Federal Court of Appeal  Cour d'appel fédérale

Date: 20190628

Docket: A-385-17

Citation: 2019 FCA 196

CORAM: **PELLETIER J.A.**
DAWSON J.A.
WEBB J.A.

BETWEEN:

THE ATTORNEY GENERAL OF CANADA

Appellant

and

GALDERMA CANADA INC.

Respondent

and

INNOVATIVE MEDICINES CANADA

Intervener

Heard at Toronto, Ontario, on January 17, 2019.

Judgment delivered at Ottawa, Ontario, on June 28, 2019.

REASONS FOR JUDGMENT BY: PELLETIER J.A.

CONCURRED IN BY: DAWSON J.A.
WEBB J.A.

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REASONS FOR JUDGMENT

PELLETIER J.A.

I. Introduction

[1] On December 19, 2016, the Patented Medicine Prices Review Board (the Board) ordered the respondent Galderma Canada Inc. (Galderma) to file certain sales and financial information with respect to its product Differin for the period between January 1, 2010 and March 14, 2016. The unusual aspect of this order is that the original patents for the medicinal ingredient in Differin expired at least seven (7) years before the Board's staff requested the information. Given that subsection 80(3) of the *Patent Act*, R.S.C. 1985, c. P-4 (the Act) provides that the obligation to provide information does not apply to a person who "has not been entitled to the benefit of the patent or to exercise any rights in relation to the patent for a period of three or more years", the Board's order precipitated a successful application for judicial review which, in turn, led to this appeal by the Attorney General, on behalf of the Board staff.

[2] For the reasons which follow, I am of the opinion that the Board acted unreasonably in limiting its review to selected portions of the patent in issue in this litigation, and as a result, it also erred in its determination of the invention of the patent. On the basis of my review of the patent, I conclude that there is only one reasonable interpretation of the patent. I would therefore return the matter to the Board for a fresh determination as to whether the invention pertains to Differin, on the basis of that reasonable interpretation.

II. Facts

[3] Galderma manufactures and markets drugs for dermatological conditions. The facts of this case relate to two of its dermatological products, Differin and Differin XP, both of which contain a single medicinal ingredient, a compound known as adapalene. The difference between the two products is the concentration of adapalene; it is 0.1% by weight in Differin and 0.3% in Differin XP. Adapalene is or was protected in five (5) patents obtained by Galderma. Only Patent no. 2,478,237 (the 237 patent), described below, is relevant to this appeal. While the proceedings before the Board also touched upon other patents and other drugs, the Board's conclusions with respect to them are not challenged.

[4] When Galderma entered the market with Differin, it advised the Board that the following two patents pertained to that drug:

> a) Patent no. 1,266,646 (the 646 patent) entitled "Benzoaphtalenic Derivatives, Process for their preparation and uses as Pharmaceutic and Cosmetic Agents." This patent describes and claims a group of compounds which includes adapalene, a process for making those compounds, and their use. This patent was issued on March 13, 1990 and expired March 13, 2007.
>
> b) Patent no. 1,312,075 (the 075 patent) entitled "Process for the Preparation of Adamant-1 Derivatives." This patent describes and claims a better process for making the compounds of the preceding patent, including adapalene. This patent was issued on December 29, 1992 and expired December 29, 2009.

[5] Later, when Galderma entered the market with Differin XP, it identified only the 237 patent entitled "Use of Adapalene for the Treatment of Dermatological Disorders" as pertaining to that product. The 237 patent, which was issued on May 12, 2009 and lapsed on March 14,

2016, describes and claims the use of a 0.3% concentration of adapalene in the treatment of dermatological disorders. Galderma did not identify the 237 patent as pertaining to Differin.

[6] In keeping with its obligations under the Act, Galderma provided the Board with the prescribed information with respect to Differin until the 646 and 075 patents expired.

[7] In January 2016, long after the 646 and 075 patents had expired, the Board staff brought an application seeking an order compelling Galderma to provide pricing and marketing information with respect to Differin on the basis that the 237 patent pertained to that product. When the Board agreed with Board staff that the 237 patent pertained to Differin, Galderma applied for judicial review of the Board's decision.

[8] The Federal Court, in reasons cited as 2017 FC 1023 (FC Reasons), allowed the application and quashed the Board's decision. The Court found that the Board's conclusion that the 237 Patent pertained to Differin was unreasonable because the Board did not explain "how the 237 Patent for 0.3% adapalene can be used for a medicine with 0.1% adapalene": FC Reasons at para. 50.

[9] The Attorney General appeals from the Federal Court's decision, alleging that the Federal Court erred in "not finding that the 237 Patent describes an invention that pertains to the "medicine" (adapalene)": Appellant's Memorandum of Fact and Law at paragraph 21.

III. The Legislative Scheme

[10] Before examining the Board's decision, it may be useful to briefly review the legislative context in which this dispute arises. The Board is established pursuant to section 91 of the Act and its composition, powers, procedures and attributes are set out in sections 92-100 of the Act. The Board's mandate is to ensure that the statutory monopoly granted to patentees of medicines is not abused by excessive pricing of those medicines.

[11] To assist it in fulfilling its mandate, the Board is given two types of powers: the power to seek and, if necessary, to compel the disclosure of certain kinds of information from patentees and the power to make remedial orders if it concludes that a patented medicine is selling, or has been sold, at excessive prices. The issues in this appeal arise in the context of a proceeding to compel Galderma to provide certain information.

[12] The powers given to the Board can only be exercised against patentees, former patentees or persons entitled to the benefit of a patent "of an invention pertaining to a medicine." This phrase is defined at subsection 79(2) of the Act as follows:

(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.	(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.

[13] Sections 80 and 81 of the Act deal with the provision of information to the Board by patentees and former patentees as required by the regulations made under the Act, or by order. In

this case, the Board made an order pursuant to section 81 that required Galderma to provide certain information with respect to Differin on the basis of Galderma's status as patentee or former patentee of the 237 patent.

IV. The Board's Decision

[14] After dealing with certain preliminary issues, the Board began its analysis by referring to the definition of "pertains to a medicine" found at subsection 79(2) of the Act, quoted above. The Board distinguished between an invention which is intended or capable of being used as medicine, on one hand, and one which is intended or capable of being used in the preparation or production of a medicine, on the other.

[15] The Board then reviewed the jurisprudence on the meaning of "pertains to". The relevant conclusions which it drew are that (1) there must be a rational connection between the invention and the medicine; (2) the connection between the medicine and the invention can be one of "the merest slender thread"; and (3) the rational connection between the invention and the medicine can be the medicine itself. In the same review, the Board noted that in examining the rational connection, it should not go beyond the face of the patent "(such as by engaging in patent or claims construction, or infringement analysis)": Board Reasons at para. 45.

[16] The Board reasoned that the 237 patent, on its face, was not intended to be, or capable of being, used to prepare or produce the molecule adapalene. It noted that the title of the 237 patent was "Use of Adapalene for the Treatment of Dermatological Disorders". The Board concluded that the 237 patent was a "use" patent in that it "pertained" to the use of adapalene to treat

dermatological disorders. This left the question as to whether the invention in the 237 patent is or can be used for Differin, which contains 0.1% adapalene and is also used to treat dermatological disorders: Board Reasons at paras. 51-53.

[17] The Board rejected Galderma's argument that the 237 patent relates only to Differin XP, which has a 0.3% concentration of adapalene, and not also to Differin which contains a 0.1% concentration of adapalene. The Board conceded that the abstract of the patent refers to a 0.3% concentration of adapalene, but noted that "it is not clear from the face of the 237 patent that the patent pertains exclusively to 0.3% adapalene": Board Reasons at para. 54. In the next paragraph, the Board observed that, although a 0.3% concentration is mentioned in the abstract of the 237 patent, that concentration is not mentioned in its introductory paragraph or its title such that the patent "does not, on its face, relate exclusively to a 0.3% concentration of adapalene."

[18] Ultimately, the Board decided that there was a rational connection, at least of "the merest slender thread", which connected the 237 patent and Differin. In other words, the Board concluded that, on its face, the 237 patent "pertains to Differin because the patent is capable of being used for Differin": Board Reasons at para. 58.

[19] As a result, the Board ordered Galderma to file the prescribed information for Differin for the period between January 1, 2010 and March 14, 2016.

V. The Federal Court's decision

[20] After dealing with a number of introductory matters, the Court began its analysis by pointing out that the Board did not identify the invention of the 237 patent. The Court noted that subsection 79(2) of the Act required the Board to identify the invention before determining whether the invention was intended or capable of being used for Differin.

[21] The Court also found that the Board focused on the fact that both Differin and Differin XP have a common active ingredient, adapalene, and never asked itself whether "the 0.3% Differin XP medicine was intended or capable of being used for the 0.1% Differin medicine": FC Reasons at para. 41. In the Court's view, there was no evidence that Differin XP could be used in that way.

[22] The Court went on to find that the Board unreasonably limited its review of the face of the patent. While noting that the Board referred to the abstract and the introductory paragraph of the patent, the Court found that the Board's failure to review the whole of the patent was contrary to its obligations under subsection 79(2) of the Act. According to the Court, the Board's approach was also inconsistent with the position taken in its own publications which refer to the need to read the patent as a whole, including the claims, in order to determine the invention of the patent.

[23] The Court indicated that it was unable to understand how the Board, if it had considered the whole of the patent including the claims, could have concluded that the patent "covered"

more than a medicine containing 0.3% adapalene: FC Reasons at para. 46. According to the Court, that conclusion ran counter to principles set out by the Supreme Court at paragraph 42 of *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, according to which "what is not claimed is considered disclaimed." The Court acknowledged that the concept of "claimed" is not the same as "pertains to", but concluded that it was nonetheless unreasonable for the Board to fail to take into account critical parts of the patent.

[24] As a result, the Federal Court allowed the application for judicial review and quashed the decision of the Board.

VI. Statement of Issues

[25] The Attorney General says that the Federal Court erred in not recognizing that the "medicine" in this case is adapalene. As a result, the Attorney General also argues that the Federal Court erred in not concluding that the 237 patent describes an invention that pertains to the medicine adapalene. Galderma, on the other hand, maintains that the Federal Court did not err when it identified the medicine as Differin, a preparation which contains 0.1% adapalene. In addition, Galderma says that the Federal Court did not err when it held that the invention of the 237 patent pertained to Differin XP, which contains a 0.3% concentration of adapalene, and not to Differin.

[26] Given that this is an appeal from the Federal Court sitting in judicial review, this Court's focus is less on the decision of the Federal Court than it is on the decision of the Board. Our role is to ensure that the Federal Court identified the right standard of review and applied it properly:

Canada (Attorney General) v. Sandoz Canada Inc., 2015 FCA 249 at para. 56, 390 D.L.R. (4th) 691, *Bayer Cropscience LP v. Canada (Attorney General)*, 2018 FCA 77 at para. 53, 155 C.P.R. (4th) 99. In effect, we step into the shoes of the Federal Court and focus on the Board's decision: *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36 at para. 46, [2013] 2 S.C.R. 559.

[27] A careful reading of the Board's decision suggests that the following issues determine the outcome of this appeal:

A. Did the Board act unreasonably in limiting its review of the 237 patent to selected portions of the patent?

B. What is the invention of the 237 patent?

C. Does the invention of the 237 patent pertain to Differin?

VII. Analysis

[28] Before addressing the substantive issues, it is necessary to address the standard of review of the Board's decision. The Federal Court found that the Board's decision was entitled to deference to the extent that it dealt with questions of mixed fact and law, such as whether an invention pertains to a medicine. On the other hand, it found that when the Board interpreted general terms of the Act, or when it applied principles of patent law, particularly when these touch upon constitutional questions, the standard of review is correctness: FC Reasons at paras. 28-29.

[29] In this case, the Board was working within the framework of sections 79-103 of the Act which sets out its mandate and its powers. In other words, it was applying its home statute. To

that extent, its interpretation of sections 79-103 of the Act is presumptively reviewed on the reasonableness standard, unless the presumption of reasonableness is rebutted: *McLean v. British Columbia (Securities Commission)*, 2013 SCC 67 at paras. 21-22, [2013] 3 S.C.R. 895 [*McLean*]. In this case, the presumption of reasonableness has not been rebutted. Questions of mixed fact and law are also to be reviewed on the standard of reasonableness: *Dunsmuir v. New Brunswick*, 2008 SCC 9, at para. 47, [2008] 1 S.C.R. [*Dunsmuir*], *Thibeault v. Canada (Attorney General)*, 2016 FCA 101 at para. 18, 1 Admin. L.R. (6th) 51.

[30] The Board's position that it is limited to examining the face of the patent is not a question of statutory interpretation since the Act does not deal with this issue. In effect, the Board's position is a matter of methods and techniques of analysis: see para. 33, below. Given that a tribunal's choices in this regard flow from its subject matter expertise, it is entitled to deference: *Hillier v. Canada (Attorney General)*, 2019 FCA 44 at para. 17, 431 D.L.R. (4th) 556. On that basis, this portion of the Board's reasons will be reviewed on the reasonableness standard.

A. *Did the Board act unreasonably in limiting its review of the 237 patent to selected portions of the patent?*

[31] In its discussion of the 237 patent, the Board limited itself to the "face of the patent", a phrase which was used in this Court's decision in *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)* (1996), [1997] 1 F.C. 32, 138 D.L.R. (4th) 7 (FCA) [*ICN*].

[32] ICN argued in the Federal Court (Trial Division) that the “use” claims in the patent in issue should be construed so as to exclude some of the uses for which the patented medicine was approved for sale in Canada, as these were part of the prior art with respect to that patent: see decision reported as 66 C.P.R. (3d) 45, 108 F.T.R. 190 (FC) [*ICN FC*]. ICN argued that the claims of the patent should be read down so as to exclude those uses. The Board staff responded by filing affidavits supporting their construction of the patent.

[33] The Board concluded that it was inappropriate for it to engage in claim construction and that it should limit its examination to the face of the patent (*ICN FC* at page 60). It found that it did not have the mandate nor the necessary experience and expertise to undertake the kind of analysis which ICN was urging upon it. The Federal Court (Trial Division) agreed with the Board.

[34] On appeal to this Court, ICN continued to press its argument based on claims construction, an argument which this Court rejected in the following terms:

> I agree with counsel for ICN that there must be a rational connection or nexus between a patent and the medicine in question in order for the Board to acquire jurisdiction. The true issue is to identify the proper rational connection test. I do not accept the one advocated by ICN, which embraces a restrictive definition of medicine and the need to engage in patent or claims construction. That test, in my view, does not conform with the one specified in subsections 83(1) and 79(2) of the Act. From those two subsections I draw two major conclusions. First, one does not have to, and ought not, go beyond the face of a patent to establish the required nexus. Second, because of the broad scope of the terms "pertaining to" and "pertains to" as used in those subsections, the nexus can be one of the merest slender thread.[…]
>
> *ICN* at para. 46.

[35] This Court returned to this issue while discussing the objective which Parliament sought to attain when introducing the price review scheme. The Court's view was that requiring a stronger nexus between an invention and a medicine than the merest slender thread would provide a window of opportunity for pharmaceutical companies to avoid the jurisdiction of the Board, and would limit the ability of the Board to protect Canadian consumers from excessive pricing. The Court found that the broad language found in subsections 83(1) and 79(2) of the Act clearly evinced an intention on the part of Parliament that the Board was not required to go beyond the face of a patent when establishing the required nexus, in part because patent construction is a question of law to be decided by the Courts: *ICN* at para. 61.

[36] I agree with the intervener, Innovative Medicines Canada, that the Board must read the patent as a whole, including the claims in order to identify the invention. On the other hand, I disagree with the intervener's position that the Board must construe the patent and the claims as a court would.

[37] It is important to remember that the Board is an administrative tribunal with the mandate of regulating the prices of patented medicines. This mandate does not require it to determine rights as between patentees and others or to determine the validity of the patents which it considers. In order to discharge its mandate, it must have a sufficient understanding of the invention of a patent so as to be able to make a reasonable determination as to whether the invention pertains to a medicine. What constitutes a sufficient understanding will depend on the circumstances of each case but, at a minimum, it will not include a view of the invention which the language of the patent will not reasonably bear.

[38] If the Board is to arrive at a reasonable understanding of the invention of the patent, it must read the whole patent, not simply certain introductory phrases. But the Board is entitled to take the language of the patent at face value. It is neither equipped nor expected to look behind that language to arrive at the "correct" interpretation of the patent. To that extent, the Board is not required to go "beyond the face of the patent" to find implied limitations or additions to the words used by the patentee.

[39] In this case, I agree with the Federal Court that the Board only referred to the abstract and an introductory paragraph to reach its conclusions, and ignored critical parts of the patent, including the claims. As a result, I find that the Board acted unreasonably in limiting its review of the patent to selected portions of the patent.

B. *What is the invention of the 237 patent?*

[40] The Federal Court was correct to say that the Board "did not determine what the invention in the 237 Patent was": FC Reasons at para. 40. The closest the Board came to doing so was when it said, at paragraph 58 of its Reasons, that "the face of the patent suggests that the invention is the use of adapalene for the treatment of dermatological disorders".

[41] The Board's reading of the patent was limited to a cursory examination of whether the patent pertained exclusively to 0.3% adapalene. At paragraph 51 of its Reasons, the Board refers to the title of the patent and its abstract and concludes that the 237 patent is not intended or capable of being used to produce 0.1% adapalene and therefore cannot pertain to Differin in that sense.

[42] At paragraph 54 of its Reasons, the Board refers to the introductory paragraph of the 237 patent and notes that it refers to adapalene "in pharmaceutical compositions, in particular dermatological compositions, for the treatment of dermatological ailments …". The Board then quotes from page 3 of the patent which states that "an object of the present invention" is the use of adapalene for producing a pharmaceutical composition intended for the treatment of dermatological ailments in that the pharmaceutical composition comprises 0.3% by weight of adapalene.

[43] The Board then observes the following at paragraph 55 of its Reasons:

> As such, although 0.3% is mentioned in the abstract, it is not mentioned in the introductory paragraph or the title of the 237 patent and the patent does not, on its face, relate exclusively to a 0.3% concentration of adapalene.

[44] Later, at paragraph 56, the Board says that, at least on its face, it appears that the use of 0.3% adapalene may be one "(and not the only one)" of the objectives of the 237 patent such that it cannot conclude that the 237 patent pertains exclusively to 0.3% adapalene.

[45] That is the extent of the Board's inquiry as to the invention of the 237 patent. Given that the Board limited its inquiry by its choice of method, the matter should be returned to the Board so that it can complete its mandate. However, as will be seen, there is only one reasonable interpretation of the words of the 237 patent as to the nature of the invention which it protects. In such circumstances, a reviewing court is entitled to supply this interpretation without referring the matter back to the Board: *Stemijon Investments Ltd. v. Canada (Attorney General)*, 2011 FCA 299 at paras. 43-46, 341 D.L.R. (4th) 710, *Maple Lodge Farms Ltd. v. Canada (Food Inspection Agency)*, 2017 FCA 45 at paras. 83-84, 411 D.L.R. (4th) 175.

[46] With that explanation, I will now consider the nature of the invention described and claimed in the 237 patent.

[47] After a very brief discussion of the state of the art, the patent notes that the applicant has developed a new pharmaceutical composition containing adapalene at concentration by weight of 0.3% which, surprisingly, exhibits better treatment efficacy and good tolerance comparable to those of the known compositions with a lower concentration of the active principle (237 patent at p. 2). The patent goes on to say that one of its objects is the use of adapalene to produce a pharmaceutical composition for the treatment of dermatological ailments comprising 0.3% by weight of adapalene in which the composition is a gel or a cream (p. 3).

[48] At pages 6-7, the patent notes that various formulations of the composition containing 0.3% of adapalene will be given by way of illustration. Various examples are given as to the effectiveness of 0.3% adapalene gel in comparison with a 0.1% adapalene gel (pp. 8-9), as well as to the tolerance of the 0.3% adapalene gel (pp. 9-10), and the side effects caused by the topical administration of the 0.3% adapalene gel (pp. 10-12). The descriptive portion of the patent concludes by noting that a pharmaceutical composition containing 0.3% adapalene exhibits a benefit/risk ratio which makes it particularly suitable for the treatment of dermatological elements with an inflammatory or proliferative component, in particular, common acne (p. 13).

[49] This is followed by seven claims, each of which refers (either directly, in the case of independent claims, or indirectly, in the case of dependent claims) to a pharmaceutical

composition comprising 0.3% by weight of adapalene. No claim is made for a pharmaceutical composition having a concentration of adapalene of less than 0.3%.

[50] As a result, I conclude that the invention of the 237 patent is a pharmaceutical composition having a concentration of 0.3% adapalene to be used in the treatment of dermatological conditions with an inflammatory or proliferative component, such as common acne.

[51] The Board's finding that it could not conclude that the 237 patent pertains exclusively to 0.3% adapalene arose from an insufficient review of the 237 patent and, as a result, was erroneous and unreasonable.

C. *Does the invention of the 237 patent pertain to Differin?*

[52] The next step in the analysis deals with the relationship between the invention of the patent and Differin. In order to address this issue, it is necessary to deal with a number of sub-issues.

[53] The first is the issue identified by the Attorney General, namely whether the medicine to which the invention of the 237 patent might pertain is adapalene or Differin. The second issue is the meaning of the phrase "pertains to a medicine". The last issue is the nub of the appeal: Does the invention of the 237 patent pertain to the medicine in question?

[54] These issues will be addressed in turn.

(1) What is the medicine to which the 237 patent might pertain?

[55] In its Memorandum of Fact and Law, the Attorney General argues that the medicine in issue in this appeal is adapalene and not Differin. The Attorney General further submits that this was the position taken by the Board in its decision. With respect, the Board's reasons do not support this conclusion.

[56] The Board's analysis begins at page 14 of its decision. The first paragraph reads as follows:

> As noted above, the only issue in dispute between the Parties was whether the patents pertain to the two medicines at issue. For the reasons that follow, the Panel finds that (a) the 237 patent pertains to Differin, and orders Galderma to file prescribed information on this basis for the period between January 1, 2010 and March 14, 2016; and (b) the 321 and 451 patents do not pertain to Differin or Differin XP.

[57] Later, the Board states the issue as follows: "The question before this Panel, therefore, is whether the 237 patent is or can be used for the medicine Differin, which is a medicine containing 0.1% adapalene that is used to treat dermatological disorders" (Board Reasons at para. 53).

[58] When stating its conclusion at paragraph 58 of its Reasons, the Board says:

> […] the Panel is satisfied that there is a rational connection, at least of the merest slender thread, which connects the 237 patent and Differin. Put differently, the Panel concludes that, on the face of the 237 patent, the patent pertains to Differin because the patent is capable of being used for Differin.

[59] Finally, the Board concludes this portion of its Reason as follows: “For these reasons, the Panel finds that the 237 patent “pertains” to Differin under section 79(2) of the *Patent Act*, and, on this basis, orders Galderma to file the prescribed information […].”

[60] These references are not easily reconciled with the proposition that the Board believed that the medicine was adapalene as opposed to Differin. The Board was clearly aware that Differin was a 0.1% concentration of adapalene and invariably referred to the medicine in issue as Differin, the commercial preparation, and not adapalene, the active ingredient.

[61] The application before the Board was a request that Galderma provide certain prescribed information so as to allow the Board to determine if Differin had been sold at an excessive price. In order for that application to succeed, Board staff had to demonstrate that Galderma was the patentee of an invention which pertained to a medicine. The medicine in question would necessarily have to be the medicine which was sold in Canada at the material time, otherwise the question of excessive price would not arise. Given that Differin was on the market and adapalene *per se* was not, it was not unreasonable for the Board to conclude that the relevant medicine was Differin.

(2) The meaning of the phrase “pertains to a medicine”

[62] As mentioned earlier, the Board summarized the key principles in relation to the phrase “pertains to” from its prior jurisprudence (Board Reasons at para. 45). Among those key principles, one finds the following:

> i. There must be a "rational connection or nexus" between the invention and the medicine;
>
> ii. There is no requirement that the invention actually has been used or be in use (in relation to the medicine or otherwise) for there to be a connection between the invention and the medicine;
>
> iii. The connection between the invention and the medicine can be one of the "merest slender thread";
>
> iv. The rational connection between a patent and a medicine can be the medicine itself;
>
> v. In ascertaining whether there is a connection between the invention and the medicine, the Panel [of the Board] should not go beyond the face of the patent (such as by engaging in patent or claims construction, or infringement analysis) […].

[63] The language of "rational connection or nexus" and "merest slender thread" used by the Board is an echo of *ICN* in which this Court indicated that it agreed with counsel that there must be "a rational connection or nexus" between the invention and the medicine (Board Reasons at para. 46). In addition, the Court found that because of the broad scope of the terms "pertaining to" and "pertains to" as they are used in subsections 79(2) and 83(1), the nexus can be "one of the merest slender thread."

[64] It does not add much to our understanding of the relationship between an invention and a medicine to say that there must be a rational connection between the two. One could hardly argue the contrary. The issue is the nature of that connection. The expression "merest slender thread" is a metaphor designed to express the idea that the connection may be tenuous. While it is true that the expressions "pertaining to" and "pertains to" express a looser association than might be conveyed by other more restrictive expressions (such as an invention "comprising" a medicine), those expressions must be understood in context.

[65] An important contextual factor is that the legislator has chosen to define the relationship expressed by “pertaining to” or “pertains to” at subsection 79(2) of the Act. It will be recalled that this provision stipulates that 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.” Since the Board concluded that the 237 patent could not be used to prepare or produce adapalene (Board Reasons at para. 51), the relevant question for the Board in this case, as the Board recognized at paragraph 53 of its reasons, was whether the 237 patent was intended or capable of being used for the medicine Differin.

[66] It goes without saying that the metaphor which describes the relationship expressed by “pertains to” cannot supplant the statutory definition of that expression. This is not to say that the metaphor is not a useful way of expressing the possibility that the relationship between the invention and a medicine may be tenuous but, at the end of the day, the question is whether the invention is intended or capable of being used for medicine, and not whether there is the merest slender thread of a connection.

[67] All of this is to say that the Board must be guided by the statutory definition of “pertains to” and must not substitute “the merest slender thread” for the words Parliament has chosen. The Board clearly indicated at a number of points in its reasons that it understood the meaning of “pertains to” such as when it distinguished between an invention which is intended or capable of being used for the preparation or production of medicine as opposed to one which is intended or capable of being used for medicine: Board Reasons at paras. 52-53. However, in other places, the Board appears to be substituting another test, that of “rational connection” and “merest slender

thread": Board Reasons at para. 58. There is only one test, namely the test set out at subsection 79(2) of the Act.

(3) Does the invention of the 237 patent pertain to Differin?

[68] The Board's repeated references to the fact that the 237 patent did not relate exclusively to a 0.3% concentration of adapalene suggests that its conclusion that the 237 patent pertains to Differin is based upon the possibility that the invention of the 237 patent included a formulation of adapalene in a concentration other than 0.3%. In other words, the Board may have reasoned that since the 237 patent did not relate exclusively to 0.3% adapalene, there was a possibility that it also related to 0.1% adapalene so that, in those circumstances, the invention of the 237 patent could be "used for" Differin as well as for Differin XP.

[69] If the possibility that the invention of the 237 patent pertained to Differin rests solely on this premise, then the Federal Court was correct when it quashed the Board's decision. As noted earlier, the only reasonable interpretation of the 237 patent, read as a whole, is that the invention of that patent is the use of a 0.3% concentration of adapalene to treat dermatological conditions.

[70] However, at another point, the Board referred to other factors which, if they had been considered, may have influenced its decision. In particular, the Board observed that (i) in both Differin and Differin XP, the same molecule is used for the same purpose and (ii) the invention of the 237 patent is the use of adapalene for the treatment of dermatological disorders: Board Reasons at para. 58.

[71] The evidence before the Board included a product monograph which applies to both Differin and Differin XP which does not appear to suggest any clinical differences between the two. The evidence also included the patent itself which, at pages 8-9, compares the effectiveness of a 0.3% concentration of adapalene to a 0.1% concentration in the treatment of acne. This comparison showed that the 0.3% concentration acted more rapidly and more effectively than the 0.1% concentration. At pages 12-13, the patent also reports on a study which shows that the occurrence of undesirable side effects is the same for both concentrations of adapalene and that the intensity of those side effects is average, leading to the conclusion that both concentrations are well tolerated by patients.

[72] On the other hand, the Board had before it evidence of clinicians who said that they would not substitute Differin XP for Differin in their practice.

[73] In cases such as this, where the question is whether an invention pertains to a specific medicine, what kind of clinical similarities would support a finding that the invention of a patent was intended or capable of being used for that medicine? The Board did not address these questions, perhaps because of its view that the 237 patent did not pertain exclusively to 0.3% adapalene. It should be allowed to do so.

[74] These questions involve policy considerations "that we presume the legislature desired *the administrative decision maker* […] to make": *McLean* at paras. 32-33 (emphasis in original). Given that it is the Board who must decide whether the 237 patent pertains to Differin, the matter

must be returned to it so that it can complete its inquiry on the basis of a proper understanding of the invention of the 237 patent.

VIII. Conclusion

[75] For these reasons, I would allow the appeal with costs in this Court and in the Federal Court. I would set aside both the judgment of the Federal Court and the Board's decision, and return the matter to the Board for redetermination on the basis that the invention of the 237 patent is the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders.

"J.D. Denis Pelletier"
J.A.

"I agree
Eleanor R. Dawson J.A."

"I agree
Wyman W. Webb J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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