Federal Court  Cour fédérale

Date: 20220107

Docket: T-906-20

Citation: 2022 FC 19

Toronto, Ontario, January 7, 2022

PRESENT: The Honourable Madam Justice Furlanetto

BETWEEN:

GALDERMA CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

ORDER AND REASONS

[1] The Respondent, the Attorney General of Canada [AGC], brings this motion to strike three affidavits filed by the Applicant, Galderma Canada Inc. [Galderma] in this proceeding. The underlying application is a judicial review of a redetermination decision of the Patented Medicine Prices Review Board [PMPRB] in which the PMPRB was ordered to determine whether the invention of Canadian Patent No. 2,478,237 [the 237 Patent], held by the Federal Court of Appeal [FCA] to be the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders, pertained to Galderma's drug Differin. The outstanding issue before

the PMPRB was whether Galderma was required to file certain prescribed sales and financial information for Differin for the period between January 1, 2010 and March 14, 2016.

[2] The evidence in question includes affidavits from two proposed experts, one in patent law and one on regulatory filings, and the affidavit of a fact witness. For the reasons that follow, I will allow the motion in part, striking the affidavit of Galderma's patent expert in full and the other regulatory expert affidavit in part, while allowing the affidavit of Galderma's fact witness, which provides non-controversial background information.

I. Background

[3] The history of the proceedings involving this matter is lengthy. A good summary is provided in the related FCA decision reported at 2019 FCA 196.

[4] By way of brief background, Galderma markets dermatological drug products, two of which contain the single medicinal ingredient adapalene – Differin (0.1% adapalene) and Differin XP (0.3% adapalene). Adapalene was protected by five patents obtained by Galderma. When Galderma entered the market with Differin, it advised the PMPRB that two of the patents (Canadian Patent No. 1,266,646 [646 Patent] and Canadian Patent No. 1,342,075 [075 Patent]) related to Differin. When it entered the market with Differin XP, it identified only the 237 Patent as being relevant. In January 2016, long after the 646 and 075 Patents expired, an application proceeded before the PMPRB seeking to compel Galderma to provide pricing and marketing information for Differin on the basis that the 237 Patent related to Differin in addition to Differin XP.

[5] On December 19, 2016, the PMPRB determined, *inter alia*, that it had jurisdiction over the medicine Differin in relation to the 237 Patent, which by then had expired. The PMPRB found the 237 Patent pertained to Differin and ordered Galderma to file prescribed sales and financial information for the period between January 1, 2010 and March 14, 2016 [2016 PMPRB Decision].

[6] On November 9, 2017, this Court granted Galderma's judicial review of the 2016 PMPRB decision [FC Decision]. The Court found that it was unreasonable for the PMPRB to conclude that the 237 Patent, on its face, pertained to Differin because the patent is capable of being used for Differin, without explaining "how the 237 Patent for 0.3% adapalene can be used for a medicine with 0.1% adapalene".

[7] On June 28, 2019, the FCA granted an appeal of the FC decision and returned the matter back to the PMPRB for redetermination as to whether the invention of the 237 Patent pertained to Differin [FCA Decision]. The FCA provided the PMPRB with directions to conduct the 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. It asked the PMPRB to consider, upon a review of the product monograph for Differin and Differin XP, the 237 Patent, and the evidence filed from clinicians, "what kind of clinical similarities would support a finding that the invention of the patent was intended or capable of being used for [Differin]".

[8] In July 2019, the PMPRB asked the parties to provide written submissions on the impact of the FCA Decision on the PMPRB's redetermination. The parties filed written submissions in

the summer of 2019. No new evidence was requested by the PMPRB and there is no correspondence indicating that the parties requested provision to file any new evidence.

[9] On May 7, 2020, the PMPRB concluded that the 237 Patent pertained to Differin and ordered Galderma to file the prescribed sales and financial information for Differin for the period between January 1, 2010 and March 14, 2016. In reaching its decision, the PMPRB considered all of the evidence initially filed by the parties before the PMPRB, including: evidence from clinicians relating to the clinical similarities and differences between Differin and Differin XP; evidence from a pharmacist relating to prescribing tendencies, efficacy and adverse events for the products; the product monograph for Differin and Differin XP (and Galderma's argument relating to the notices of compliance and drug identification numbers); and the language of the 237 Patent itself. This application is a judicial review of the May 7, 2020 decision [Redetermination Decision].

[10] On September 25, 2020, Galderma served the three affidavits [collectively the Affidavits], which are the subject of this motion: the affidavit of an expert in patent law, Dino Clarizio, Partner with Goodmans LLP [Clarizio Affidavit]; the affidavit of a Regulatory Affairs professional, Madhur Jadawala, employed by Quality & Compliance Services Inc., a pharmaceutical consulting firm located in Mississauga, Ontario [Jadawala Affidavit]; and the affidavit of a fact witness, Jacklyn Shipp, Manager of Regulatory Affairs at Galderma [Shipp Affidavit].

II. Issue

[11] The sole issue on this motion is whether the affidavits served by Galderma should be struck before the hearing of the judicial review application.

III. Analysis

A. *Legal Principles*

[12] The general rule on judicial review proceedings is that the evidentiary record on the application is restricted to the material that was before the administrative decision-maker and any other evidence that was not before the decision-maker, or that could have been placed before the decision-maker, that goes to the merits of the matter is not admissible (*Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22 [*Access Copyright*] at para 19; *Bernard v Canada (Revenue Agency)*, 2015 FCA 263 [*Bernard*] at para 13; *Delios v Canada (Attorney General)*, 2015 FCA 117 [*Delios*] at para 42). The rationale behind the general rule is to promote judicial efficiency and to recognize the differing roles of administrative decision-makers and reviewing courts (*Bernard* at paras 15-16); the Court is to review the decision of the administrative decision-maker rather than conduct a trial *de novo* on new evidence.

[13] There are limited recognized exceptions that do not offend the rationale behind the general rule. The first exception provides that general background information that will assist the Court in understanding the issues in the judicial review may be permissible as long as it does not include additional evidence, argument, or comments on the evidence before the decision-maker (*Access Copyright* at para 20a; *Delios* at paras 44-48; *Bernard* at paras 20-23).

In *Delios*, at paragraph 45, this was described as "non-argumentative orienting statements that assist the reviewing court in understanding the history and nature of the case that was before the decision-maker".

[14] The second exception provides for raising issues of natural justice or procedural fairness. This evidence must be raised at the first opportunity and cannot be raised in judicial review if it could have been raised before the decision-maker (*Access Copyright* at para 20b; *Bernard* at paras 25-27).

[15] The third exception allows for evidence highlighting the complete absence of evidence on a conclusion reached by the decision-maker (*Access Copyright* at para 20c; *Bernard* at para 24; *Keeprite Workers' Independent Union v Keeprite Products Ltd*.(1980), 29 O.R. (2d) 513 (C.A.)).

[16] Other exceptions may also apply, including evidence that goes to a jurisdictional error (*Alberta Wilderness Association v Canada (Environment)*, 2009 FC 710 [*AWA*] at para 30), provided that such evidence does not interfere with the role of the administrative decision-maker as fact-finder and merits-decider (*Bernard* at para 28).

[17] Whether the Court should make an advance ruling on the admissibility of evidence is a discretionary matter that is to be guided by consideration of whether:

a. the advance ruling would allow the hearing to proceed in a timelier and more orderly fashion;

b. the issue is relatively clear cut or obvious;

c. it is a discretionary matter on which reasonable minds may differ or a question of law;

d. a party would suffer prejudice if the matter is not determined before the hearing; and,

e. it is in the interests of justice.

(*Bernard* at para 11; *Access Copyright* at para 12; *Armstrong v Canada (Attorney General)*, 2005 FC 1013 at para 40; *Tsleil-Waututh Nation v Canada (Attorney General)*, 2017 FCA 128 at para 23)

B. *The Affidavits*

[18] The AGC asserts that the Affidavits are tendentious, opinionated, argumentative and prejudicial to the Respondent. Galderma asserts in its written submissions that the Affidavits do nothing more than provide additional background information that will assist the Court. It asserts that the expert opinions given do not extend to the merits of the Redetermination Decision, that the evidence can be dealt with in cross-examination, and that any questions concerning admissibility should be left to the reviewing Court.

[19] In its oral submissions, Galderma raised additional arguments, asserting that the expert affidavits addressed an absence of evidence on the conclusion reached by the PMPRB, that there was a procedural defect in the handling of the redetermination by the PMPRB, and that the expert evidence supported a challenge made by Galderma to the PMPRB's jurisdiction. None of these arguments were reflected substantively in Galderma's written materials and it was acknowledged that the procedural fairness argument is not currently included in the notice of application.

[20] As set out further below, in my view, irrespective of these arguments both the Clarizio Affidavit and Jadawala Affidavit provide objectionable opinion evidence that must be struck.

(1) Clarizio Affidavit

[21] In the Clarizio Affidavit, Mr. Clarizio provides opinions on the following questions set out at paragraph 3:

> a. Do the inventions described in Canadian Patent No. 1,266,646 (the "646 Patent") and Canadian Patent No. 1,312,075 (the "075 Patent") pertain to Differin, a pharmaceutical composition comprising 0.1% adapalene by weight? In other words, are the inventions of the 646 and 075 Patents intended or capable of being used for Differin or for the preparation or production of Differin?
>
> b. When did the 646 and 075 Patents expire and, if so, did Differin effectively become 'off-patent' (no-longer protected by a patent in Canada) and available for competitors to make, use or sell a pharmaceutical composition comprising 0.1% adapalene by weight in Canada? When did this occur?
>
> c. What does the invention of Canadian Patent No. 2,478,237 (the "237 Patent") pertain to? Is this invention restricted or limited to a particular pharmaceutical composition of adapalene? Is the invention as described and claimed in the 237 Patent intended or capable of being used for Differin?
>
> d. Does the scope of the rights provided by 237 Patent extend to pharmaceutical compositions comprising 0.1% adapalene by weight (e.g. Differin)?

[22] He concludes in his paragraphs 4c and 4d that:

> c. .... The invention described and claimed in the 237 Patent is limited to a 0.3% adapalene product and explicitly excludes a 0.1% adapalene product. The invention of the 237 Patent does not, therefore, pertain to Differin (0.1% adapalene), and is not intended or capable of being used for any adapalene composition other than a composition containing 0.3% adapalene.

d. The invention and rights provided by 237 Patent do not extend, directly or indirectly, to pharmaceutical compositions comprising 0.1% adapalene by weight such as Differin.

[23] The AGC asserts that the first two questions are not relevant. It further asserts that the opinions on the 237 Patent go to the merits of the proceeding and put forward a conclusion that the PMPRB was incorrect in its decision on the redetermination. It asserts that these opinions were not before the PMPRB and that to allow this evidence would improperly transform the application into a trial *de novo*.

[24] Galderma argues that the Clarizio Affidavit provides a summary of the patents that is relevant to the proceeding. It asserts that the opinion evidence on the scope of the 237 Patent and whether Differin is off-patent is consistent with the Redetermination Decision.

[25] In my view, the Clarizio Affidavit runs contrary to the general principles on admissibility of evidence in a judicial review and does not satisfy the criteria for any allowable exception.

[26] First, it opines on the 646 Patent and 075 Patent (paragraphs 3a, 3b, 4a, 4b and related paragraphs 15-27), which are not relevant to the issues before the Court on the Redetermination Decision. As noted in the FCA Decision, the 646 Patent expired on March 13, 2007 and the 075 Patent expired on December 29, 2009. Galderma provided the PMPRB with the prescribed information with respect to Differin until the 646 and 075 Patents expired. The only issue on the redetermination relates to the 237 Patent. An analysis of the 646 and 075 Patents is not relevant to the redetermination issue, which relates only to the 237 Patent.

[27] Second, it states facts and opines on issues already decided by the FCA, including the nature of the invention of the 237 Patent (for example, paragraphs 30 and 34-36 of the affidavit). Mr. Clarizio's evidence that the 237 Patent is a selection patent directed at pharmaceutical compositions contained within the broader composition ranges of adapalene disclosed and claimed in the 646 and 075 Patents (paragraph 35) seeks to expand on findings regarding the invention already made by the FCA. This type of evidence conflicts with the role of the PMPRB as stated in the FCA Decision:

> [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] ... 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.

[28] Moreover, it opines on the very legal issue that was before the PMPRB – whether the invention of the 237 Patent pertains to Differin (questions 3c and 3d, opinions 4c, 4d and related paragraphs 31, 33-40, and 42), providing an opinion that is contrary to that found by the PMPRB.

[29] An affidavit that expresses an opinion on the facts before the decision-maker may be struck in its entirety where the purpose of the evidence is to argue against the conclusions made

by the tribunal. This includes the opinion evidence of an expert. As stated in *Canadian Tire Corporation v Canadian Bicycle Manufacturers Association*, 2006 FCA 56 [*Canadian Tire*]:

> [7] For the reasons that follow, it is my view that there can be no doubt whatsoever that the affidavit must be struck in its entirety.
>
> [8] To begin with, it is clear that the Dovey affidavit constitutes opinion evidence, the purpose of which is to demonstrate to this Court that the conclusions reached by the CITT in its Report and, in particular, that the increase in the number of bicycles and finished painted bicycle frames in to Canada is a principal cause of the serious injury caused to the domestic market, are not supported by, nor are they consistent with the financial evidence and information contained in the CITT Report.
>
> [9] Recently, in *Ly* v. *Canada (Minister of Citizenship and Immigration),* 2003 FC 1184, dated October 10, 2003, Mr. Justice von Finkenstein, in the context of an application for judicial review of a decision of the Appeals Division of the Immigration and Refugee Board, correctly, in my view, dealt with the nature of affidavits that could be filed in support of a judicial review application. At paragraph 10 of his Reasons the learned Judge expressed his view as follows:
>
> > Except on motions, affidavits shall be confined to facts within the personal knowledge of the deponent: Rule 81(1), Federal Courts rules, 1998. The affidavit must be free from argumentative materials and the deponent must not interpret evidence previously considered by a tribunal or draw legal conclusion (*Deigan* v. *Canada (AG)* (1996), 206 N,R. `95 (Fed. C.A.) ...
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> [10] In *Deigan* v. *Canada, supra,* to which Mr. Justice von Finkenstein refers in support of his view this Court agreed that the Motions Judge was correct in striking out certain paragraphs of the affidavit at issue on the grounds that these paragraphs were tendentious, opinionated, argumentative.
>
> [11] Although I agree with counsel for the applicant that certain paragraphs of Mr. Dovey's affidavit are factual statements and not opinion, they cannot be dissociated from the paragraphs which, in effect, constitute Mr. Dovey's opinion. Further, some of the paragraphs, namely paragraphs 1 to 4, which set out Mr. Dovey's qualifications and experience, are of no use to this Court on their

> own. Indeed, the true purpose of the Dovey affidavit is not to present facts for consideration of the Court, but to present facts which are already within the existing record so as to argue that the conclusions reached by the CITT are not justified. Paragraph 8 of Mr. Dovey's affidavit, which I again reproduce, makes that perfectly clear:
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> > 8. In the context of the above, I was asked to address and answer from a financial and accounting point of view the following questions:
> >
> > > Are the determinations and recommendations by the Tribunal concerning bicycles pursuant to the Global Safeguard Inquiry consistent with and supported by the financial evidence and information set out in the Tribunal Report?
>
> [12] In other words, the purpose of the affidavit is to provide to this Court an assessment of the evidence which differs from that made by the CITT. That evidence is, in my view, not admissible in this judicial review application.
>
> [13] Another reason for striking the Dovey affidavit is that it constitutes evidence that was not before the CITT when it issued its Report. Allowing the introduction of the affidavit would have the effect of transforming the application before this Court into a *de novo* application. Were I to conclude that the affidavit is admissible, I would then have to grant, if they so wished, leave to the respondents to file their own "expert" affidavits in response to that of Mr. Dovey. The parties would most certainly proceed to discovery and file the transcripts of the evidence adduced thereat. In the end, this Court would be called upon to decide the issues raised by the judicial review application on evidence which the CITT had never considered.

[30] Opinion evidence from an expert may be admissible only if it is relevant and necessary to assist the trier of fact and is not subject to any exclusionary rule (*AWA* at para 33). However, the necessity requirement must be applied strictly where an expert purports to opine on the ultimate issue. As stated in *AWA* with respect to the expert evidence filed in that case by Dr. Boyce:

> [34] I do not find that Dr. Boyce's expert opinion on the issues before the Court, including the issue of "critical habitat," is

> necessary in the sense that without it, the Court could not appreciate the technical nature of the issues before it, which is how necessity is defined in *Mohan*. Further, the Supreme Court in *Mohan* directs that the necessity requirement is to be interpreted strictly where an expert provides an opinion on the "ultimate issue." The Boyce affidavit notably includes explicit opinion evidence on the ultimate issue at paragraphs 10, 18, 24 and 27. The statement in these paragraphs go well beyond a description of the evidence before the decision-maker, or helpful background information; their inadmissibility in this proceeding is obvious. The remainder of Dr. Boyce's affidavit contains factual information which arguably constitutes helpful background information on graduate work supervised by Dr. Boyce, which was then relied upon by the respondent in preparing the Greater Sage-Grouse Recovery Strategy. However, in my view, this factual information is so intertwined with unnecessary opinion evidence that it cannot realistically be severed and its admission would prejudice the respondent. As was the case in *Canadian Tire Corporation v. Canadian Bicycle Manufacturers Association*, 2006 FCA 56, the entirety of the contentious affidavit should be struck. Accordingly, the respondent's motion with respect to the Boyce affidavit is granted and it is struck in its entirety.

[31] I do not agree with Galderma that Mr. Clarizio's evidence is either relevant or necessary to assist the Court in this application. This is not the same circumstance as in *Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FC 700 at paragraphs 15-16, where the construction of the patent was an issue before the Court and the assistance of an expert was required.

[32] In this case, the 646 and 075 Patents are not in issue and the FCA already determined the invention of the 237 Patent. A further interpretation of the invention of the 237 Patent is not necessary. The narrow issue put before the PMPRB was set out at paragraphs 73-75 of the FCA Decision:

> [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.
>
> ...
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> [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.

[33] Galderma argues that Mr. Clarizio's evidence is necessary because the PMPRB relied on insufficient evidence to conclude that the 237 Patent was intended or capable of being used for Differin. It asserts that the PMPRB used a results driven approach (*Alexion Pharmaceuticals Inc v Canada (Attorney General)*, 2021 FCA 157) and that the clinical evidence and product monograph relied upon by the PMPRB were not probative and were incapable of being used to determine the issue before the PMPRB.

[34] However, 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.

[35] The FCA posed a very narrow issue for determination by the PMPRB based on a characterization of the invention of the 237 Patent made by the FCA. Neither party indicated to the PMPRB that further evidence was necessary to be filed to address this narrow issue. There is no basis to expand the evidence now simply because the Applicant disagrees with the decision made. An expert's opinion on the 237 Patent is not required for the Court to assess the reasonableness of the decision made.

[36] I agree with the AGC, the Clarizio Affidavit includes explicit opinion evidence on the ultimate issue. The opinions given are not necessary and go well beyond a description of the evidence before the decision-maker, or helpful background information. To allow such expert evidence now would be to seek a trial *de novo*. This is not the purpose of a judicial review proceeding.

[37] Further, Galderma's assertion that Mr. Clarizio's evidence will be of assistance to its jurisdictional argument is not persuasive. Leaving aside the AGC's argument as to whether the jurisdictional argument can be raised on the application in view of paragraphs 12, 13, 28 and 29 of the FCA Decision and whether it can be raised on this motion (*Rouleau-Halpin v Bell Solutions Techniques Inc*, 2021 FC 177 at para 33-34), the argument is premised on whether the

PMPRB has jurisdiction to consider medicines that are off-patent because the relevant patents have expired. The FCA Decision already establishes the expiry date of the 646, 075 and 237 Patents. Mr. Clarizio's evidence is not required to set out these facts.

[38] It is clear that the Clarizio Affidavit is intended to demonstrate to the Court that the conclusion reached by the PMPRB is not correct and is inconsistent with the 237 Patent. The comments made by the Court in *Canadian Tire* apply.

[39] The Clarizio Affidavit is improper opinion evidence and must be struck in its entirety. As was decided in *Canadian Tire*, where the evidence is so clearly inadmissible as in this case, the time to strike the affidavit is now to avoid further unnecessary steps and to assist with the efficient and orderly hearing of this application on its merits.

(2) Jadawala Affidavit

[40] The Jadawala Affidavit addresses the following two mandates. First, Mr. Jadawala was asked to "provide information about the regulatory framework and process established by Health Canada to grant marketing authorization for new drugs, filing a Supplement to a New Drug Submission and the form, content, and approval of product monographs." Second, he was asked to review the product monograph for Differin and Differin XP and to provide his opinion on "whether Differin and Differin XP are different drug products."

[41] In completing these mandates Mr. Jadawala concludes that:

a. "Differin and Differin XP are two distinct and separate drug products" (paragraphs 5a and 30-36);

b. shared product monographs for both drug products are required for supplements to a new drug submission, the form and content of which follows Health Canada guidelines (paragraphs 5b and 18-29);

c. each drug included in a shared product monograph is considered a separate medicine or drug by Health Canada with its own DIN (paragraphs 5c and 27); and,

d. shared product monographs are common and do not indicate that Differin and Differin XP are the same medicine/drug product (paragraphs 5d, 27-29 and 37).

[42] The AGC asserts that the Jadawala Affidavit opines on the ultimate issue by providing an opinion that Differin and Differin XP are not the same medicine or drug product. It asserts that determination of whether Differin and Differin XP are the same medicine is the exact issue the FCA ordered the PMPRB to consider and is the finding from which the PMPRB concluded that the 237 Patent pertained to Differin.

[43] Galderma asserts that the Jadawala Affidavit provides helpful guidance on the purpose and contents of product monographs. It does not dispute that Mr. Jadawala provides an opinion on Differin being a different drug product than Differin XP, but asserts that this opinion does not go to the merits. I disagree.

[44] In reaching its decision, the PMPRB reviewed all of the evidence filed by the parties, including the shared product monograph for Differin and Differin XP and opined in paragraph 60 that: “Differin and Differin XP are the same medicine”. In so finding, it concluded that this supports the view that Galderma should file the prescribed sales and financial information. Mr. Jadawala’s opinion in “a” and “d” above, that Differin and Differin XP are not the same drug products, and that shared product monographs for different drug products do not indicate

that Differin and Differin XP are the same medicine, challenges part of the justification for the PMPRB's conclusion that Differin and Differin XP are the same medicine.

[45] Similarly, in my view, the additional opinions provided by Mr. Jadawala on the commonality and use of shared product monographs also go to the merits of the decision.

[46] At paragraph 35 of the Redetermination Decision, the PMPRB comments on the argument made by Galderma before the PMPRB, namely "that the fact that Differin and Differin XP share the same product monograph is of little importance, because shared product monographs are a relatively common feature of medicines marketed in Canada by the same manufacturer." The PMPRB indicates that it does not accept this argument because no evidence was provided to support it and it downplays the status of a product monograph. As stated by the PMPRB:

> A product monograph is an official document with prescribed requirements that is required by the *Patented Medicines Regulations* to be provided to the Board. It is a factual, scientific document that, devoid of promotional material, describes the essential characteristics of the medicine, including the properties, claims, indications, proper dosages, method of administration and side effects and contains any other information that may be required for the optimal, safe and effective use of the drug. <u>While not determinative, the fact that the Respondent chose to include Differin and Differin XP in the same product monograph supports Board Staff's position that Differin and Differin XP are simply different strengths or dosage forms of the same medicine.</u>
>
> [<u>emphasis added</u>] [footnotes removed]

[47] The additional opinions provided by Mr. Jadawala in his paragraphs 5b and 5c and related paragraphs seek to rebut the finding made by the PMPRB by filling the evidentiary gap

noted by the PMPRB and relying on evidence that was not before the board. This is akin to requesting a trial *de novo* on a supplemental evidentiary record.

[48] Further, Galderma has not established that the opinion evidence of Mr. Jadawala is necessary (*R v Mohan*, [1994] 2 S.C.R. 9). In my view, it is clear that the Court is fully able to review the reasonableness of the PMPRB's assessment of the information in the product monograph for Differin and Differin XP without the assistance of Mr. Jadawala. Indeed, it has already commented on the product monograph at paragraph 71 of the FCA Decision.

[49] Paragraphs 28 and 29 of the Notice of Application allege:

> 28. The Board unreasonably relied on the existence of a shared Product Monograph and its contents to conclude that Differin 0.1 and Differin XP are the same medicine.
>
> 29. The Board unreasonably relied upon the language required by Health Canada to be included in the Product Monograph, including the use of drug in the singular form, to conclude that Differin 0.1 and Differin XP are the same medicine.

[50] I note that there is some information included in the Jadawala Affidavit that is non-contentious factual information relating to the regulatory requirements for product monographs that may be of assistance to the Court as background information for the purpose of evaluating paragraphs 28 and 29 of the Notice of Application. However, this information must be separated from the opinions given and from new evidence that goes to the merits of the decision or that is seeking to extend the evidentiary record to other regulatory areas. The Jadawala Affidavit shall be limited to the factual information found in paragraphs 3, 25 and 26 and the brief background on Mr. Jadawala provided in paragraphs 8-11. The evidence found in the remainder of the affidavit is improper opinion or fact evidence that will be struck now.

(3) Shipp Affidavit

[51] The Shipp Affidavit sets out documents and party filings relating to the 2016 PMPRB Decision, the FC Decision, the FCA Decision and the Redetermination Decision. It also provides additional background on Galderma's various patents relating to adapalene and earlier proceedings with the PMPRB relating to other Galderma products, TactuPump and TactuPump Forte.

[52] The AGC asserts that the Shipp Affidavit contains inadmissible hearsay, opinion, and argument and is irrelevant to the application. It asserts that the affidavit does not introduce any information that will not already be before the Court through PMPRB's Certified Tribunal Record.

[53] The AGC takes particular issue with paragraphs 24, 26, and 31 of the affidavit, which it contends constitutes legal argument disguised as evidence. Paragraphs 24, 26 and 31 state as follows:

> 24. I have been informed by counsel that on February 23, 2016 Board Staff of the PMPRB issued a Notice of Application against Galderma Canada alleging that Galderma Canada had failed to file information regarding the medicines Differin, Differin XP, TactuPump and TauctuPump [*sic*] Forte. The Board Staff alleged that the PMPRB had jurisdiction over the medicines based upon the 451 Patent and the 237 Patent.
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> ...
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> 26. In its pre-hearing written arguments the Board Staff raised for the first time that the 321 Patent pertained to Differin and Differin XP.
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> ...

> 31. On July 11, 2019, the PMPRB directed the parties to provide written submissions on the impact of the Federal Court of Appeal Decision on the redetermination of this matter. The submissions were to be served and filed by July 31, 2019 and reply submissions, if any, were to be served and file [*sic*] by August 9, 2019. Galderma Canada and the Board Staff filed written submissions and reply written submissions to the PMPRB on July 31, 2019 and August 9, 2019, respectively. The PMPRB's direction neither permitted, nor raised the possibility of, the parties filing any further evidence in relation to the matters to be re-determined.

[54] Galderma asserts that the Shipp Affidavit provides non-prejudicial background information that will assist the Court. Galderma asserts that paragraphs 24, 26 and 31 relate to uncontroversial facts that are already in the record.

[55] While I agree with the AGC that paragraphs 3-10 and 17-23 relate to patents that were not in issue on the Redetermination Decision, in my view these paragraphs, along with paragraphs 11-16, 25, 27-30 and 32-33 and their accompanying documents, provide non-prejudicial, non-contentious background information on the history of the proceeding. These documents may be helpful to the hearings judge in considering the assertions made in its Notice of Application that the PMPRB "failed to consider, and in fact disregarded, the entire record" (Notice of Application, paragraph 4).

[56] Similarly, I find paragraph 24 to be non-objectionable. While I agree that this paragraph includes hearsay information, the information is reliable and the hearsay is necessary as the initial Notice of Application referenced in the paragraph was undated when served. The remainder of the information in this paragraph, in my view, while not a direct quote from the document itself, is non-prejudicial.

[57] The information in paragraph 26 is taken from the 2016 PMPRB Decision. Similarly, the information in the first three sentences of paragraph 31 is taken from a July 11, 2019 PMPRB Direction [Direction]. While I agree with the AGC that the last sentence of paragraph 31 could be considered to be argument, I do not consider this sentence to be prejudicial as the Direction speaks for itself.

[58] In my view, the Shipp Affidavit should be permitted to stand.

IV. Conclusion

[59] For the reasons set out above, the motion will be granted in part. The Clarizio Affidavit will be struck in full and paragraphs 1, 2, 4-7, 12-24, 27-37 of the Jadawala Affidavit will be struck. The motion will be dismissed with respect to the Shipp Affidavit.

[60] As agreed by the parties, the costs of the motion shall be in the cause and a schedule shall be set for the service of any responding evidence.

ORDER IN T-906-20

THIS COURT ORDERS that

1. The motion to strike the Affidavits is granted in part as follows:

    a. the affidavit of Dino P. Clarizio, sworn September 25, 2020, is struck in its entirety;

    b. paragraphs 1, 2, 4-7, 12-24, 27-37 of the affidavit of Madhur Jadawala, sworn September 24, 2020, are struck; and

    c. the motion is dismissed with respect to the affidavit of Jaclyn Shipp, sworn September 23, 2020.

2. The Respondent shall have 45 days from the date of this Order to serve any responding evidence.

3. Costs of the motion shall be in the cause.

"Angela Furlanetto"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-906-20
STYLE OF CAUSE:	GALDERMA CANADA INC. v ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	HEARD BY VIDEOCONFERENCE
DATE OF HEARING:	NOVEMBER 2, 2021
ORDER AND REASONS:	FURLANETTO J.
DATED:	JANUARY 7, 2022

APPEARANCES:

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Victor Paolone Abigail Brown	FOR THE RESPONDENT

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