Federal Court Cour fédérale

Date: 20240111

Docket: T-906-20

Citation: 2024 FC 46

Ottawa, Ontario, January 11, 2024

PRESENT: The Honourable Mr. Justice Fothergill

BETWEEN:

GALDERMA CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

I. Overview

[1] Galderma Canada Inc [Galderma] is a producer and seller of dermatological medicines. Two of its products are Differin and Differin XP. Both products contain the active ingredient adapalene.

[2] Adapalene is a retinoid that is used to treat acne. Differin contains 0.1% adapalene, while Differin XP contains 0.3% adapalene.

[3] Differin was the subject of two Canadian patents, the later of which expired in December 2009. Differin XP was the subject of Canadian Patent No. 2,478,237 [237 Patent], which was issued on May 12, 2009 and lapsed on March 14, 2016.

[4] In a decision dated December 19, 2016, the Board determined that the 237 Patent was capable of being "used for" Differin, within the meaning of s 79(2) of the *Patent Act*, RSC 1985, c P-4, and ordered Galderma to provide pricing information for Differin. Galderma sought judicial review in this Court.

[5] On November 9, 2017, Justice Michael Phelan quashed the Board's decision, holding as follows (*Galderma Canada Inc v Canada (Attorney General)*, 2017 FC 1023 at para 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.

[6] The Attorney General of Canada appealed this Court's decision to the Federal Court of Appeal. In a decision dated June 28, 2019, the Federal Court of Appeal granted the appeal and remitted the matter to the Board for redetermination (*Canada (Attorney General) v Galderma Canada Inc*, 2019 FCA 196 [*Galderma FCA*]. The Judgment of the Federal Court of Appeal reads as follows:

> The appeal is allowed with costs in this Court and in the Federal Court. The judgment of the Federal Court is set aside and the decision of the Patented Medicines Prices Review Board is quashed. The matter is referred back to the Patented Medicines Prices Review Board for determination on the basis that the invention of Canadian Patent No. 2,478,237 is the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders.

[7] On May 7, 2020, the Board issued its redetermination decision, concluding as follows:

> […] the Board concludes that the 237 patent pertains to Differin and orders Galderma to file the prescribed sales and financial information for Differin for the period between January 1, 2010 and March 14, 2016.

[8] Galderma has once again sought judicial review of the Board's decision in this Court.

[9] For the reasons that follow, the Board reasonably found that the invention of the 237 Patent pertained to, or could be used for, Differin. The application for judicial review is therefore dismissed.

II. Decision of the Federal Court of Appeal

[10] In *Galderma FCA*, the Federal Court of Appeal held that the Board had erred in its characterization of the 237 patent as a "use" patent for the molecule adapalene. The Court of Appeal found there was "only one reasonable interpretation of the words of the 237 patent as to the nature of the invention which it protects" (at para 45). 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" (at para 50).

[11] The Federal Court of Appeal also provided guidance on the proper test to be applied under s 79(2). While not resiling from its previous articulation of the low threshold for establishing that a patented invention pertains to a particular medicine (*ICN Pharmaceuticals Inc v Canada*, [1997] 1 FC 32 (FCA) [*ICN*]), the Court of Appeal cautioned that metaphoric language – "merest slender thread" – cannot replace the statutory definition of "pertains to" in s 79(2).

[12] The Federal Court of Appeal noted that the same product monograph applied to both Differin and Differin XP, and did not appear to suggest any clinical differences between the two. The 237 Patent demonstrated that "the 0.3% concentration of adapalene acted more rapidly and more effectively than the 0.1% concentration" in the treatment of acne. The 237 Patent also indicated the same rate and similar intensity of undesirable side effects for both concentrations, suggesting they are both well-tolerated by patients (at para 71).

[13] Clinicians who testified before the Board said they would not substitute Differin XP for Differin. The Federal Court of Appeal concluded (at para 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.

[14] The matter was remitted to the Board to decide whether the 237 patent pertains to Differin "on the basis of a proper understanding of the invention of the 237 patent" (at para 74). Using the language of s 79(2) of the *Patent Act*, the relevant question for the Board was "whether the 237 patent was intended or capable of being used for the medicine Differin" (at para 65).

III. Decision Under Review

A. *The Parties' Positions*

[15] Board Staff argued that the invention of the 237 Patent and Differin use the same molecule and same mechanism of action to treat the same condition, with similar clinical efficacy and side effects. The 237 Patent was therefore capable of being used for Differin.

[16] Galderma argued that "pertains to" in s 79(2) of the *Patent Act* meant encompassing the off-patent medicine, such that one must be capable of being used for the other. Galderma noted that differences in concentrations of adapalene produced differences in effectiveness, tolerance, and side effects. The 237 Patent, the product monograph, and prescribing clinicians all treated the two medicines differently.

B. *The Product Monograph*

[17] The Board observed that the product monograph was identical for the two medicines. The document often referred to Differin XP and Differin as a single "drug" or "medicine". In the

"Consumer Information" section, the two were described as different "dosage forms" of the same medicine. Furthermore, the non-medicinal ingredients used in both were nearly identical.

[18] The only difference mentioned in the product monograph was a slightly greater incidence of adverse reactions from the use of Differin XP compared to Differin, due to the higher concentration of adapalene. The Board noted that the two medicines produced the same kinds of adverse reactions, and in both cases the reactions were of average intensity and occurred within the same window of time.

[19] The Board rejected Galderma's argument that the single product monograph was of little importance given the prevalence of shared product monographs in its medicines. Galderma did not support this argument with evidence. It also tended to downplay the significance of a product monograph, which is an official, scientific document with prescribed requirements. While not determinative, the shared product monograph supported the position of Board Staff.

C. *The 237 Patent*

[20] The 237 Patent included a discussion of 0.1% and 0.3% adapalene formulations. The 237 Patent characterized the tolerance of 0.3% adapalene as "good" and "comparable to those of the known compositions with a lower concentration". Clinical tests showed that the 0.3% concentration acted more quickly than the 0.1% concentration, although the therapeutic effects were similar. The 237 Patent stated that the same kinds of side effects were observed with both medicines, with the occurrence of undesirable side effects being "statistically the same for the

two gels with different concentrations of the active agent". According to the 237 Patent, the "intensity of undesirable side effects is average, which leads to the conclusion that the two gels are well-tolerated by the patients".

D. *The Evidence of Clinicians*

[21] Dr. Vincent Ho provided expert testimony on behalf of Board Staff. In his opinion, Differin XP and Differin differed only in their concentration of adapalene, and the concentration did not change the chemical structure or the medicine's mechanism of action. The different formulations allowed clinicians the flexibility to tailor the medication to an individual's skin colour and type. According to Dr. Ho, "there is no topical acne product that would be considered irreplaceable, or that cannot be substituted".

[22] Dr. Charles Lynde and Dr. Jerry Tan provided expert testimony on behalf of Galderma. They agreed that Differin XP and Differin work in the same way, with the 0.3% adapalene concentration allowing for slightly higher efficacy in patients able to tolerate its slightly greater propensity for irritation. Dr. Tan also stated that, for certain types of acne, he would use either Differin XP or Differin. Dr. Lynde shared this view.

[23] Leithe Holowaty, a prescribing pharmacist who testified on behalf of Galderma, stated that Differin XP and Differin are different due to their efficacy and adverse events. However, she also described them both as "medium strength recommendations" for treating certain types of acne. She stated that she was unaware of any instance in which prescriptions containing

adapalene were substituted for each other or with other products, and that no provincial formulary or private insurer considered Differin XP and Differin to be substitutable.

[24] The Board was unmoved by the practices of provincial formularies and private insurers, observing that their decisions are guided by reimbursement, not clinical effectiveness. Many provincial formularies do not include drugs that contain adapalene, and in some provinces retinoids are not among the substitutable classes of drugs.

E. *The Notices of Compliance and Drug Identification Numbers*

[25] The Board ascribed no importance to Differin XP and Differin having different Notices of Compliance [NOCs] and Drug Identification Numbers [DINs]. It noted that NOCs and DINs are administrative conventions, imposed under a separate regulatory regime with a different focus.

F. *The Board's Conclusion*

[26] The Board rejected Galderma's argument that, for an invention to pertain to a medicine under s 79(2) of the *Patent Act*, it must "encompass" the medicine that a patentee is selling. The Board found this position to be inconsistent with the wording of the provision, and precluded by the decisions of the Federal Court of Appeal in *Galderma FCA* and *ICN*. These decisions establish that the provision is to be given a broad interpretation, consistent with its wording and the Board's mandate to protect Canadians from excessive prices.

[27] Given its findings respecting the clinical similarities between Differin XP and Differin, the Board was satisfied, on a balance of probabilities, that the invention of the 237 Patent pertained to, or could be used for, Differin. The Board acknowledged the slightly higher efficacy and incidence of adverse reactions associated with Differin XP. However, the Board found these to be the normal consequences of the dose-response relationship, and insufficient to outweigh the significant similarities between the two medicines.

[28] The Board therefore required Galderma to provide sales and financial information for Differin for the period January 1, 2010 to March 14, 2016.

IV. Issues

[29] This application for judicial review raises the following issues:

A. What is the standard of review?

B. Was the Board's decision procedurally fair?

C. Was the Board's decision reasonable?

V. Analysis

A. *What is the standard of review?*

[30] The applicable standard of review was explained by the Federal Court of Appeal in *Galderma FCA* as follows (at para 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.

[31] In decisions issued subsequent to *Galderma FCA*, the Supreme Court of Canada confirmed that reasonableness is the presumptive standard of review in all cases, subject to only limited exceptions. None of the exceptions apply here, and accordingly the Board's decision is subject to review by this Court against the standard of reasonableness (*Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*] at paras 25, 53; *Society of Composers, Authors and Music Publishers of Canada v Entertainment Software Association*, 2022 SCC 30 at para 28).

[32] The Supreme Court of Canada has cautioned against conducting "a preliminary analysis of the text, context, and purpose of the legislation just to understand the lay of the land" before examining the reasons given for a tribunal's interpretation of a statutory provision. Such a preliminary step is inconsistent with the reasons-first framework of *Vavilov*, and threatens a "slip

into correctness review" (*Mason v Canada (Citizenship and Immigration)*, 2023 SCC 21 at para 79).

[33] In its written submissions, Galderma suggested that the constitutional dimension of the Board's jurisdiction over non-patented medicines necessitated a correctness standard of review. However, in oral argument counsel for Galderma conceded that the applicable standard of review is reasonableness, as found in *Galderma FCA*.

[34] The Court will intervene only where "there are sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency" (*Vavilov* at para 100). The criteria of "justification, intelligibility and transparency" are met if the reasons allow the Court to understand why the decision was made, and determine whether the decision falls within the range of acceptable outcomes defensible in respect of the facts and law (*Vavilov* at paras 85-86, citing *Dunsmuir v New Brunswick*, 2008 SCC 9 at para 47).

[35] Procedural fairness is subject to a reviewing exercise best reflected in the correctness standard, although strictly speaking no standard of review is being applied (*Canadian Pacific Railway Company v Canada (Attorney General)*, 2018 FCA 69 at para 54). The ultimate question is whether Galderma knew the case to meet, and had a full and fair chance to respond (*Siffort v Canada (Citizenship and Immigration)*, 2020 FC 351 at para 18).

B. *Was the Board's decision procedurally fair?*

[36] Galderma says the Board improperly based its decision on material facts that were not included in its originating Notice of Application. Specifically, the shared product monograph was not mentioned in the Notice of Application. The product monograph nevertheless figured prominently in the arguments of Board Staff, and Galderma maintains that it did not have an adequate opportunity to respond.

[37] Galderma did not object to this alleged breach of procedural fairness before the Board, and it is therefore precluded from raising it for the first time on judicial review (*Canada v Raposo*, 2019 FCA 208 at para 17). Furthermore, the shared product monograph was referred to by the Board in its original decision, by this Court in its previous decision, and by the Federal Court of Appeal in *Galderma FCA*. Galderma has addressed the significance of this document at every stage of the preceding litigation, and has never previously argued that it should not form a part of the analysis.

[38] As Justice Angela Furlanetto noted in her decision rejecting Galderma's motion to adduce new evidence in this application for judicial review (*Galderma Canada Inc v Canada (Attorney General)*, 2022 FC 19 at para 34):

> […] this argument is at odds with the FCA Decision and what was argued by Galderma before the PMPRB in its written submissions relating to the Redetermination Decision. Indeed, nowhere in Galderma's written submissions before the PMPRB was there any indication that there was insufficient evidence for the PMPRB to determine the issue directed by the FCA or that the product monograph should not be used. To the contrary, Galderma acknowledged that the FCA directed the PMPRB to consider the

> product monograph, the 237 Patent and the evidence from clinicians as filed by the parties. It also referred to these sources in its argument. Similarly, the PMPRB referred to each of these sources of evidence in the Redetermination Decision.

[39] There is therefore no merit to Galderma's complaint that the Board improperly relied on the shared product monograph, and thereby breached its right to procedural fairness.

C. *Was the Board's decision reasonable?*

[40] Galderma says there was no evidence before the Board of any market distortion in relation to Differin that might be attributed to the limited monopoly conferred by the 237 Patent. Galderma argues that the Board's failure to assess whether the 237 Patent conferred an ongoing market benefit in relation to Differin renders its decision unreasonable.

[41] Galderma also maintains that the Board wrongly found that Differin XP and Differin are the same medicine, when the clinical evidence tended to show they are distinct. According to Galderma, "the [Board], in effect, defined the medicine at issue as adapalene, and not Differin".

[42] The Board is a creature of statute, established by s 91(1) of the *Patent Act*. Its purpose is to prevent the abuse of patented medicine monopolies in Canada.

[43] Pursuant to ss 91(22) and 92(13) of the *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3, jurisdiction over patents rests with the federal government, while property and civil rights are

assigned to the provinces. The Board is federal, and its jurisdiction cannot encroach on provincial powers.

[44] The Board is limited in its authority by the scope of patent monopolies (*Alexion Pharmaceuticals Inc v Canada (Attorney General)*, 2017 FCA 241 at paras 61-63). However, where a patented invention "pertains to" a medicine, the Board is empowered to regulate and prevent abuse.

[45] The definition of "pertains to" is found in s 79(2) of the *Patent Act*:

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.	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.

[46] Section 80 of the *Patent Act* describes the Board's power to require pricing information for medicines to which patented inventions pertain.

[47] In *Galderma FCA*, the Federal Court of Appeal reproduced the Board's summary of the key principles that inform the meaning of the phrase "pertains to" in s 79(2) of the *Patent Act* (at para 62):

> 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) […].

[48] The Federal Court of Appeal noted that the expressions "rational connection or nexus" and "merest slender thread" were echoes of its decision in *ICN* (*Galderma FCA* at para 63). However, the Court of Appeal was careful to emphasize the nature of the connection (*Galderma FCA* at para 64):

> […] 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.

[49] The metaphor that describes the relationship expressed by "pertains to" cannot supplant the statutory definition of that expression (*Galderma FCA* at para 66). While the relationship between the invention and a medicine may be tenuous, the fundamental question is whether the invention is intended or capable of being used for the medicine.

[50] The existence of a rational connection or nexus between the invention outlined in a patent and the medicine in question is a precondition to Parliament exercising constitutional authority over price control legislation: "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" (*ICN* at page 63). The Court of Appeal in *ICN* continued:

> Putting aside legal arguments for a moment, it seems to me that there are two competing views on the impact of a patent on competition in the marketplace. One view is founded on the premise that where it appears that a patent confers exclusivity with respect to a portion of the market relating to the medicine being sold in Canada, there is a presumption that its mere existence confers market power by distorting the competitive process. Competitors are dissuaded from entering the marketplace by the unpalatable prospect of incurring significant research costs only to run afoul of an existing patent. As a result, the patentee is left with a field of relative exclusivity in the market. This market power in turn translates into the ability to increase prices, perhaps excessively, which establishes the Board's jurisdiction to regulate.

[51] The other view, advanced by ICN, was that a patentee should have an opportunity to adduce evidence to demonstrate that its patent could not reasonably be said to confer market power on the patentee, obviating the basis or need for the Board to assume jurisdiction. The Federal Court of Appeal concluded that ICN's position was incompatible with the approach adopted by Parliament (*ICN* at page 64):

> In my opinion, subsection 83(1) of the Act is concerned only with the existence of a related patent and not its potential or actual effect on the ability of potential competitors to enter a market, or for that matter the ability of patent holders to exercise market power. In my view, the phrase, "an invention pertaining to a

> medicine" [underlining added], and in particular the word pertaining, evinces a clear intention that the nexus between the patent and the medicine is of broad import. For example, there is no requirement that the patent actually be used in the production of the medicine. Nor could subsection 83(1) be reasonably construed to support such a construction. […]

[52] Most recently, in *Merck Canada inc c Procureur général du Canada*, 2022 QCCA 240, the Quebec Court of Appeal observed as follows (at para 195, citing *ICN* at page 63):

> Indeed, the federal jurisdiction also extends to patented inventions that permit the making and marketing of medicines so that the patentee can logically benefit from the commercial advantage conferred by the monopoly granted by the patent, whether or not the medicine itself is patented. It is the ***monopoly*** granted by a patent that permits the federal government to act, whether the monopoly is the result of a patent directly concerning the medicine itself or is rather the result of a patented invention that logically grants the same type of monopoly [emphasis original].

[53] *ICN* concerned an anti-viral medication called Virazole, also known as ribavirin, which is used to treat severe respiratory infections in infants and children. ICN was the holder of three Canadian patents pertaining to ribavirin. At the time the Board sought pricing information for Virazole, two of the patents had expired but the third had not.

[54] ICN argued that the invention described in the third patent could not be used to make ribavirin for pharmaceutical applications. Even if the chemical substance generated in accordance with the patent were available in sufficient quantities, the cost would be prohibitive and it would be too difficult and expensive to store. ICN therefore maintained that the patent could not pertain to Virazole within the meaning of s 79(2) of the *Patent Act*. The Board

disagreed, holding that whether a patentee is making use of the patent in question is irrelevant to the legal question of whether that patent pertains to a medicine.

[55] On judicial review, Justice Bud Cullen noted that the Board had no power to investigate and determine whether a patent is actually being used, and the interpretation advanced by ICN, if accepted, could result in the jurisdiction of the Board being easily circumvented by a patentee declaring that it was not using a particular patent. For the same reasons, Justice Cullen agreed with the Board that the relative efficacy of the patent in producing commercial quantities of a medicine was irrelevant to the issue of whether it pertained to Virazole (*ICN* at page 51).

[56] The Board in *ICN* concluded that it should not engage in the task of claim construction. The Board observed that its statutory mandate required it to have experience in the pricing of "patented medicines". It had neither the further mandate, nor the necessary experience and expertise, to go beyond the face of the patent to construe the use claims before determining whether they corresponded to the uses stipulated in the notice of compliance for Virazole. On its face, the patent that remained in effect was intended for the preparation or production of the medicine ribavirin, and that finding alone was sufficient to establish the Board's jurisdiction. This determination was upheld by both Justice Cullen and the Federal Court of Appeal (*ICN* at page 52).

[57] The following principles may be gleaned from the jurisprudence regarding the Board's application of s 79(2) of the *Patent Act*:

(a) While the relationship between a patented invention and an off-patent medicine may be tenuous, the fundamental question is whether the invention is intended or capable of being used for the medicine, not whether there is the merest slender thread of a connection.

(b) Where it appears that a patent confers exclusivity with respect to a portion of the market relating to the medicine being sold in Canada, there is a presumption that its mere existence confers market power by distorting the competitive process and competitors are dissuaded from entering the marketplace. There is no need for Board Staff to demonstrate actual market distortion, and no opportunity for a patentee to prove the contrary.

(c) The Board has neither the mandate, nor the necessary experience and expertise, to go beyond the face of a patent to construe the use claims before determining whether they correspond to the uses stipulated in the NOC for an off-patent medicine. A finding that, on its face, the patent is intended or capable of being used for the off-patent medicine is sufficient to establish the Board's jurisdiction.

[58] There was no evidence before the Board of any market distortion in relation to Differin that might be attributed to the limited monopoly conferred by the 237 Patent. Galderma argues that the Board's failure to assess whether the 237 Patent conferred an ongoing market benefit in relation to Differin renders its decision unreasonable. However, it is clear from the jurisprudence that the mere existence of a patent that pertains to a medicine gives rise to a presumption of market power due to distortion of the competitive process.

[59] The Board reasonably found that the clinical similarities between Differin XP and Differin supported the conclusion that the 237 Patent pertained to Differin for the purposes of s 79(2) of the *Patent Act*. There was a clear rational connection between the patented invention and the medicine, one that was considerably stronger than the nexus between the patented invention and Virazole in *ICN*.

[60] Galderma asserts that the Board wrongly characterized Differin XP and Differin as the same medicine, when the clinical evidence tended to show they are distinct. The Board expressed the view (at para 31) that "Differin and Differin XP use the same medicinal ingredient, are indicated for the same dermatological disorder and work in the same way". This caused the Board to conclude (at para 60) that "Differin and Differin XP are the same medicine, albeit in different concentrations". This conclusion was reasonably supported by the evidence.

[61] The shared product monograph for the two products supported the existence of a rational connection between them. Indeed, the Federal Court of Appeal observed in *Galderma FCA* that the "product monograph which applies to both Differin and Differin XP […] does not appear to suggest any clinical differences between the two" (at para 71).

[62] The Board found that the invention of the 237 Patent and Differin produced similar clinical effects, with the former acting more rapidly and producing a greater therapeutic effect after eight weeks. The side effects were comparable between the two, although experienced at different rates, and both were well-tolerated. The two medicines were not interchangeable, but

they were prescribed for similar conditions and could in some circumstances be substituted for each other.

[63] The Board's assessment was to involve "policy considerations", which the Federal Court of Appeal presumed Parliament had assigned to the Board (*Galderma FCA* at para 74). The Board referred to its mandate "to ensure that the statutory monopoly granted to patentees of medicines is not abused by excessive pricing of those medicines" (at para 48). The Board also noted that it could exercise its powers only against "patentees, former patentees or persons entitled to the benefit of a patent 'of an invention pertaining to a medicine'" (at para 49).

[64] The Federal Court of Appeal remitted a narrow issue for redetermination by the Board, taking into account its determination that the "invention of the 237 patent is the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders" (*Galderma FCA* at para 75). The Board was directed to consider the kind of clinical similarities that would support a finding that the invention of a patent was intended or capable of being used for that medicine. The Board found significant clinical similarities between Differin XP and Differin, and reasonably concluded that the invention of the 237 Patent pertained to, or could be used for, Differin.

VI. Conclusion

[65] The application for judicial review is dismissed.

[66] By agreement of the parties, costs in the all-inclusive lump sum of $10,000 are awarded to the successful party – the Attorney General of Canada.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed.

2. Costs are awarded to the Attorney General of Canada in the all-inclusive lump sum of $10,000.

"Simon Fothergill"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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