Federal Court  Cour fédérale

Date: 20150810

Docket: T-1774-14

Citation: 2015 FC 959

Ottawa, Ontario, August 10, 2015

PRESENT: The Honourable Madam Justice Kane

BETWEEN:

PHOTOCURE ASA

Applicant

and

THE MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA

Respondents

PUBLIC JUDGMENT AND REASONS

[1] This is an application for judicial review of a decision of the Minister of Health [Minister], dated July 21, 2014, which found that CYSVIEW (previously known as HEXVIX) is not eligible for data protection pursuant to section C.08.004.1 of the *Food and Drug Regulations*, CRC, c 870 [Regulations], made under the *Food and Drugs Act*, RSC 1985, c F-27 because it is not an "innovative drug" and, as a result, will not be added to the Register of Innovative Drugs [Register].

Overview

[2] The applicant, Photocure ASA [Photocure], submitted the drug CYSVIEW for approval by the Minister in accordance with the Regulations. The Minister (in a decision made by the Office of Patented Medicines and Liaison [OPML] by Ms Anne Bowes, Director of the Office of Submissions and Intellectual Property, Therapeutic Products Directorate, Health Canada, on behalf of the Minister) determined that the drug's medicinal ingredient, hexaminolevulinate hydrochloride [HAL HCl], is an ester variation of a previously approved medicinal ingredient, aminolevulinic acid hydrochloride [ALA HCL].

[3] Section C.08.004.1 of the Regulations provides that new drugs are eligible to receive data protection if they contain a medicinal ingredient that has not been previously approved in a drug by the Minister or are not a variation of a previously approved medicinal ingredient, such as a salt, ester, enantiomer, solvate or polymorph. The Director considered the application of Photocure, provided a preliminary opinion, considered written submissions and then oral submissions at an in person meeting, and determined that CYSVIEW (HAL HCI) is an ester of a previously approved medicinal ingredient, and is not eligible for data protection and cannot be listed on the Register.

[4] On this judicial review the applicant argues that the Minister erred and was incorrect in finding that HAL HCl is an "ester" of a "previously approved medicinal ingredient". The applicant argues that the issues are the interpretation of "innovative drug" and the scope (or as

described by the applicant, the "metes and bounds") of "medicinal ingredient", which are questions of law and, therefore, the standard of correctness applies.

[5] The applicant also argues that the Minister erred in interpreting the enumerated variations; because HAL HCI is both a salt and an ester, it would not fall within the variations and should have been considered as an "arguable variation" of a previously approved medicinal ingredient. As such, the Minister should have considered the clinical data submitted and should have granted data protection.

[6] The applicant notes the importance of data protection, which recognizes the value of the research, the process for approval, and the need to promote innovation and access to beneficial drugs. The applicant also notes that the Notice of Compliance has been issued for CYSVIEW, but without data protection, a third party (generic drug manufacturer) could rely on Photocure's data to support the third party's own Abbreviated New Drug Submission [ANDS].

[7] The applicant also submits that because the decision is incorrect, the Court could and should direct that HAL HCI is not an ester of the previously approved medicinal ingredient and the only issue to refer back to the Minister for determination is whether HAL HCI is an arguable variation of a previously approved medicinal ingredient.

[8] Alternatively, the applicant argues the decision is unreasonable.

[9] The applicant now seeks to admit the affidavit of Dr James Wuest, an expert in organic chemistry to support its position. This affidavit was not provided to the OPML, which makes the decision on behalf of the Minister. The applicant argues that this affidavit provides the Court with helpful background and scientific information.

[10] The applicant argues that the affidavit of Ms Bowes, which was submitted by the respondent in response to the affidavit of Dr Wuest, is not admissible, at least in part, because Ms Bowes is not an expert witness on matters of chemistry and her affidavit seeks to supplement the reasons for the decision.

[11] The respondent submits that the question on judicial review is one of fact or at most mixed fact and law and, therefore, the reasonableness standard applies. The Minister's decision that HAL HCI is an ester of a previously approved medicinal ingredient is based on a comparison of the medicinal ingredients. This involves science, more specifically, chemistry, and is not a question of statutory interpretation.

[12] The respondent argues that Dr Wuest's affidavit is inadmissible; it was not part of the record before the decision-maker and it includes argument and opinion on the very issue that the Minister is responsible for deciding.

[13] The respondent seeks to admit the affidavit of Ms Bowes, in response to the affidavit of Dr Wuest. Ms Bowes' affidavit describes the process for data protection in general, the particular proceedings and elaborates on the decision making process.

[14] The admissibility of the affidavits is addressed below as a preliminary issue.

[15] I find that the affidavit of Dr Wuest is not admissible. It includes opinion evidence on the very question the Minister is responsible for deciding and did decide. Although the applicant seeks to recharacterize the issue as a question of law and argues that Dr Wuest does not offer any opinion on the question of law, the question on this judicial review is not a question of law. I also find that the affidavit of Ms Bowes is not admissible.

[16] This judicial review focuses on the Minister's decision whether HAL HCI is a variation of a previously approved medicinal ingredient. This is based on an assessment of the medicinal ingredient in HAL HCI which involves the facts, and more particularly, the science.

[17] The reasonableness standard applies and the decision is reviewed on the basis of the record that was before the Minister. For the reasons elaborated upon below, I find that the Minister's decision is reasonable and the application is, therefore, dismissed.

The Minister's Decision Under Review

[18] Photocure filed a New Drug Submission [NDS] seeking approval for CYSVIEW in December 2013.

[19] CYSVIEW is used as an imaging agent for the detection and management of non-muscle invasive bladder cancer. CYSVIEW contains the medicinal ingredient HAL HCl.

Preliminary Decision Letter

[20] On January 20, 2014, the OPML issued a preliminary decision which set out the definition of "innovative drug" in section C.08.004.1 of the Regulations, the medicinal ingredient in CYSVIEW and its chemical structure, and the chemical structure of ALA HCI. The OPML found that the medicinal ingredient of CYSVIEW, HAL HCl, is an ester of ALA HCI or HCL, which was previously approved by the Minister and is known as LEVULAN KERASTICK, and indicated its preliminary position that CYSVIEW is therefore not an "innovative drug".

[21] The OPML invited Photocure to make submissions in response to this preliminary decision.

Submissions by the Applicant to the OPML/Minister

[22] Photocure's submissions, dated March 17, 2014 argue that the definition of "innovative drug" does not expressly exclude CYSVIEW, because HAL HCl is a salt of HAL, which has not previously been approved; HAL is an ester of ALA, which has also not previously been approved; and, therefore, HAL HCl is not an ester of ALA HCl. Photocure concludes that CYSVIEW is not a drug containing a salt, ester, enantiomer, solvate or polymorph of a previously approved medicinal ingredient and is not excluded from the definition of "innovative drug".

[23] Photocure noted that other variations – i.e., those not specifically enumerated and excluded as minor variations – are considered on a case-by-case basis. Photocure argued that the

data submitted with its NDS was new and significant, that the NDS does not include any comparative studies against previously approved drugs, and that CYSVIEW is not simply a minor change to LEVULAN KERASTICK. Photocure further submitted that other named drugs (that are esters or prodrugs of previously approved medicinal ingredients) have been previously approved by the Minister.

[24] The submissions also explain that CYSVIEW is a prodrug for the intracellular delivery of ALA, and then note in detail the differences between ALA and HAL.

[25] Photocure provided several articles from medical and pharmacological journals describing the results of various experiments and developments in the detection of bladder cancer dated from 1995 to 2006.

[26] Photocure also requested an in person meeting with the OPML, which was held on May 21, 2014.

[27] At the meeting, Photocure presented slides reiterating its position as noted above and as set out in its written submissions. The slides indicate that HAL HCI is a salt of HAL (which was not previously approved) and that HAL HCI is an ester of ALA (which was not previously approved) and concludes that HAL HCI is, therefore, not an ester of ALA HCI (which was previously approved) within the meaning of "innovative drug".

[28] The slides also compare the Minister's treatment of HAL HCI and ALA HCI to that of temsirolimus and sirolimus, noting that temsirolimus and sirolimus were both found to be innovative drugs.

[29] The slides address the "other variations", noting the factors for a case- by-case analysis as set out in the Guidance Document. The slides note that CYSVIEW is a prodrug for the intracellular delivery of ALA and highlight the differences between ALA and HAL, as described in the written submissions, and the new, significant and extensive data provided in the NDS. The slides also state that CYSVIEW is not a minor change to LEVULAN KERASTICK, note that its indications are very distinct, and describe the distinctions.

The Final Decision Letter

[30] The decision of Ms Bowes of the OPML, on behalf of the Minister, was set out in a letter dated July 21, 2014. The decision acknowledges the written and oral submissions of Photocure that CYSVIEW is not a variation of a previously approved medicinal ingredient within the meaning of "innovative drug," but disagrees. The decision notes the definition of "innovative drug" and the relevant part of the Regulatory Impact Analysis Statement [RIAS] which accompanied the 2006 amendments that added C.08.004 [definition] to the Regulations, explains the list of excluded variations, and notes that data submitted in support of the approval is relevant only when the variation is not explicitly enumerated. The decision also notes the interpretation of "innovative drug" established by the Federal Court of Appeal in *Takeda Canada Inc v Canada (Minister of Health)*, 2013 FCA 13 at paras 125-126, 440 NR 346 [*Takeda*]. In addition, it

indicates that each determination of data protection is case-specific and, consequently, previously approved drugs are not a relevant consideration.

[31] The decision acknowledges that HAL HCI is a salt of HAL and that HAL is an ester of ALA and that both HAL HCl and ALA HCl are salts. The decision then concludes that, because the structure of HAL HCl is identical to ALA HCl, both of which are salts, but with the addition of an ester group, HAL HCl is an ester of ALA HCl. The decision includes a depiction of the structure of HAL HCI, ALA, HAL and ALA HCI in making the relevant comparisons.

[32] The decision concludes that CYSVIEW is a previously approved medicinal ingredient and is specifically excluded from the scope of data protection in accordance with the definition of "innovative drug".

The Relevant Provisions of the Regulations

C.08.004.1 (1) The following definitions apply in this section.	C.08.004.1 (1) Les définitions qui suivent s'appliquent au présent article.
"abbreviated new drug submission" "abbreviated new drug submission" includes an abbreviated extraordinary use new drug submission. (présentation abrégée de drogue nouvelle)	« présentation abrégée de drogue nouvelle » « présentation abrégée de drogue nouvelle » S'entend également d'une présentation abrégée de drogue nouvelle pour usage exceptionnel. (abbreviated new drug submission)
"innovative drug" "innovative drug" means a drug that contains a	« drogue innovante » « drogue innovante » S'entend de toute drogue

medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (drogue innovante)	qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d'un ingrédient médicinal déjà approuvé tel un changement de sel, d'ester, d'énantiomère, de solvate ou de polymorphe. (innovative drug)
"new drug submission" "new drug submission" includes an extraordinary use new drug submission. (présentation de drogue nouvelle)	« présentation de drogue nouvelle » « présentation de drogue nouvelle » S'entend également d'une présentation de drogue nouvelle pour usage exceptionnel. (new drug submission)
"pediatric populations" "pediatric populations" means the following groups: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (population pédiatrique)	« population pédiatrique » « population pédiatrique » S'entend de chacun des groupes suivants : les bébés prématurés nés avant la 37e semaine de gestation, les bébés menés à terme et âgés de 0 à 27 jours, tous les enfants âgés de 28 jours à deux ans, ceux âgés de deux ans et un jour à 11 ans et ceux âgés de 11 ans et un jour à 18 ans. (pediatric populations)

[33] The data protection provisions were described by Justice David Near (as he then was) in *Takeda Canada v Canada (Minister of Health)*, 2011 FC 1444 at paras 11-13, 401 FTR 259 [*Takeda* (FC)]:

> The Regulations provide protection for data submitted as part of the drug marketing approval process leading to the issuance of a NOC. This protection can, however, only be extended to an "innovative drug" defined in subsection C.08.004.1(1) as a "drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."
>
> Once deemed eligible for listing on the Register, an "innovative drug" receives data protection consisting of two formal restrictions. Firstly, a generic drug manufacturer cannot file a submission based on a comparison to an "innovative drug" within the first six years of the eight-year period after the drug has received a NOC (subsection C.08.004.01(3)(a)). Secondly, the Minister may not issue a NOC to the generic drug manufacturer before the end of the eight-year period (subsection C.08.004.01 (3)(b)).
>
> As stated in subsection C.08.004.1(2), the data protection provisions apply to the implementation of Article 1711 of the *North American Free Trade Agreement*, 1992, 32 ILM 296 (NAFTA) and paragraph 3 of Article 39 in the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 UNTS 299 (TRIPS). Where a person submits undisclosed data for approval of a pharmaceutical product, and the product utilizes a "new chemical entity", signatory states commit to preventing other persons from making "unfair commercial use" of that data and (for a reasonable time) from relying on that data in their own applications for approval.

The Preliminary Issue: Admission of the Affidavits

Dr Wuest's Affidavit

[34] The applicant filed the affidavit of Dr Wuest in support of its application for judicial review. Dr Wuest is an expert in organic chemistry. His affidavit provides a "chemistry primer" relating to covalent bonds, esters, salts, the ranking of functional groups and how chemists would classify a salt with an ester group; how the chemistry primer relates to HAL HCl; how a chemist

would understand the relationship between HAL HCl and ALA HCl; and whether a chemist would consider temsirolimus (a medicinal ingredient that was approved by the Minister) to be an ester of sirolimus.

Ms Bowes' Affidavit

[35] In response to the evidence of Photocure, the respondent filed the affidavit of Anne Bowes. As noted above, Ms Bowes is the Director of the Office of Submissions and Intellectual Property, Therapeutic Products Directorate, Health Canada, of which the OPML is a Division, and made the decision on behalf of the Minister. Ms Bowes provides a background of the relevant regulatory scheme; general scientific information regarding the scientific terms in the regulations (including esters); the process the OPML applies in determining whether a drug is an "innovative drug"; the specific process that took place in the decision under review (including that the affidavit of Dr Wuest was not provided to the OPML by Photocure in its written and oral submissions); and the basis upon which the OPML disagrees with the characterization of "esters" by Photocure and Dr Wuest.

The Respondent's Motion to Strike the Affidavit of Dr Wuest

[36] The respondent moves to strike Dr Wuest's affidavit and submits that it should be addressed at the outset of the hearing of the application for judicial review.

[37] The applicant argues that because the admissibility of the affidavit is linked to the characterization of the question on judicial review, the motion to strike should be considered simultaneously or in the context of the merits of the judicial review.

[38] The Court heard arguments on the admissibility of the affidavits at the outset of the hearing but reserved decision on their admissibility. The parties' position on the merits provided context for their arguments on the admissibility of the affidavits. The arguments on the merits could not be isolated or divorced from consideration of the admissibility of the affidavits.

The Respondent's Submissions on the Motion to Strike the Affidavit of Dr Wuest

[39] The respondent argues that Dr Wuest's affidavit does not comply with Rule 306 of the *Federal Courts Rules*, SOR/98-106 [Rules] and does not fall within any of the recognized exceptions to the principle that only the material that was available to the decision-maker should be considered on an application for judicial review (*Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22 at para 20, 428 NR 297 [*Access Copyright*]; *Ochapowace First Nation (Indian Band No 71) v Canada (Attorney General)*, 2007 FC 920 at para 9, 73 Admin LR (4th) 182 [*Ochapowace First Nation*]).

[40] The respondent acknowledges that the Court has identified exceptions to the principle that no new material or evidence should be admitted on judicial review that was not before the decision-maker, but argues that this affidavit does not fall within any of the exceptions recognized to date (*Access Copyright*, at para 20). The respondent submits that the issue is not one of procedural fairness; the evidence does not provide general background to assist the court

in understanding the issues on the judicial review and there was ample evidence on the record for the decision to be made, therefore the affidavit does not highlight the lack of evidence before the decision-maker.

[41] The respondent submits that Dr Wuest's affidavit does not provide general or helpful background that would assist the Court; on the contrary, the chemistry primer offered in the affidavit confuses the issues by offering alternate scientific propositions to contradict the Minister's findings after the fact.

[42] The respondent also submits that the affidavit includes improper opinion evidence seeking to bolster the record and lead to a *de novo* determination on the issue of whether HAL HCI is an ester of ALA HCI, which is the decision the Minister should make and did make. Dr Wuest offers his opinion on the very issue that the Minister is responsible for deciding.

[43] Photocure had a full opportunity to advance its position before the decision-maker and could have presented this evidence with its submissions. The respondent submits that, although some of the evidence in Dr Wuest's affidavit is the same as in Photocure's submissions, Dr Wuest provides additional opinions to bolster the submissions and to suggest the Minister's decision is wrong from the perspective of a Harvard scientist.

[44] The respondent notes that Dr Wuest's affidavit describes his mandate at paragraphs 9-12, with the key task at paragraph 11: "to determine whether a chemist would consider HAL HCI to be an ester of aminolevulinic acid hydrochloride ("ALA HCI")".

[45] Dr Wuest provides his opinion at paragraph 16 on the very issue that the OPML is responsible to decide on behalf of the Minister, and Dr Wuest takes the opposite view.

[46] The respondent also notes the recent decision in *Delios v Canada (Attorney General)*, 2015 FCA 117, [2015] FCJ No 549 (QL) [*Delios*], which provides further clarity regarding the admissibility of affidavits under the "general background" exception, noting that it is limited to non-argumentative statements and should not include any spin or advocacy (at para 45). More importantly, the Court of Appeal noted at para 46:

> But "[c]are must be taken to ensure that the affidavit does not go further and provide evidence relevant to the merits of the matter decided by the administrative decision-maker, invading the role of the latter as fact-finder and merits-decider": *Access Copyright*, above at paragraph 20(a).

[47] In the present case, the respondent submits that Dr Wuest's affidavit goes beyond the acceptable limits; it provides evidence on the merits and usurps the role of the Minister as fact finder and merits decider; and it opines on the question the Minister was to determine, which was whether HAL HCI is a variation of a previously approved medicinal ingredient.

[48] In response to the submission by Photocure that the admission of expert evidence is permissible to provide context and explanation where the legal and scientific issues are linked, the respondent argues that the facts in *Apotex v Canada (Minister of Health)*, 2013 FC 1217, 69 Admin LR (5th) 1 [*Apotex*], relied on by the applicant, differ as the substance of the evidence in the affidavits was already before the decision-maker and was not in dispute and, therefore, did not contravene Rule 306 of the Rules.

[49] The respondent notes that the parts of the affidavit regarding Dr Wuest's qualifications are not in dispute, but all of the other parts are linked to his opinion on the central issue and the paragraphs cannot be isolated. Therefore, the respondent objects to the affidavit in total.

[50] Contrary to the applicant's assertion that Dr Wuest's affidavit is not challenged, the respondent points out that it disputes Dr Wuest's affidavit in the Ms Bowes' affidavit. The applicant notes that upon receipt of the affidavit, the Minister immediately noted its objection.

[51] The respondent submits that the issue in the present case is the application of the facts and the science to the definition (i.e., the Minister's decision was a factual one, based on the science) and is not a question of law. The issue is whether the decision-maker considered the relevant information on the record and made a reasonable decision.

The Applicant's Submissions on the Motion to Strike the Affidavit of Dr Wuest

[52] Photocure's position regarding the admissibility of Dr Wuest's affidavit is linked to its position on the merits of the application, in particular the characterization of the question for this judicial review and the applicable standard of review. This is elaborated upon later in the decision.

[53] Photocure submits that the statutory interpretation of "innovative drug" and the approach to considering "medicinal ingredient" is the issue. When the entirety of the medicinal ingredient is considered, the conclusion can only be that HAL HCI is a salt of HAL, HAL is an ester of

ALA and, therefore, HAL HCI is not an ester of ALA HCI. The Minister did not interpret the medicinal ingredient correctly because the Minister did not consider its structure in its entirety.

[54] Photocure argues that once the issue is understood as the proper interpretation of "innovative drug" and "medicinal ingredient," it is clear that Dr Wuest's affidavit does not opine on the legal question that the Court must now deal with but does provide helpful background on matters of science.

[55] Photocure notes that there are well-recognized exceptions to the general rule that the Federal Court should not admit evidence that was not before the decision-maker. These exceptions include where the evidence is general background information and where the evidence provides context and knowledge not otherwise in the Court's knowledge or on the record and where the legal and scientific issues are linked (*Access Copyright*, at paras 19-20; *Apotex*, at para 60; and *Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FC 700 at para 16, 329 FTR 190 [*Abbott*]). The list of exceptions is not closed (*Access Copyright*, at para 20).

[56] Photocure submits that Dr Wuest's affidavit provides helpful background to assist the Court in understanding how a chemist would assess a salt with an ester functional group, particularly because the Minister's decision is silent on this issue.

[57] With respect to the recent guidance in *Delios*, Photocure submits that Dr Wuest's affidavit does not advocate a position on the legal issue the Court must address, which is the

correct interpretation of "innovative drug" and/or "medicinal ingredient" and it does not usurp the role of the Minister, spin the information, nor is it argumentative, (*Delios*, at para 45). Dr Wuest sets out the same position advanced by Photocure in its submissions to the Minister.

[58] Dr Wuest's mandate focused on whether the medicinal ingredient is a salt or an ester and of what other chemical. The applicant submits that Dr Wuest takes the correct approach by focusing on the entire medicinal ingredient. The applicant notes that it is not in dispute that HLA HCI is a salt of an ester of ALA.

[59] If Photocure is correct on the legal interpretation of medicinal ingredient, the decision-maker must look at the entirety of the structure, and then must find that HAL HCI is not an ester of ALA HCI.

[60] Photocure also notes that in *Apotex*, I admitted parts of the expert affidavits because their content was already before the Court and submits that this is also the case regarding the content of Dr Wuest's affidavit; the same submissions were made regarding HAL HCI by Photocure in its memorandum of argument.

[61] The applicant submits that even if Dr Wuest's affidavit is not admitted, the decision is clearly incorrect or unreasonable. The Minister failed to look at the entire structure of the medicinal ingredient in determining whether it is an ester of a previously approved drug.

The Applicant's Submissions Regarding Ms Bowes' Affidavit

[62] Photocure objects to the admission of paragraphs in Ms Bowes' affidavit which includes "inadmissible opinion evidence on technical matters of chemistry," specifically paragraphs 6, 24, 25 and 37-41. Photocure submits that Ms Bowes is not qualified as an expert and, as a result, the paragraphs of her affidavit that opine on matters of chemistry are not admissible.

[63] Although Photocure noted its objection to specific paragraphs in its submissions, it also indicates that it is content to permit at least parts of the affidavit to remain on the record to show Ms Bowes' reasoning process, with the qualification that it should not be considered as opinion evidence on technical matters of organic chemistry.

[64] Photocure argues that Ms Bowes' affidavit puts forward new grounds for the decision which were not in the decision letter. Ms Bowes refers to excerpts from Photocure's own NDS which were not set out as reasons for the decision (for example, that Photocure refers to […]). Ms Bowes noted that the word "ester" was included in the chemical name of CYSVIEW. Photocure argues that even if this information were taken from its own submission, it was not part of the original decision.

The Respondent's Submissions Regarding Ms Bowes' Affidavit

[65] The respondent submits that Ms Bowes' affidavit is confined to facts within her personal knowledge and therefore respects the scope of Rule 81(1) of the Rules. Her affidavit relates to the drug submission and review process regarding the data protection provisions, and is related

to her office and qualifications (*Canada (Minister of Citizenship and Immigration) v Pierre*, 2012 FC 1169 at para 23, [2012] FCJ No 1257 (QL)). Her evidence regarding the determination for CYSVIEW is related to her understanding of official Health Canada records, her personal knowledge of organic chemistry and her participation in the final decision.

[66] The respondent notes that Ms Bowes' affidavit was tendered in response to the respondent's submission of the affidavit of Dr Wuest and that Ms Bowes was not put forward as an expert witness.

[67] The respondent submits that paragraphs of the affidavit that Photocure argues are "inadmissible opinion evidence on technical matters of chemistry" simply summarize the decision, provide a chemical formula and refer to a standard organic chemistry textbook. These portions of the affidavit would assist the Court understanding what an "ester" means within the Regulations.

[68] In response to Photocure's submission that Ms Bowes offers new reasons that were not part of the decision, the respondent acknowledges that they were not part of this decision, but submits that Ms Bowes' affidavit does not set out new reasons or new evidence. Paragraphs 37-41 respond to a statement in Dr Wuest's affidavit that HAL HCI is not an ester of ALA HCI by pointing to […].

[69] The respondent notes that Photocure has indicated that it does not object to this evidence remaining in the record to explain the Minister's interpretation of the provision.

The Affidavits are Not Admissible

[70] To some extent, the issue of the admissibility of both affidavits is tied to the characterization of the issue in this judicial review.

[71] Photocure argues that the question on this judicial review is a question of law to be determined on the correctness standard and that the decision is not correct. It argues that Dr Wuest's affidavit does not opine on this question of law and should be admissible to assist the Court to correctly interpret the meaning of medicinal ingredient and/ or innovative drug. Photocure alternatively argues that even if the Court finds that the issue is one of fact; whether HAL HCI is an ester of a previously approved medicinal ingredient, based on the application of the facts and the science, Dr Wuest's affidavit should still be admitted because Dr Wuest's opinion on the science would be helpful to the Court.

[72] The general rule is that the Court should not admit evidence that was not before the decision-maker.

[73] In *Ochapowace First Nation* the Court of Appeal noted two exceptions to the general rule: where the evidence was introduced to support an argument going to procedural fairness or

jurisdiction; and, where the material is considered general background information that would assist the Court.

[74] In *Access Copyright*, at para 20, the Court of Appeal recognized three exceptions, noting that the list of exceptions is not exhaustive, but that these exceptions only exist where the new evidence is not inconsistent with the differing roles of the court and the decision-maker:

> [20] There are a few recognized exceptions to the general rule against this Court receiving evidence in an application for judicial review, and the list of exceptions may not be closed. These exceptions exist only in situations where the receipt of evidence by this Court is not inconsistent with the differing roles of the judicial review court and the administrative decision-maker (described in paragraphs 17-18, above). In fact, many of these exceptions tend to facilitate or advance the role of the judicial review court without offending the role of the administrative decision-maker. Three such exceptions are as follows:
>
> > (a) Sometimes this Court will receive an affidavit that provides general background in circumstances where that information might assist it in understanding the issues relevant to the judicial review: see, e.g., *Estate of Corinne Kelley v. Canada*, 2011 FC 1335 at paragraphs 26-27; *Armstrong v. Canada (Attorney General)*, 2005 FC 1013 at paragraphs 39-40; *Chopra v. Canada (Treasury Board)* (1999), 168 FTR 273 at paragraph 9. Care must be taken to ensure that the affidavit does not go further and provide evidence relevant to the merits of the matter decided by the administrative decision-maker, invading the role of the latter as fact-finder and merits-decider. In this case, the applicants invoke this exception for much of the Juliano affidavit.
> >
> > (b) Sometimes affidavits are necessary to bring to the attention of the judicial review court procedural defects that cannot be found in the evidentiary record of the administrative decision-maker, so that the judicial review court can fulfil its role of reviewing for procedural unfairness: e.g., *Keeprite Workers' Independent Union v. Keeprite Products*

> *Ltd*. (1980), 29 OR (2d) 513 (CA). For example, if it were discovered that one of the parties was bribing an administrative decision-maker, evidence of the bribe could be placed before this Court in support of a bias argument.
>
> (c) Sometimes an affidavit is received on judicial review in order to highlight the complete absence of evidence before the administrative decision-maker when it made a particular finding: *Keeprite*, *supra*.
>
> [Emphasis added]

[75] The only exception noted in *Access Copyright* which is relevant to the present case is (a), general background.

[76] As the applicant pointed out, *Apotex* and *Abbott* support the view that, where the legal and scientific issues are linked, the Court may benefit from expert affidavits that were not before the decision-maker (which generally falls within exception (a) from *Access Copyright*).

[77] In *Apotex*, which dealt with the Minster's decision on identical medicinal ingredients, I found that parts of the affidavits were admissible, noting that the content was already before the Court in other affidavits which were not objected to; however, I struck the parts of the affidavit which stated an opinion. I noted, at para 60:

> I agree that in appropriate circumstances on judicial review, such as in this case, where the legal issues and scientific issues are linked, the Court may benefit from expert affidavits which were not before the decision maker in order to provide important context and knowledge not otherwise in the Court's knowledge or on the record.

[78] In *Abbott*, which dealt with patent construction, the substance of the evidence included in the affidavit had been admitted orally before the decision-maker (noted in the Federal Court of Appeal decision, *Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FCA 354 at para 40, 382 NR 280).

[79] The Court of Appeal reiterated that new evidence on judicial review is exceptional, noting the key reasons for the general rule at para 37:

> The general rule in an application for judicial review is that the record before the Federal Court should not include any documentary evidence that was not before the maker of the decision sought to be reviewed. The rationale for this rule is judicial efficiency. In an application for judicial review, unlike an originating application (such as an application for prohibition under the NOC Regulations), the Federal Court is not the decision maker of first instance, but rather is reviewing the decision of someone else, in this case the Minister. Judicial resources would be wasted if the parties to an application for judicial review of the Minister's decision, having failed to put their best foot forward before the Minister, could hope to provide additional evidence in the Federal Court to impugn the Minister's decision.

[80] More recently, the Federal Court of Appeal provided additional guidance regarding the receipt of evidence on judicial review under the general background exception in *Delios*.

[81] The Court of Appeal first noted the basic principles established in *Access Copyright*: that the reviewing court cannot allow itself to become a forum for fact-finding on the merits of the matter (at para 41) and that the general rule is that the evidentiary record before the Federal Court on judicial review is restricted to the evidentiary record that was before the administrative decision-maker (at para 42). The Court of Appeal then clarified the limitations on the "general background" exception to the general rule established in *Access Copyright* noting at paras 44-46:

> Under this exception, a party can file an affidavit providing "general background in circumstances where that information might assist [the review court to understand] the issues relevant to the judicial review": *Access Copyright*, above at paragraph 20(a).
>
> The "general background" exception applies to non-argumentative orienting statements that assist the reviewing court in understanding the history and nature of the case that was before the administrative decision-maker. In judicial reviews of complex administrative decisions where there is procedural and factual complexity and a record comprised of hundreds or thousands of documents, reviewing courts find it useful to receive an affidavit that briefly reviews in a neutral and uncontroversial way the procedures that took place below and the categories of evidence that the parties placed before the administrator. As long as the affidavit does not engage in spin or advocacy – that is the role of the memorandum of fact and law – it is admissible as an exception to the general rule.
>
> But "[c]are must be taken to ensure that the affidavit does not go further and provide evidence relevant to the merits of the matter decided by the administrative decision-maker, invading the role of the latter as fact-finder and merits-decider": *Access Copyright*, above at paragraph 20(a).

[82] Dr Wuest's expert evidence provides additional scientific background information that is more detailed than the evidence that was before the Minister, the written representations submitted on March 17, 2014 and the presentation that accompanied the May 21, 2014 meeting, regarding the issue of and the approach to determining whether HAL HCI is a variation of a previously approved medicinal ingredient. For example, it advances the notion that the presence of a salt should take precedence over an ester in the nomenclature of chemical compounds, and that chemists would regard HAL HCI as simply HAL, which reflects its core molecular structure, and would regard CYSVIEW first, as a salt of HAL and secondly, as an ester of ALA. This information may have been helpful to the decision-maker, but it was not provided to the

decision-maker. It might also be helpful to the Court in some circumstances. However, the affidavit goes beyond the acceptable limits of exceptions to the general rule.

[83] Dr Wuest opines on the very issue the Minister was asked to determine and the very issue that Photocure addressed in its submissions to the Minister, albeit with more and different details. Although the applicant seeks to recharacterize the question as one of statutory interpretation, a question of law, I find that it is not. The submissions to the Minister were directed to the issue of whether HAL HCI is an innovative drug and whether it is a variation of a previously approved drug. The submissions were about the composition of HAL HCI and the previously approved medicinal ingredient (ALA HCl), i.e., about the facts and the science and not about the interpretation of the regulations or the approach the applicant now argues should have been taken in assessing the medicinal ingredient (although there is nothing on the record to suggest that this approach was not taken by the Minister).

[84] As elaborated upon later in these reasons, the issue on this judicial review is not whether the Minister erred in interpreting the meaning of "innovative drug" or "medicinal ingredient"; rather, it is whether the Minister erred in making the factual determination that HAL HCI is an ester of a previously approved medicinal ingredient.

[85] Dr Wuest's mandate clearly asks him to answer the same question the Minister was responsible for determining, specifically "to determine whether a chemist would consider HAL HCI to be an ester of aminolevulinic acid hydrochloride ("ALA HCI")." In addition to other

aspects of his mandate, Dr Wuest was also asked to consider whether a chemist would consider HAL HCI to be a salt or an ester and of what other medicinal ingredient.

[86] Dr Wuest's affidavit advocates the position that HAL HCI is not an ester of a previously approved medicinal ingredient. The affidavit does not fall within the limits of the exceptions noted in *Access Copyright* and elaborated upon in *Delios*. It provides evidence on the merits of the issue and invades the role of the "merits decider."

[87] The evidence in the affidavit crosses the line and attempts to impugn the decision after the fact with information that was not provided to the decision-maker.

[88] Photocure's position that Dr Wuest's evidence is undisputed or unchallenged and, as a result, should be admitted regardless of whether the issue is framed as one of law or fact, ignores the respondent's early objection to this affidavit and the filing of Ms Bowes' affidavit in response. I disagree with the applicant's position that in the absence of Dr Wuest's affidavit there is no evidence to assist the Court in determining if the decision is incorrect or unreasonable. The evidence to guide this judicial review is that which is on the record and was considered by the decision-maker.

Ms Bowes' Affidavit

[89] Ms Bowes' affidavit was not proffered as an expert opinion, but rather as a response to the assertions and opinion in Dr Wuest's affidavit.

[90] Rule 81(1) of the Rules provides that affidavits must be confined to facts within the deponent's personal knowledge. The affidavit would be admissible to describe Ms Bowes' understanding of official Health Canada records, her personal knowledge of organic chemistry (as it relates to the decision), the decision-making process and her participation in the final decision.

[91] Paragraphs 37-41 refer to Photocure's NDS, which was not referred to in the decision. Although Photocure did refer to its NDS in its submissions to the Minister (for example, in its slide presentation), this information could be construed as bolstering the reasons of the decision-maker. Despite that this information was included in the Photocure's NDS and was within Photocure's knowledge, these paragraphs would be struck if the affidavit were admitted.

[92] Otherwise, Ms Bowes' affidavit does not include any information which is not already in the record.

[93] Given my finding that Dr Wuest's affidavit is not admissible, I also find that Ms Bowes' affidavit is not admissible, given that it was filed in response and to challenge or dispute the content of Dr Wuest's affidavit and, for the most part, does not provide any additional information not on the record.

The Issues on the Judicial Review

The Applicant's Position

[94] Photocure argues that the Minister erred in finding that CYSVIEW does not fall within the definition of "innovative drug" in the Regulations and as a result will not be subject to data protection. According to the current jurisprudence, if a medicinal ingredient falls within any of the variations listed in the Regulations (i.e., a salt, ester, enantiomer, solvate or polymorph) data protection is not possible.

[95] Photocure submits that the Minister was incorrect (or alternatively, unreasonable) in interpreting the regulations in two respects:

- The Minister erred in interpreting the listed variations as simply requiring the presence of an ester functional group rather than considering the whole structure of the medicinal ingredient to determine whether it is a salt or an ester and if it is, whether it is a salt or an ester of a previously approved medicinal ingredient. The applicant argues that the Minister ignored the salt aspect and if the Minister had considered the entire structure, the Minister would have concluded that HAL HCI was a salt of HAL, which was not previously approved; and,

- The Minister erred in interpreting the listed variations – a salt, ester, enantiomer, solvate *or* polymorph – as including a medicinal ingredient that has both a salt *and* an ester functional group. The applicant argues that because HAL HCI has both a salt and an ester functional group, it does not fall within the list of excluded variations. Therefore, the Minister should have regarded HAL HCI as an "arguable variation" and considered Photocure's clinical data.

[96] The applicant submits that both issues are questions of law that arise from the interpretation of the wording of the regulations. The applicant adds that the jurisprudence has

consistently found that the standard of correctness applies to the interpretation of the regulations including "innovative drug" and that it would inject uncertainty into the law to apply the standard of reasonableness.

[97] The applicant submits that the specific legal issue in this case – the interpretation of "innovative drug" and the "metes and bounds" of "medicinal ingredient" within that definition – has not been previously decided by the Court, however, it is the same type of legal question in other cases found by this Court to demand the correctness standard of review.

[98] The applicant points to *Epicept Corporation v Canada (Minister of Health)*, 2011 FCA 209, 425 NR 353 [*Epicept*], where the issue was the issue was the meaning of "previously approved" and the correctness standard of review was applied by the Court. The Federal Court of Appeal was not required to comment on the standard of review because the issue became moot prior to the appeal.

[99] Similarly, in *Teva Canada Limited v Canada (Minister of Health)*, 2011 FC 507, 95 CPR (4th) 423 [*Teva*], the Court applied the correctness standard to the judicial review on the question whether the drug was "previously approved". The Federal Court of Appeal found that the Minister "correctly" interpreted the regulations and that it did not need to address the parties' submissions on the standard of review (*Teva Canada Limited v Canada (Minister of Health)*, 2012 FCA 106, 431 NR 185).

[100] In *Takeda* (FC), the issue was whether the Minister erred in interpreting the definition of "innovative drug" to exclude DEXILANT as a "variation" because it was an enantiomer of a previously approved drug. *Takeda* argued that the words "variation … such as … enantiomer" [emphasis added] did not mean that all enantiomers were "variations". The Court found that the issue was the statutory interpretation of the provision and the standard of review was correctness.

[101] The applicant notes that Justice Stratas, in his dissenting reasons in *Takeda* considered the developments in the jurisprudence regarding the applicable standard of review for the interpretation of legislation by administrative decision-makers, noting that the starting point is the rebuttable presumption of reasonableness, but that this can be overcome. Justice Stratas conducted a standard of review analysis and concluded that all the factors to rebut the presumptive standard favoured correctness as the standard of review to address the interpretation of "variation."

[102] Justice Dawson, for the majority, agreed that the standard of review was correctness based on consideration of the factors set out in *Dunsmuir v New Brunswic*k, 2008 SCC 9, [2008] 1 SCR 190 [*Dunsmuir*]. Justice Dawson disagreed that reasonableness was the presumptive standard for a Minister's interpretation of the applicable regulation based on *Alberta (Information and Privacy Commissioner) v Alberta Teachers' Association*, 2011 SCC 61, [2011] 3 SCR 654.

[103] The applicant also notes that in *Celgene Inc v Canada (Minister of Health)*, 2012 FC 154, 405 FTR 8, the question was the interpretation of "previously approved" and the parties agreed that the standard of correctness applied.

[104] The Court of Appeal agreed, noting at para 34, that in *Takeda*, the Court of Appeal held that correctness is the appropriate standard of review to be applied to "such questions" (*Canada (Minister of Health) v Celgene Inc*, 2013 FCA 43, [2014] 3 FCR 524).

[105] The applicant acknowledges that the Federal Court of Appeal settled the interpretation of "innovative drug" in subsection C.08.004.1(1) of the Regulations in *Takeda*. An innovative drug is a drug that: contains a medicinal ingredient not previously approved in a drug by the Minister; is not a variation of a previously approved drug; a salt, ester, enantiomer, solvate or polymorph of a previously approved medicinal ingredient is such a variation; and, for other substances, not specifically mentioned, referred to as arguable variations, the Minister can consider the nature and extent of the data. The applicant characterizes this as a three step process, but submits that this interpretation does not settle the questions it now raises.

[106] The applicant also points to the more recent decision in *Viiv Healthcare ULC v Teva Canada Limited*, 2015 FCA 93, [2015] FCJ No 455 (QL), where the question was the eligibility for listing a single medicinal ingredient against a fixed dose combination drug containing more than one medicinal ingredient on the Register. The parties agreed that this was a question of law to be reviewed on the correctness standard.

[107] The applicant notes the decision of Justice Gleason (as she then was) in *Pfizer Canada Inc v Canada (Minister of Health)*, 2014 FC 1243, 249 ACWS (3d) 192 [*Pfizer*], a judicial review of the Minister`s decision to award an early Notice of Compliance to Teva Canada Ltd (one of the respondents). Justice Gleason conducted a review of the developments in the jurisprudence, including whether distinctions should be made between a Minister's decision and that of an administrative tribunal and whether a standard of review analysis was required where the Court had not previously considered the applicable standard of review, and proposed a framework for the standard of review analysis at paras 99-104.

[108] The applicant submits that in accordance with the principle of judicial comity, this Court should now take the same approach and conclude that correctness is the applicable standard of review.

[109] The applicant also notes that the recent jurisprudence establishes that the presumptive standard of reasonableness can be rebutted by considering the factors in *Dunsmuir*. In *Takeda*, the Court did the analysis and concluded the standard was correctness.

[110] The applicant submits that once the Court finds that the question is one of law to be determined on a correctness standard, the Court should determine the correct interpretation of the provisions and then find that the decision is not correct.

[111] The applicant argues that based on the ordinary meaning or plain reading of the provision, the question is whether the medicinal ingredient is an "ester" and not whether it has an

ester functional group […], and, if it is an ester, whether the other medicinal ingredient has been previously approved.

[112] The applicant also points to the context and purpose of section C.08.004.1, aided by the RIAS and Guidance Document, noting the purpose is to prevent minor variations of previously approved medicinal ingredients being granted additional years of data protection. Where the medicinal ingredient is not a listed variation, a case-by-case assessment should be done.

[113] The applicant submits that a correct interpretation requires that the whole medicinal ingredient be considered. Dr Wuest's evidence is necessary to assist the Court on this point. Dr Wuest explains that HAL HCI would be understood by a chemist, first and foremost, as a salt (i.e., a variation) of HAL, which was not previously approved.

[114] Photocure submits that "an ester is an integral part of the covalently bound part of the molecular core, as defined by HAL," according to Dr Wuest. Therefore, a chemist would not view HAL HCI as an ester, but would only regard HAL as an ester of ALA. The applicant argues that Dr Wuest's evidence is "uncontradicted."

[115] Photocure also disputes the respondent's submission that the Minister did consider the whole structure, arguing that there is no evidence that this was the approach.

[116] Photocure further submits that the enumerated variations do not include the combination of a salt of an ester or a salt and an ester. HAL HCI has both a salt and an ester, so it does not fall

within the list of variations, and is therefore an "arguable variation". Photocure submits that the Minister erred by interpreting the definition as "one or more of", by finding HAL HCI was a salt of an ester of ALA HCI or both a salt and an ester.

[117] The applicant notes that the purpose of the regulations is not to award data protection to drugs that are only minor changes from previously approved drugs. However, for HAL HCI, the presence of a salt and an ester is more than a minor change.

[118] The applicant submits that once the Court finds that the Minister incorrectly interpreted the provisions, and provides the correct interpretation, as advocated by the applicant, the Court should correct the impact of the error. The applicant requests the Court to make the determination that HAL HCI is not an ester of ALA HCI and argues that the evidence is before the Court to make such a determination. Following this finding or direction, the Minister would consider the third step (in the *Takeda* approach) and would only need to consider whether HAL HCI is an arguable variation based on a case-by-case assessment, considering the data presented.

[119] On the issue of urgency, Photocure submits that it is not accurate for the Minister to suggest that because Photocure has not marketed a Canadian Reference Product, there is no risk to Photocure due to its lack of data protection. Moreover, it should not have to refrain from marketing in order to protect its data.

[120] In the event that the Court finds that the standard of review is reasonableness, the applicant argues that the decision is not reasonable, noting that the reasonableness standard requires justification, transparency and intelligibility within the decision-making process and that the decision must fall within a range of acceptable outcomes justified by the facts and the law.

[121] Photocure asserts that the respondent did not advance any evidence to establish that the Minister's decision is reasonable.

The Respondent's Position

[122] The respondent submits that CYSVIEW contains a medicinal ingredient that is an ester of a previously approved medicinal ingredient and it is not eligible for data protection. The Minister notes […].

[123] The respondent notes that the three step approach endorsed in *Takeda* to determine if a drug is an innovative drug is routinely followed, as it was in this case, by the Minister.

[124] The respondent notes that the term "ester" is not defined in the Regulations. Whether a medicinal ingredient is an ester of another is a factual determination. An ester is a compound with a particular formula. The respondent notes the […].

[125] The respondent submits that once the Minister found that the medicinal ingredient is an ester of a previously approved medicinal ingredient, the Minister was not required to consider whether the medicinal ingredient is an arguable variation and to then consider the clinical data. As established in *Takeda* at para 127, it is only for substances other than salts, esters, enantiomers, solvates and polymorphs that it is necessary to consider the clinical data. Therefore, contrary to the applicant's argument, the Minister was not silent on an issue that should have been addressed.

[126] The respondent submits that the issue on this judicial review is a question of fact, or alternatively, mixed fact and law which cannot be separated. The applicable standard of review is, therefore, reasonableness (*Nor-Man Regional Health Authority Inc v Manitoba Association of Health Care Professionals*, 2011 SCC 59 at paras 35-36, [2011] 3 SCR 616).

[127] The respondent points out that Photocure has made varying submissions on the question to be answered by the Court, including that the issue is the interpretation or the "metes and bounds" of the term "medicinal ingredient", the interpretation of "innovative drug" or the interpretation of "variation". The respondent submits that the applicant cannot characterize the question before the Court as a legal question to support its view that the standard of correctness applies; restating the question does not make it a question of law.

[128] The respondent also points out that there is no dispute that HAL HCI is the medicinal ingredient in question. The respondent submits that the Minister compared the entire structure of HAL HCI to the entire structure of the previously approved medicinal ingredient, ALA HCI, and both have a salt group.

[129] The respondent argues that, contrary to the applicant's position, the salt does not trump the ester as this would focus only on the salt part of the structure and the salt is part of the medicinal ingredient in HAL HCI and part of the whole structure.

[130] There is no dispute about the interpretation of "variation" in the definition of "innovative drug" as this was settled in *Takeda*. The question in the present case is not one of interpretation but of determining if the medicinal ingredient, HAL HCI, is an ester and this is a question of fact, which involves science.

[131] The question is similar to that in *Reddy-Cheminor Inc v Canada (Attorney General)*, 2004 FCA 102, 319 NR 185 [*Reddy-Cheminor*] regarding "identical medicinal ingredient", where the Court of Appeal found that the determination required scientific understanding rather than knowledge of the law or legal principles (at para 8). The respondent acknowledges the developments in the jurisprudence since *Reddy-Cheminor* that have found the standard of correctness applies to issues regarding the interpretation of the regulations (for example, *Epicept*, *Teva*, *Takeda*). However, the most recent case law supports the view that the presumptive standard of review is reasonableness and the presumption would not be rebutted in the present

case, given that the question is one of fact, or at most, mixed fact and law (*Tervita Corp v Canada (Commissioner of Competition)*, 2015 SCC 3, [2015] 1 SCR 161 [*Tervita*]).

[132] In the event that the question is found to be one of statutory interpretation, the respondent argues that the standard of review would presumptively be reasonableness and a contextual analysis would not rebut the presumptive standard of reasonableness (*Tervita*, at para 39; *Canadian National Railway Co v Canada (Attorney General)*, 2014 SCC 40 at para 54, [2014] 2 SCR 135).

[133] The determination of whether one medicinal ingredient is an ester of another medicinal ingredient depends on organic chemistry principles. The Minister relied on these principles in making the determination, based on a comparison of the drug submitted and the previously approved medicinal ingredient. The Minister considered the entire structure, which includes the salt, and compared it to the entire structure of the previously approved medicinal ingredient (ALA HCI).

[134] The respondent also notes that Photocure's […]. Relying on basic chemistry, the Minister concluded that HAL HCI is an ester of the previously approved ALA HCI.

[135] The respondent submits that the Minister's interpretation is reasonable. The Minister fully considered the submissions of Photocure at every stage, which advanced its position that HAL HCI is not an ester of ALA HCI.

[136] The Federal Court of Appeal recently clarified the role of the Court in conducting a reasonableness review in *Delios*, at paras 39 and 41, and this does not extend to fact finding on the merits of the issue. With respect to Photocure's request that the Court declare that HAL HCI is not an ester of ALA HCI, the respondent submits that the Court has no such jurisdiction on judicial review (subsection 18.1(3), *Federal Courts Act*, RSC, 1985, c F-7). If the decision is found to not be reasonable, the Court must remit the matter to the Minister for redetermination.

[137] The respondent adds, with respect to Photocure's submission that a determination of this judicial review is urgent because Photocure has received a Notice of Compliance but does not have data protection, that there is little risk to Photocure's data because it has not given market notification and there is no Canadian Reference Product.

The Standard of Review is Reasonableness

[138] I have considered Photocure's submissions that the standard of review is correctness because the issue at stake is the interpretation of the regulations, which is a matter of statutory interpretation and a legal issue.

[139] While the issue relates to the interpretation of the regulations and what is a "variation", in my view, this is very closely linked with and dependant on the science involved and with issues that fall within the role and expertise of the OPML, which makes decisions on behalf of the Minister. The issue involves the application of the regulations, not how to interpret them, and

whether the particular medicinal ingredient is a variation of one that has been previously approved.

[140] The applicant seeks to restate the question to frame it as one of statutory interpretation and a question of law. However, this was not the question before the OPML nor was it the question addressed in the extensive submissions of Photocure to the OPML. The issue and the submissions were about whether the medicinal ingredient in CYSVIEW, which the applicant acknowledges is HAL HCI, is a variation of a previously approved medicinal ingredient. No submissions were made to the OPML regarding how the regulations should be interpreted; rather, the submissions were about what HAL HCI was and what it was not.

[141] The respondent points to *Reddy-Cheminor* where the Court conducted a standard of review analysis and concluded that the appropriate standard of review on the issue of identical medicinal ingredients was that of patent unreasonableness. In the post-*Dunsmuir* era, this would be reasonableness.

[142] *Reddy-Cheminor* was decided pre-*Dunsmuir* and the jurisprudence has evolved even since *Dunsmuir* regarding the standard of review for Ministerial decisions, including those that involve the interpretation of statutory provisions. However, *Reddy-Cheminor* still provides guidance on the characterization of a similar question and whether it is a question of fact or mixed fact and law or a pure question of law.

[143] With respect to the standard of review, the Court of Appeal noted at para 8:

> Second, I agree with Layden-Stevenson J. that the pragmatic and functional analysis indicates that the decision under review is entitled to a high degree of deference. The drug approval process is a complex and technical area of public administration with a direct impact on the health of Canadians. Determining whether two products contain "identical medicinal ingredients" requires scientific understanding and regulatory experience, rather than knowledge of the law or legal principles.

[144] Similarly, whether the medicinal ingredient is a variation, as an ester, salt or otherwise requires scientific understanding. The applicant appears to acknowledge this, given its position that the Court needs the scientific evidence and expertise of Dr Wuest to determine if the decision is correct and to determine if it is reasonable. Yet the applicant asserts that this is a question of law.

[145] The issue in this judicial review is not whether the Minister properly interpreted the regulations, more specifically the interpretation of "innovative drug", "medicinal ingredient" or "variation". The issue is whether the specific medicinal ingredient in CYSVIEW, which the applicant acknowledges is HAL HCI, is a variation of a previously approved medicinal ingredient.

[146] The applicant argues that "medicinal ingredient" requires consideration of the entire structure or "the metes and bounds" of the term and that a correct interpretation of the term would reflect this.

[147] The applicant also argues that the Minister incorrectly interpreted and applied the term "variation" in finding that a medicinal ingredient with both a salt and an ester was a variation.

Although the applicant acknowledges that the interpretation of "variation" was settled by the Court of Appeal in *Takeda*, the applicant submits that the specific question is now different.

[148] In my view, if the Court were to find that the question on judicial review is one of statutory interpretation, the Court would be ill-equipped to identify the "metes and bounds" of the term. If called upon to consider the meaning of medicinal ingredient, it would likely arrive at a plain meaning – that it is the ingredient which delivers the medicine. The consideration of the context and purpose may not offer more than this and would not provide guidance on the "metes and bounds" of the term. This is not very helpful to the applicant's position.

[149] The applicant has already acknowledged that the medicinal ingredient is HAL HCI. Although the applicant argues that the salt aspect or element is less important and should be almost ignored, it is part of the medicinal ingredient, just as it is part of the medicinal ingredient in the previously approved ALA HCI. In addition, this argument is inconsistent with the applicant's argument that the correct interpretation of medicinal ingredient requires consideration of the whole structure – which would include the salt. The applicant seeks to rely on Dr Wuest, but his opinion is that the whole structure is not really the whole structure, because the molecular core is simply HAL. The affidavit is not admitted, but the applicant's submissions reflecting this demonstrate some inconsistency.

[150] On a standard of review analysis, whether or not the issue is characterized as a question of statutory interpretation (a question of law) or a question of fact (or mixed fact and law), I would arrive at the same standard: the standard of review is reasonableness. Starting from a

presumptive standard of reasonableness and conducting a contextual analysis to determine if that presumption is rebutted or starting from the established principle that questions of fact are reviewed on the standard of reasonableness, the nature of the question is a key factor. This analysis becomes a bit circular in the present circumstances.

[151] The jurisprudence relied on by the applicant to support its position that the nature of the question is the same or similar to questions considered by this Court and the Court of Appeal which found that the standard of review is correctness can be distinguished. In the cases referred to by the applicant, the question was about the interpretation of the regulations, for example, the interpretation of "variation" and whether the examples set out were all such variations, rather than whether a particular medicinal ingredient was such a variation. In addition, in most of those cases, the parties agreed that correctness was the standard.

[152] I agree that some post-*Dunsmuir* cases have found that the correctness standard of review applies to questions of statutory interpretation regarding the regulations as these are questions of law. This was based on previous case law rather than a standard of review analysis. In those cases the parties agreed that the correctness standard applied and the questions were truly questions of statutory interpretation rather than application of the facts to the regulations. Justice Stratas, in his dissenting reasons in *Takeda*, took the approach that the presumptive standard of review is reasonableness, but found on the facts of *Takeda* that the presumption was rebutted and correctness was the standard.

[153] In *Pfizer*, Justice Gleason reviewed the post-*Dunsmuir* jurisprudence, including many of the cases relied on by the applicant, and proposed a framework to determine the appropriate standard of review at paras 99-104:

> In light of the forgoing, I believe the required steps in determining the appropriate standard of review are the following.
>
> First, one must consider whether the previous case law has satisfactorily settled the standard of review to be applied.
>
> Where the case law in question is post-*Dunsmuir* and applies the standard of review analysis mandated by the Supreme Court of Canada, it will have satisfactorily settled the issue and may be applied. Likewise, where the case law pre-dates *Dunsmuir* and mandates reasonableness or patent unreasonableness as the standard of review, then it will have satisfactorily established that the standard of review is reasonableness, given the preference for deference set out in *Dunsmuir* and subsequent cases.
>
> The case law will also settle the standard of review where the issue being reviewed involves a constitutional question, a question of general importance to the legal system as a whole that is outside the administrative decision-maker's specialized expertise, determination of the respective jurisdiction of two or more administrative decision-makers or a true question of vires. All the decisions from the Supreme Court post-*Dunsmuir* indicate that the correctness standard applies to these sorts of determinations.
>
> Conversely, where the issue being determined involves a factual determination, a determination of mixed fact and law from which a pure legal question cannot be extricated, the exercise of a statutorily-conferred discretion or the making of a policy decision that the decision-maker is mandated to make, then the reasonableness standard is applicable as the case law post-*Dunsmuir* indicates that such decisions are to be afforded deference (see e.g. *Khosa v Canada (Minister of Citizenship and Immigration)*, 2009 SCC 12, [2009] 1 SCR 339 at paras 46-47, Binnie J and para 89, Rothstein J, concurring; *Agraira* at para 50; and *Smith* at para 26).
>
> Finally, where what is being reviewed is a legal issue that involves the interpretation of the decision-maker's constituent statute or a statute or regulation closely related to its function, there is a presumption that reasonableness applies. That presumption, however, may be rebutted by a contextual analysis if it

> demonstrates that the issue in question is not one that the legislature intended to leave to the decision-maker to determine because it falls more appropriately within the expertise of a reviewing court. In conducting the contextual analysis, the reviewing court may have regard to such factors as the presence or absence of a privative clause, the purpose of the tribunal, the nature of the question at issue, and the expertise of the tribunal.

[154] The applicant argues that on the basis of judicial comity, I should follow the approach outlined by Justice Gleason and conclude that the standard of review is correctness.

[155] I fully agree with the approach of Justice Gleason, but applying this approach does not lead me to conclude that the standard of review is correctness.

[156] First, although the case law has settled the standard of review to be applied for questions regarding the statutory interpretation of the regulations, the question in the present case, as noted above, is not such a question.

[157] I would characterize the question as a factual determination or a determination of mixed fact and law. No pure legal question arises apart from application of the law to the facts. The case law post-*Dunsmuir* establishes that the reasonableness standard remains applicable.

[158] Second, if I were to take the opposite view, that the question is the "interpretation of the decision-maker's constituent statute or a statute or regulation closely related to its function," the starting point or presumptive standard would be reasonableness. A contextual analysis would be conducted to determine if the presumption is rebutted in favour of the correctness standard.

[159] Third, a contextual analysis does not rebut the reasonableness standard. The question, as characterized by the applicant as the interpretation of "medicinal ingredient" and primarily the "metes and bounds of medicinal ingredient," or the proper approach to determine the medicinal ingredient, falls more within the expertise of the OPML. The Court is ill-equipped to determine the "metes and bounds" of the term "medicinal ingredient" or to determine how medicinal ingredients should be compared (whether the whole structure or whether aspects of the whole structure should be given more importance than other aspects). As noted above, the plain meaning, context and purpose do not lead to the interpretation sought by the applicant.

[160] The Minister has been mandated to determine whether the drug is an innovative drug and should be listed on the Register and has delegated this to an expert group, the OPML, to assess the facts and consider the science in accordance with the established processes. The nature of the question is best described as factual or mixed fact and law and involves science, and the OPML has expertise to determine which drugs are variations. The Court has no such expertise.

[161] In addition, a contextual analysis requires consideration of the nature of the question at issue, which appears to bring us full circle to the starting point. As previously noted, the nature of the question before the Minister as decision-maker and as stated in the applicant's submissions to the Minister is not the interpretation of the regulations or a part thereof or the approach to assessing the medicinal ingredient, but whether HAL HCI, the medicinal ingredient in CYSVIEW, is a variation (an ester) of a previously approved medicinal ingredient.

[162] Therefore, although I find that the question is one of fact or mixed fact and law, and the reasonableness standard applies, I would also find that the reasonableness standard applies if the question were characterized as more in the nature of the interpretation of the regulations, and a question of law.

The Minister's Decision is Reasonable

[163] A reasonable decision is one that can withstand a somewhat probing examination (*Baker v Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817 at para 65, 174 DLR (4th)).

[164] Where the reasonableness standard applies, the role of the Court is to consider the existence of justification, transparency and intelligibility within the decision-making process, as well as to determine whether the Minister's decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law (*Dunsmuir*, at para 47).

[165] In *Newfoundland and Labrador Nurses' Union v Newfoundland and Labrador (Treasury Board)*, 2011 SCC 62, [2011] 3 SCR 708 [*Newfoundland Nurses*], the Supreme Court of Canada elaborated on the requirements of *Dunsmuir*, noting that reasons are to "be read together with the outcome and serve the purpose of showing whether the result falls within a range of possible outcomes" and that courts "may, if they find it necessary, look to the record for the purpose of assessing the reasonableness of the outcome" (at paras 14-16).

[166] The Court does not reweigh the evidence or remake the decision. Where the standard of reasonableness is met, the Court defers to the decision-maker.

[167] The applicant did not advance specific arguments regarding the reasonableness of the decision. The applicant argued more generally that the decision was not correct and alternatively that it was not reasonable.

[168] The applicant conveyed the general view that it would be at a disadvantage if the Court applies the reasonableness standard. This view overlooks that the Court conducts countless judicial reviews on the standard of reasonableness. Decisions are not immune from review if they do not meet the *Dunsmuir* standard and are not justified by the facts and the law.

[169] The applicant's arguments that the Minister was incorrect have been considered in the reasonableness context.

[170] This includes whether the Minister erred in her understanding of organic chemistry and failed to consider the whole structure of the medicinal ingredient, and therefore erred in deciding that the medicinal ingredient HAL HCI is an ester of a previously approved medicinal ingredient. In addition, the applicant's argument that the term "variation" of a previously approved medicinal ingredient includes a salt or an ester, but does not include a medicinal ingredient that is both a salt and an ester, and therefore the Minister erred, has been considered.

[171] The applicant also asserted that the respondent had not advanced any evidence that the decision was reasonable. This assertion overlooks that the evidence to determine whether the decision is reasonable is that which is on the record and, as noted above regarding the admissibility of the affidavits, only in limited exceptions will the Court consider evidence that was not on the record before the decision-maker.

[172] The Court has carefully reviewed the final decision and the complete record, including the applicant's original submissions, the Minister's preliminary decision, the applicant's written submissions in response to the preliminary decision, and the applicant's slides presented with the oral submissions in response to the preliminary decision.

[173] The decision clearly conveys that the Minister considered the whole structure of the medicinal ingredient, HAL HCI, as well as the whole structure of ALA HCI. This is apparent from the detailed description and depiction of the structures that were compared – HAL HCI to HAL, ALA to HAL, and HAL HCI to ALA HCI.

[174] The decision acknowledges that HAL HCI is a salt of HAL, that HAL is an ester of ALA, and that both HAL HCl and ALA HCl are salts. The decision then concludes that, because the structure of HAL HCl is identical to ALA HCl, both of which are salts, but with the addition of an ester group, HAL HCl is an ester of ALA HCl.

[175] The decision cites *Takeda* which has interpreted "innovative drug", explains the list of excluded variations and notes that data submitted in support of the approval is relevant only

when the variation is not explicitly enumerated. The decision also notes that each determination of data protection is case-specific.

[176] Although Photocure's submissions to the Minister argued that it was innovative and not a minor change and the submissions and slides noted the differences in CYSVIEW and LEVULAN KERASTIK (ALA HCI), it did not argue that the interpretation of "variation" could not include a variation that was both a salt and an ester.

[177] Contrary to the applicant's assertion that the Minister was silent on this issue and erred in the interpretation, the Minister was not required to respond to an issue that was not raised. Moreover, having found that the medicinal ingredient is an ester of a previously approved medicinal ingredient, in accordance with *Takeda*, the Minister was not required to go on to consider whether the medicinal ingredient is an "arguable variation".

[178] In addition, I do not agree that the Minister erred in finding that the medicinal ingredient is an ester and that such a finding is not possible because it contains both a salt and an ester. It is not in dispute that HAL HCI is a salt and is also an ester. The regulations define "innovative drug" as a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

[179] The examples of "variations" do not foreclose a drug that is both a salt and an ester or other combinations of those examples from being found to be variations. In my view, that would

not make sense grammatically or practically. The Minister reasonably found that the medicinal ingredient is an ester of a previously approved medicinal ingredient, even though it is also a salt.

[180] The Minister's decision falls within a range of possible, acceptable outcomes. The decision is transparent as it reveals how the Minister reached the decision and it reflects consideration of all the evidence on the record. Deference is owed to the decision-maker and the Court will not reweigh the evidence.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The affidavits are not admissible;

2. The application for judicial review is dismissed; and

3. The respondent shall have its costs.

"Catherine M. Kane"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1774-14
STYLE OF CAUSE:	PHOTOCURE ASA v THE MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	JUNE 3, 2015
PUBLIC JUDGMENT AND REASONS:	KANE J.
DATED:	AUGUST 10, 2015

APPEARANCES:

Mr Gunars A.Gaikis Ms Nancy Pei	FOR THE APPLICANT
Ms Abigail Browne	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

SMART & BIGGAR Barristers & Solicitors Toronto, Ontario	FOR THE APPLICANT
William F. Pentney Deputy Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENTS