*patent*)

[40] The Board did not determine what the invention in the 237 Patent was. Section 79(2) requires the Board to focus on the invention before it determines whether the invention is intended or capable of being used for the "medicine." A central question was whether the 237 invention was intended or capable of being used for the Differin 0.1 medicine.

[41] The Board focused its attention on the commonality of the active ingredient adapalene in both medicines and never determined whether the 0.3% Differin XP medicine was intended or capable of being used for the 0.1% Differin medicine. There was no evidence that it was so capable. It appears that the Board assumed that one merely had to dilute the 0.3% medicine to arrive at the 0.1% medicine capable of performing the same function. However, the evidence

was that there were two separate medicines and there was no evidence that the 0.3% invention could be used to create a 0.1% medicine or that it was capable of doing so.

[42] The Board focused on the issue of whether the 237 Patent could be used for 0.1 Differin not, as it should, whether the 0.3 Differin XP medicine was intended or capable of being used for 0.1 Differin medicine.

[43] In the interpretative process of the Board, it reviewed the "face of the patent" in reaching its decision that the 237 Patent pertains to Differin 0.1. While the first part of the analysis – the face of the patent – is the proper analysis, the second part, as detailed above, is not.

[44] Further, in conducting the review of the face of the patent, the Board limited its review unreasonably. While the Board is not to engage in claims construction, the Board never referred to even the face of the claims nor to the description or scope of the invention. The Board did refer to the abstract and an introductory paragraph of the patent to conclude that one of the objects of the 237 Patent was 0.3% adapalene and that the patent did not pertain exclusively to 0.3% adapalene.

[45] The Board's failure to review the whole of the 237 Patent is contrary to its obligation under section 79(2) or at the very least is an unreasonable approach to "reviewing the face of the patent" and is inconsistent with the Board's own policy as evidenced by its own publication, "The Scope of the PMPRB's Jurisdiction: When Does a Patent Pertain to a Medicine?", *NEWSletter* 10:3 (July 2006) 8 at 9:

> In order to establish the required nexus or rational connection between an invention described in a patent and a medicine, the patent must first be read as a whole and, in particular, all the claims of the patent must be examined as a whole to determine the invention the patent describes on its face.

[46] It is not clear how the Board, if it had examined the whole of the 237 Patent, particularly its claims, could have concluded that the patent covered more than 0.3% adapalene. Yet the Board appeared to conclude that the 237 Patent was intended to cover more than 0.3% adapalene. However, such a conclusion would run contrary to the principle taught in *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 42, [2000] 2 SCR 1067, that "that what is not claimed is considered disclaimed":

> The content of a patent specification is regulated by s. 34 of the *Patent Act*. The first part is a "disclosure" in which the patentee must describe the invention "with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired": *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, at p. 517. The disclosure is the *quid* provided by the inventor in exchange for the *quo* of a 17-year (now 20-year) monopoly on the exploitation of the invention. The monopoly is enforceable by an array of statutory and equitable remedies and it is therefore important for the public to know what is prohibited and where they may safely go while the patent is still in existence. The public notice function is performed by the claims that conclude the specification and must state "distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive property or privilege" (s. 34(2))". An inventor is not obliged to claim a monopoly on everything new, ingenious and useful disclosed in the specification. The usual rule is that what is not claimed is considered disclaimed.

[47] While the concept of "claimed" is not the same as "pertains," it was unreasonable for the Board to engage in the analysis it did and ignore critical parts of the face of the patent.

[48] In carrying out its analysis, the Board made comments which, when combined with the matters already raised, make the decision less transparent than it ought to be. The Board found at paragraph 57 of its decision that "[t]he decision of whether a patent pertains to a medicine is a discretionary one."

[49] While the Board goes on to discuss a "holistic evaluation" of the various factors, which is potentially a reasonable approach, the reference to a discretionary exercise is not consistent with section 79(2) or the reporting obligations in section 80.

[50] It was unreasonable (and irrelevant) to conclude that, on the face of the 237 Patent, it pertained to Differin because the patent is capable of being used for Differin. The Board does not explain how the 237 Patent for 0.3% adapalene can be used for a medicine with 0.1% adapalene.

[51] With respect, the Board misapprehended the question it was to address and engaged in an unreasonable analysis of the issue before it.

VI. Conclusion

[52] For these reasons, this judicial review will be granted, and the decision of the Board will be quashed. The Applicant shall have its costs.

JUDGMENT in T-83-17

THIS COURT'S JUDGMENT is that the application for judicial review is granted with costs, and the decision of the Patented Medicine Prices Review Board Panel is quashed.

"Michael L. Phelan"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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