Federal Court  Cour fédérale

Date: 20141219

Docket: T-1703-13

Citation: 2014 FC 1243

Ottawa, Ontario, December 19, 2014

PRESENT: The Honourable Madam Justice Gleason

BETWEEN:

PFIZER CANADA INC.

Applicant

and

THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL OF CANADA
AND TEVA CANADA LIMITED

Respondents

JUDGMENT AND REASONS

[1] In this application for judicial review the applicant, Pfizer Canada Inc. [Pfizer], seeks an order setting aside the decision of the Minister of Health, awarding an early Notice of Compliance [NOC] to the respondent, Teva Canada Limited [Teva], for a drug that is the pharmaceutical and bioequivalent of a drug that Pfizer produces and holds patent rights for under a patent listed on the Patent Register established under sections 3 – 4 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the PMNOC Regulations].

[2] The Minister of Health issued the NOC in question to Teva pursuant to amendments to its *Guidance Document, Patented Medicines (Notice of Compliance) Regulations* [the Guidance Document]. These amendments purport to allow the Minister of Health to issue early NOCs to companies who market a generic version of a drug listed on the Patent Register, without being required to serve a Notice of Allegation [NOA] on the patent-holder under section 5 of the PMNOC Regulations, if the company has been licensed to sell the drug by another company that has previously complied with section 5 of the PMNOC Regulations.

[3] To put this matter into context, it is necessary to review the relevant regulatory provisions as well as the background to this application.

I. The Regulations

[4] In approving drugs for sale in Canada, the Minister of Health, through the officials at Health Canada, applies two sets of regulations, the *Food and Drug Regulations*, CRC 1978, c 870 [the FDA Regulations], promulgated under the *Food and Drugs Act*, RSC 1985, c F-27, and the PMNOC Regulations, promulgated under section 55.2 of the *Patent Act*, RSC 1985, c P-4.

A. *The FDA Regulations*

[5] Under the FDA Regulations, no one can sell a new drug in Canada unless the Minister of Health issues the person or company who proposes to sell the drug an NOC, authorizing the sale. Section C.08.001 of the FDA Regulations defines a new drug in relevant part as follows:

(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug […]	a) une drogue qui est constituée d'une substance ou renferme une substance, sous forme d'ingrédient actif ou inerte, de véhicule, d'enrobage, d'excipient, de solvant ou de tout autre constituant, laquelle substance n'a pas été vendue comme drogue au Canada pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de ladite substance employée comme drogue […]

[6] It is common ground between the parties that the drug for which Teva was issued an NOC in this case falls within the FDA Regulation's definition of a "new drug". Therefore, Teva required an NOC to legally offer it for sale in Canada.

[7] Under the FDA Regulations, there are three main methods by which a drug company can obtain an NOC.

[8] First, it may file an application called a "new drug submission" [NDS]. This is typically the route chosen by innovator companies when they develop new drugs. The production of an NDS is usually a complex and expensive undertaking as the innovator company is required to conduct and produce evidence of clinical trials. It must also file a long list of other information set out in subsection C.08.002(2) of the FDA Regulations to "enable the Minister to assess the safety and effectiveness of the new drug".

[9] The FDA Regulations secondly allow for a shorter process, called an abbreviated new drug submission [ANDS], under which a drug company may be authorized to sell a drug if it establishes that it is the same or very similar to another drug that has been authorized for sale in Canada. Subsection C.08.002.1(1) of the FDA Regulations provides in this regard:

(1) A manufacturer of a new drug may file an abbreviated new drug submission or an abbreviated extraordinary use new drug submission for the new drug where, in comparison with a Canadian reference product, (a) the new drug is the pharmaceutical equivalent of the Canadian reference product; (b) the new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister considers it necessary, bioavailability characteristics; (c) the route of administration of the new drug is the same as that of the Canadian reference product; and (d) the conditions of use for the new drug fall within the conditions of use for the Canadian reference product.	(1) Le fabricant d'une drogue nouvelle peut déposer à l'égard de celle-ci une présentation abrégée de drogue nouvelle ou une présentation abrégée de drogue nouvelle pour usage exceptionnel si, par comparaison à un produit de référence canadien : a) la drogue nouvelle est un équivalent pharmaceutique du produit de référence canadien; b) elle est bioéquivalente au produit de référence canadien d'après les caractéristiques pharmaceutiques et, si le ministre l'estime nécessaire, d'après les caractéristiques en matière de biodisponibilité; c) la voie d'administration de la drogue nouvelle est identique à celle du produit de référence canadien; d) les conditions thérapeutiques relatives à la drogue nouvelle figurent parmi celles qui s'appliquent au produit de référence canadien.

[10] A "Canadian Reference product" is defined in paragraph C.08.001.1(a) of the Regulations as meaning "a drug in respect of which a notice of compliance is issued under section C.08.004 or C.08.004.01 and which is marketed in Canada by the innovator of the drug".

[11] Thus, under the ANDS process, to obtain an NOC, a drug company needs to satisfy the Minister of Health of the matters referred to in subsection C.08.002.1(1) of the FDA Regulations by comparing its product to a Canadian Reference product.

[12] The process to produce an ANDS is much more streamlined and less expensive than that required for an NDS as the applicant under the ANDS process need only show comparability to another drug already approved by Health Canada. Generic drug manufacturers typically seek their NOCs through the ANDS process and generally compare their drugs to those of an innovator company that obtained approval through the NDS process.

[13] Finally, the FDA Regulations provide for the filing of supplemental submissions where a drug company makes certain changes to its process, labels, drug name, representations regarding the drug or other similar matters. Section C.08.003 of the FDA Regulations provides in this regard in relevant part as follows:

(1) […] no person shall sell a new drug in respect of which a notice of compliance has been issued to the manufacturer of that new drug[…] if any of the matters specified in subsection (2) are significantly different from the information or material contained in the new drug submission, extraordinary use new drug submission, abbreviated new drug submission or abbreviated extraordinary use new drug submission, unless (a) the manufacturer of the new drug has filed with the Minister a supplement to that	(1) […] il est interdit de vendre une drogue nouvelle à l'égard de laquelle un avis de conformité a été délivré à son fabricant et n'a pas été suspendu aux termes de l'article C.08.006, lorsqu'un des éléments visés au paragraphe (2) diffère sensiblement des renseignements ou du matériel contenus dans la présentation de drogue nouvelle, la présentation de drogue nouvelle pour usage exceptionnel, la présentation abrégée de drogue nouvelle ou la présentation abrégée de

submission;
(b) the Minister has issued a notice of compliance to the manufacturer of the new drug in respect of the supplement;
[…] and
(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any label, including any package insert, product brochure and file card, intended for use in connection with the new drug, where a change with respect to any of the matters specified in subsection (2) is made that would require a change to the label.
(2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:
[…]
(b) the brand name of the new drug or the identifying name or code proposed for the new drug;
[…]
(g) the labels used in connection with the new drug;
[…]
(3) A supplement to a submission referred to in subsection (1), with respect to the matters that are significantly different from those contained in the submission, shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug in relation to those matters.

drogue nouvelle pour usage exceptionnel, à moins que les conditions ci-après ne soient réunies :
a) le fabricant de la drogue nouvelle a déposé auprès du ministre un supplément à la présentation;
[…]
b) le ministre a délivré au fabricant un avis de conformité relativement au supplément;
d) le fabricant de la drogue nouvelle a présenté au ministre, sous leur forme définitive, des échantillons de toute étiquette — y compris une notice jointe à l'emballage, un dépliant et une fiche sur le produit — destinée à être utilisée pour la drogue nouvelle, dans le cas où la modification d'un des éléments visés au paragraphe (2) nécessite un changement dans l'étiquette.
(2) Pour l'application du paragraphe (1), les éléments ayant trait à la drogue nouvelle sont les suivants :
[…]
b) sa marque nominative ou le nom ou code sous lequel il est proposé de l'identifier;
[…]
g) les étiquettes à utiliser pour la drogue nouvelle;
[…]
(3) Le supplément à toute présentation visée au paragraphe (1) contient, à l'égard des éléments qui diffèrent sensiblement de ce qui figure dans la présentation, suffisamment de renseignements et de matériel

	pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle relativement à ces éléments.

[14] As is apparent from the forgoing provisions (and from the FDA Regulations in their entirety), the role of the Minister of Health in issuing an NOC under these Regulations is to assess the safety and efficacy of drugs to be sold in Canada. Indeed, that this is the purpose of these provisions in the FDA Regulations has been confirmed by the case law (see, e.g., *Bristol-Myers Squibb Co. v Canada (Attorney General)*, 2005 SCC 26, [2005] 1 SCR 533 [*Biolyse*] at para 13; *AstraZeneca Canada Inc. v Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 SCR 560 [*AstraZeneca*] at para 12; *Harris v GlaxoSmithKline Inc.*, 2010 ONCA 872, 78 CCLT (3d) 52 at para 8; *Teva Canada Ltd. v Canada (Minister of Health)*, 2011 FC 507, 95 CPR (4th) 423 at para 23).

B. *The PMNOC Regulations*

[15] The PMNOC Regulations were passed when Parliament abolished the previous system for compulsory licensing of generic drug manufacturers and enacted section 55.2 of the *Patent Act*. This section allows generic companies to "early work" a product, without infringing an innovator company's patents for the drug, in order to develop a generic version of the drug and make it available as soon as possible following expiry of the relevant patents. As counsel for the Attorney General premised much of her arguments on section 55.2 of the *Patent Act*, the relevant portions of the section are reproduced; they provide as follows:

(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

(2) and (3) [Repealed, 2001, c. 10, s. 2]

(4) The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations

(a) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;

(b) respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph (a) that

(1) 55.2 (1) Il n'y a pas contrefaçon de brevet lorsque l'utilisation, la fabrication, la construction ou la vente d'une invention brevetée se justifie dans la seule mesure nécessaire à la préparation et à la production du dossier d'information qu'oblige à fournir une loi fédérale, provinciale ou étrangère réglementant la fabrication, la construction, l'utilisation ou la vente d'un produit.

(2) et (3) [Abrogés, 2001, ch. 10, art. 2]

(4) Afin d'empêcher la contrefaçon d'un brevet d'invention par l'utilisateur, le fabricant, le constructeur ou le vendeur d'une invention brevetée au sens du paragraphe (1), le gouverneur en conseil peut prendre des règlements, notamment :

a) fixant des conditions complémentaires nécessaires à la délivrance, en vertu de lois fédérales régissant l'exploitation, la fabrication, la construction ou la vente de produits sur lesquels porte un brevet, d'avis, de certificats, de permis ou de tout autre titre à quiconque n'est pas le breveté;

b) concernant la première date, et la manière de la fixer, à laquelle un titre visé à l'alinéa a) peut être délivré à quelqu'un qui n'est pas le breveté et à laquelle elle peut prendre effet;

c) concernant le règlement des

is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;	litiges entre le breveté, ou l'ancien titulaire du brevet, et le demandeur d'un titre visé à l'alinéa a), quant à la date à laquelle le titre en question peut être délivré ou prendre effet;
(c) governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice, certificate, permit or other document referred to in paragraph (a) as to the date on which that notice, certificate, permit or other document may be issued or take effect;	d) conférant des droits d'action devant tout tribunal compétent concernant les litiges visés à l'alinéa c), les conclusions qui peuvent être recherchées, la procédure devant ce tribunal et les décisions qui peuvent être rendues;
(d) conferring rights of action in any court of competent jurisdiction with respect to any disputes referred to in paragraph (c) and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and	e) sur toute autre mesure concernant la délivrance d'un titre visé à l'alinéa a) lorsque celle-ci peut avoir pour effet la contrefaçon de brevet.
(e) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (a) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.	

[16] The PMNOC Regulations, unlike the FDA Regulations, are not aimed at protecting the public from unsafe or inefficacious drugs but, rather, are aimed at protecting the patent rights of innovator companies and balancing those rights with the timely entry of lower priced generic

competitors into the market place. The Regulatory Impact Analysis Statement [RIAS] published in the *Canada Gazette Part II* on October 18, 2006, when a number of amendments were made to the PMNOC Regulations, notes in this regard that the PMNOC Regulations are designed to "balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors". It elaborates as follows:

> … while early-working is intended to promote the timely market entry of generic drugs by allowing them to undergo the regulatory approval process in advance of patent expiry, the PM(NOC) Regulations are intended to provide effective patent enforcement by ensuring the former does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the court or innovator considers justified having regard to the generic company's allegation. Despite their seemingly competing policy objectives, it is important that neither instrument be considered in isolation as the intended policy can only be achieved when the two operate in a balanced fashion.

[17] The case law confirms the PMNOC Regulations are aimed at protecting the rights of patentees while ensuring that generic versions of patented medicines are available to the public as early as possible (see e.g. *Biolyse* at paras 45-47; *Nu-Pharm Inc. v Canada (Attorney General)* (1997), 73 CPR (3d) 510, [1997] FCJ No 624 at para 22, aff'd (1998), 80 CPR (3d) 74, [1998] FCJ No 274 (FCA) [*Nu-Pharm 1*]; *Apotex Inc. v Merck & Co.*, 2009 FCA 187, 76 CPR (4th) 1 at para 60; *Apotex Inc. v Canada (Minister of Health)*, 2009 FC 721, 79 CPR (4th) 23 at para 55).

[18] Under the PMNOC Regulations, innovator companies may have their drug-related patents listed on the Patent Register, established under the Regulations, provided they meet the criteria for registration. Registration allows a patentee to forestall the entry of a generic version of the patented drug onto the Canadian market until the patents expire, the innovator company consents to the generic company's producing the drug or this Court determines that the generic

company's allegation of non-infringement or invalidity is justified. This is accomplished through the combined effect of sections 5–7 of the PMNOC Regulations.

[19] By virtue of section 5 of the PMNOC Regulations, a "second person" (typically, a generic company), who files a submission for an NOC that directly or indirectly compares or references its product to that of a "first person" (typically the innovator company) whose patent(s) is listed on the Patent Register, must either (1) wait for patent expiry before receiving an NOC, or (2) serve an NOA upon the first person alleging invalidity and/or non-infringement of the listed patents. Subsection 5(1) of the PMNOC Regulations, which is the key provision in this application for judicial review, provides in this regard as follows:

5. (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug, (a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or (b) allege that (i) the statement made by the first person under paragraph 4(4)(d) is false, (ii) the patent has expired, (iii) the patent is not valid, or	5. (1) Dans le cas où la seconde personne dépose une présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans sa présentation : a) soit une déclaration portant qu'elle accepte que l'avis de conformité ne sera pas délivré avant l'expiration du brevet; b) soit une allégation portant que, selon le cas : (i) la déclaration présentée par

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.	la première personne aux termes de l'alinéa 4(4)d) est fausse, (ii) le brevet est expiré, (iii) le brevet n'est pas valide, (iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle la présentation est déposée.

[20] Under section 6 of the PMNOC Regulations, the first person (i.e. the innovator company) who receives an NOA may seek an order of prohibition from this Court to prevent the Minister of Health from issuing an NOC to the second person (i.e. the generic company). Where this occurs, the Court is called upon to determine if the NOA is substantiated. If the Court determines that the NOA is not substantiated, a prohibition order will issue, preventing the Minister from issuing an NOC to the generic company until the expiry of the patent(s) at issue.

[21] Section 7 of the PMNOC Regulations prevents the Minister of Health from issuing an NOC to a second person until the latest of the following events: (1) the second person complies with section 5 of the PMNOC Regulations; (2) the patents at issue expire; (3) 45 days elapse after the service of the NOA and the first person has not filed a prohibition application with the Court; (4) the Court dismisses a prohibition application; (5) the first person consents to the making, constructing, using or selling of the drug in Canada by the second person; or (6) 24

months elapse following the date the first person commenced a prohibition application in this Court.

[22] Subsection 7(1) of the PMNOC Regulations is cast in mandatory terms, stating that the Minister of Health "shall not" issue a second company an NOC until the latest of the events described in the foregoing paragraph has occurred. It provides in relevant part:

The Minister shall not issue a notice of compliance to a second person before the latest of […] (b) the day on which the second person complies with section 5, (c) […] the expiration of any patent on the register that is not the subject of an allegation, (d) […] the expiration of 45 days after the receipt of proof of service of a notice of allegation under paragraph 5(3)(a) in respect of any patent on the register, (e) […] the expiration of 24 months after the receipt of proof of the making of any application under subsection 6(1), and (f) the expiration of any patent that is the subject of an order pursuant to subsection 6(1).	Le ministre ne peut délivrer un avis de conformité à la seconde personne avant la plus tardive des dates suivantes : […] b) la date à laquelle la seconde personne se conforme à l'article 5; c) […] la date d'expiration de tout brevet inscrit au registre qui ne fait pas l'objet d'une allégation; d) […] la date qui suit de quarante-cinq jours la date de réception de la preuve de signification de l'avis d'allégation visé à l'alinéa 5(3)a) à l'égard de tout brevet ajouté au registre; e) […] la date qui suit de 24 mois la date de réception de la preuve de présentation de la demande visée au paragraphe 6(1); f) la date d'expiration de tout brevet faisant l'objet d'une ordonnance rendue aux termes du paragraphe 6(1).

[23] By virtue of the foregoing provisions, innovator drug companies possess the ability to enjoin generic companies from entering the Canadian market with a competing version of a

patented drug for 24 months or a shorter period if the prohibition application is dismissed, withdrawn or discontinued before the 24 months have elapsed. The filing of an application for prohibition therefore functions like an injunction, preventing the second company from entering the market for up to 24 months.

[24] The PMNOC Regulations tie into the FDA Regulations through the definition of an "NOC", which is defined in section 2 of the PMNOC Regulations as "a notice issued under section C.08.004 or C.08.004.01 of the Food and Drug Regulations".

[25] A final point bears mention as concerns the two Regulations, namely, that neither provides for "administrative" drug submissions, which, as is discussed below, constitute another type of submission that Health Canada recognizes.

II. The Guidelines and Health Canada's Practices

[26] For some time, Health Canada has required filings it terms "administrative" drug submissions when drug companies make changes that Health Canada views as being purely administrative in nature. Such administrative matters include changes in a vendor company's name (which may have been the result of a corporate merger, buy-out or a licensing agreement) or changes in the product name. Vendor companies are termed "manufacturers" under the FDA Regulations by virtue of section A.01.010 of those Regulations which defines a "manufacturer" as a person that sells a drug under its own name in Canada. Thus, when a vendor company is different or changes its name, it must file an administrative drug submission with Health Canada

to obtain a new NOC to allow it to sell the same drug for which an NOC had previously been issued.

[27] Health Canada defines what it considers an administrative drug submission in its policy document entitled *Guidance for Industry Management of Drug Submissions* as "a submission that does not require scientific review (for example [e.g.] changes in manufacturer or product name)".

[28] Another Health Canada policy, the *Change in Manufacturer's Name and/or Product Name Policy*, details the requirements for an administrative drug submission and the circumstances in which such a submission can be utilized. This policy provides that administrative submissions may be filed where there has been "a change in the manufacturer's name and/or product name subsequent to a merger, buy-out or other corporate restructuring or the establishment of a licensing agreement". It further defines a licensing agreement as "an agreement between two firms whereby one firm supplies a drug product to another firm for sale under the second firm's name".

[29] In terms of the content of an administrative submission, this policy provides that all that is required is the submission of a simplified, one-page form. In that form the applicant is required to set out the reason for the submission, identify the previous submission and manufacturer approved by Health Canada through the issuance of an NOC and certify that "all aspects of the [administrative] submission pertaining to [the drug] are identical to [the previously approved submission] except for a change in the manufacture/sponsor's name and/or product name and

that the product will be manufactured at the same location with identical specifications and procedures".

[30] Such minimal information is required because, from a safety and efficacy point of view, nothing changes when the manufacturer and/or the product name are the only variations from a drug previously approved under an NDS or ANDS.

[31] Until the changes to the Guidance Document giving rise to this litigation, which became effective in April 2012, Health Canada required licensees who submitted administrative drug submissions as a result of a licensing agreement to comply with section 5 of the PMNOC Regulations and therefore required them to address any patents on the Patent Register to which they directly or indirectly compared their products. Thus, prior to the disputed amendments to the Guidance Document, a second generic company that obtained a licence from a first generic company to sell an identical drug, under the label and name of the second generic company, was required to comply with section 5 of the PMNOC Regulations. In some circumstances, this, in turn, afforded the innovator company that held the listed patents for the drug in question the ability to benefit from sections 6 and 7 of the PMNOC Regulations.

[32] More specifically, such rights previously accrued to an innovator company whose patents were listed on the Patent Register in any circumstance involving licensing from one generic company to another except where the innovator company had already lost a prohibition application on similar grounds before this Court in respect of the drug produced by the first generic company. If that had occurred, the doctrine of abuse of process, as provided for in

paragraph 6(5)(b) of the PMNOC Regulations, would have prevented the innovator company from re-litigating the same allegations against the second generic company (see in this regard *Sanofi-Aventis Canada Inc v Novopharm Limited*, 2007 FCA 163, 59 CPR (4th) 416).

[33] Under the disputed change to the Guidance Document, Health Canada no longer requires compliance with section 5 of the PMNOC Regulations by licensees who obtain a licence from another generic company to market a drug that is identical to the drug produced by a licensor who has been issued an NOC. Health Canada described this change in the following terms in the current version of the Guidance Document:

> When a manufacturer of a currently marketed drug licenses another manufacturer to sell the identical drug in Canada under a different name, the licensee is required to file an administrative drug submission and such a submission must be cross-referenced to the licensor's drug submission. Under the previous requirements, drug manufacturers who submitted administrative drug submissions pursuant to a licensing agreement triggered the application of section 5 of the *PM(NOC) Regulations*.
>
> While compliance with section 5 is appropriate for most new drug submissions approved on the basis of a direct or indirect comparison or reference to an innovative drug, such compliance becomes redundant, for example, in the case where an administrative drug submission is approved on the basis of a cross-reference to a previously submitted new drug submission (NDS) or ANDS, which in turn was approved on the basis of a direct or indirect comparison or reference to an innovative drug. Requiring a licensee, who seeks approval to sell the identical drug in Canada as that of the licensor under a different name, to re-address patents already addressed by the licensor in its submission is not specifically required under section 5 of the *PM(NOC) Regulations*.
>
> Under the current requirements, only the originating NDS or originating ANDS (i.e. the licensor's drug submission) which directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under an NOC issued to a first person, triggers the application of section 5 of the *PM(NOC) Regulations* and, as such, the licensor must address any patents listed on the Patent Register in respect of the innovative product.

[34] Health Canada provided advance notice to affected parties of its intent to change the Guidance Document in this fashion and invited comments from interested parties. Pfizer made no complaints about the proposed changes, and there is no suggestion that it was not aware of them.

III. The Background to this Application

[35] Having reviewed the relevant regulatory provisions and policy documents, I turn now to discuss the background to the present judicial review application.

[36] In this regard, Pfizer sells exemestane, a breast cancer drug, in Canada under the brand name AROMASIN. Since May 18, 2006, the Patent Register has listed Patent No. 2,409,059 [the 059 Patent] against AROMASIN. The 059 Patent expires on April 25, 2021.

A. *The first NOC to Teva*

[37] On May 22, 2012, a generic company called Generic Medical Partners Inc. [GMP] filed an ANDS with the Minister seeking approval to market 25 mg exemestane tablets under the trade-name MED-EXEMESTANE.

[38] On June 27, 2012, GMP sent Pfizer an NOA with respect to the drug CRESTOR (rosuvastatin calcium), which is not marketed by Pfizer but, rather, by another innovator company, AstraZeneca Canada Inc. It seems that GMP meant to serve Pfizer with an NOA for AROMASIN but accidentally sent the wrong one.

[39] Health Canada issued an NOC for exemestane to GMP on June 10, 2013.

[40] On June 18, 2013, Teva filed an administrative drug submission with Health Canada seeking approval to market exemestane tablets under the trade-name TEVA-EXEMESTANE. Health Canada granted an NOC to Teva on July 4, 2013.

[41] On July 10, 2013, Pfizer discovered that NOCs had been issued to GMP and Teva for exemestane. On August 10, 2013, Pfizer commenced an application for judicial review in this Court seeking to quash the NOC issued to Teva (in Court File T-1321-13).

[42] On August 13, 2013, GMP sent a letter to the Office of Patented Medicines and Liaison [OPML] at Health Canada indicating that it had sent the wrong NOA to Pfizer. On August 14, 2013, Health Canada informed GMP and Teva that the NOCs issued to them in respect of exemestane should not have been issued and would be rescinded. Consequently, Pfizer discontinued its judicial review application in Court File T-1321-13.

[43] As a result of these proceedings, Pfizer was put on notice of the likelihood that GMP would license Teva to produce exemestane under Teva's label if GMP were issued an NOC for its version of the drug. Teva is engaged in the Canadian market as a marketer of generic drugs but GMP is not.

B. *The second NOC to GMP and Teva*

[44] On August 16, 2013, Pfizer received an NOA from GMP with respect to the 059 Patent. Pfizer chose not to commence a prohibition application against GMP, and claims that it made this choice because GMP does not sell products in Canada.

[45] On October 1, 2013, Health Canada issued a new NOC to GMP for exemestane. An excerpt from Health Canada's database shows that Health Canada determined the Canadian Reference product for GMP's second NOC was AROMASIN.

[46] On October 1, 2013, Health Canada also issued an NOC to Teva with respect to exemestane. The printout from Health Canada's Drug Submission Tracking System that Health Canada filed as part of the tribunal record in this matter shows that Teva filed an administrative ANDS with Health Canada, based on a licensing agreement with GMP, and that Health Canada determined the Canadian Reference product for Teva's NOC was AROMASIN. The NOC issued to Teva also shows AROMASIN as the Canadian Reference product.

IV. The Parties' Positions

[47] Pfizer submits that the Minister of Health was prohibited from issuing the NOC to Teva under the PMNOC Regulations, arguing that both the clear wording of the Regulations and the decided authorities support its position as Teva made a comparison to AROMASIN in its submission, thereby falling within the scope of subsection 5(1) of the PMNOC Regulations. Although the administrative submission Teva made was not filed, the NOC issued by the

Minister of Health names AROMASIN as the Canadian Reference Product, which Pfizer says shows that Teva either directly or indirectly compared its product to AROMASIN. It submits that under the clear wording of subsection 5(1) of the PMNOC Regulations, Teva was required to serve it with an NOA because its submission made such a comparison. As it failed to do so, Pfizer says that the Minister of Health was prohibited from issuing the NOC by virtue of the combined effect of subsections 7(1) and 5(1) of the PMNOC Regulations.

[48] Pfizer submits that in reviewing the Minister's decision to issue the NOCs, the Court should apply the correctness standard of review. It points to several cases in support of this assertion, where this Court and the Federal Court of Appeal have applied the correctness standard to similar decisions. It concedes, though, that these authorities pre-date several of the recent pronouncements by the Supreme Court of Canada on standard of review issues which mandate a greater degree of deference to administrative decision-makers' decisions.

[49] Pfizer argues in the alternative that even if the reasonableness standard of review is applied by reason of the recent Supreme Court jurisprudence, Pfizer nonetheless should be afforded the remedies it seeks because the Minister's interpretation of the PMNOC Regulations is unreasonable in light of their clear wording.

[50] Counsel for the Minister of Health submitted as a preliminary matter that the Attorney General should be added as a respondent. None of the other parties takes issue with this and the style of cause will accordingly be amended to add the Attorney General as a respondent. For simplicity's sake I term the governmental respondents in these Reasons the Attorney General.

[51] On the merits of the application, counsel for the Attorney General, who carried the argument in response, submits that the recent standard of review jurisprudence requires that the reasonableness standard be applied to the review of the Minister's decision to issue an NOC to Teva because the decision was premised on the interpretation of the PMNOC Regulations, which she argues are the Minister of Health's "home territory". More specifically, counsel argued that under the recent jurisprudence from the Supreme Court of Canada and some of the case law from the Federal Court of Appeal, decisions like the present—that involve interpretation of an administrative decision-maker's home statute or regulation—must be afforded deference. Counsel for the Attorney General in addition submits that officials at the OPML possess significant expertise in the interpretation of the PMNOC Regulations, which this Court lacks, providing another reason why the applicable standard of review should be reasonableness. She also says that the change in interpretation of the PMNOC Regulations, reflected in the impugned amendments to the Guidance Document, represents policy choices made by the Minister of Health, which should be afforded deference.

[52] The Attorney General also argues that the PMNOC Regulations allow for two reasonable interpretations as to whether a licensee like Teva needs to comply with subsection 5(1) of the PMNOC Regulations, particularly when one applies a purposive approach to interpretation. In this regard, the Attorney General says that the PMNOC Regulations exist to balance the rights of patentees, generic companies and the public so as to afford patentees the opportunity to protect their patents while ensuring the entry onto the market of cheaper generic versions of a drug as soon as possible. When read in this light, the PMNOC Regulations do not require Teva to address the 059 Patent, according to the Attorney General, because Pfizer had the

opportunity to protect its rights to the 059 Patent and could have commenced a prohibition application when GMP served it with an NOA, particularly as it should have realized that GMP was likely to issue a licence to Teva. Thus, according to counsel for the Attorney General, it was not necessary that Pfizer receive an NOA from Teva as Pfizer was given but declined to take up the opportunity to protect its rights to the 059 Patent when it received the NOA from GMP for its exemestane product. In addition, the Attorney General says that the equities of the situation should weigh heavily in favour of the respondents as the current interpretation afforded to the PMNOC Regulations by the Minister of Health fully protects innovator companies' patent rights and avoids unnecessary administrative burdens.

[53] In the alternative, the Attorney General argues that the current interpretation afforded to the PMNOC Regulations by the Minister of Health is correct and that this application should therefore be dismissed.

V. The Issues and Summary of the Conclusions Reached

[54] As is apparent from the foregoing, the first issue that must be determined is whether the correctness or reasonableness standard is to be applied to the review of the Minister of Health's decision to award an NOC to Teva. Implicit in this decision is the adoption by the Minister of the new interpretation of the PMNOC Regulations, set out in the amendments to the Guidance Document. Thus, determination of the appropriate standard of review requires assessment of the standard applicable to the Minister's interpretation of the PMNOC Regulations.

[55] For the reasons more fully set out below, I have concluded that the correctness standard is applicable to this decision and interpretation, despite the recent case law of the Supreme Court of Canada which mandates a greater degree of deference by reviewing courts. I have so concluded because the relevant regulatory and statutory context indicates that the interpretation of the PMNOC Regulations is not a matter in respect of which the Minister of Health (or more accurately officials in the OPML at Health Canada) are to be afforded deference.

[56] Selection of the appropriate standard of review in this case determines the outcome as I agree with the Attorney General that there is more than one reasonable interpretation of the PMNOC Regulations. However, there is only one correct interpretation and, as is more fully discussed below, under that interpretation the Minister was prevented from issuing the impugned NOC to Teva as subsection 5(1) and 7(1) of the PMNOC Regulations prevent this.

VI. The Appropriate Standard of Review

[57] Turning, first, to more fully discuss the standard of review, the parties raise several issues with respect to the principles applicable to the selection of the appropriate standard of review in this case.

[58] First, they differ as to whether the jurisprudence of this Court and of the Federal Court of Appeal, previously applying a correctness standard to decisions of the Minister of Health under the PMNOC Regulations, settles the question because that jurisprudence predates much of the recent case law from the Supreme Court of Canada and several recent decisions from the Federal Court of Appeal, mandating increased deference to administrative decision-makers'

decisions. Pfizer argues that despite this, the previous decisions under the PMNOC Regulations are binding and that I am therefore required to apply a correctness standard to the review of the Minister's decision in this case. The Attorney General argues the converse.

[59] Second, the parties differ as to the impact of the fact that the decision-maker in this case is the Minister of Health (through officials at the OPML) as opposed to an administrative tribunal. Pfizer argues that in light of the decisions of the Federal Court of Appeal in *Eli Lilly Canada Inc. v Canada (Minister of Health)*, 2003 FCA 24, 23 CPR (4th) 289 [*Tazidime*] at para 5 and *Takeda Canada Inc. v Canada (Minister of Health)*, 2013 FCA 13, 225 ACWS (3d) 524 [*Takeda*] at paras 26-30, Ministers and ministerial delegates are not to be afforded deference in respect of their interpretations of the statutory provisions they are applying. The respondents disagree and note that this line of authority from the Federal Court of Appeal is not unanimous and say that in any event it has been foreclosed by the decisions of the Supreme Court of Canada in *Agraira v Canada (Minister of Public Safety and Emergency Preparedness*), 2013 SCC 36, [2013] 2 SCR 559 [*Agraira*] and *Canadian National Railway Company v Canada (Attorney General)*, 2014 SCC 40, 240 ACWS (3d) 262 [*CN*]. They therefore argue that the identity of the decision-maker in this case does not necessarily mandate the selection of the correctness standard of review.

[60] Finally, the parties differ as to the impact of the decision of the Supreme Court of Canada in *CN*, a recent authority on standard of review issues. The Attorney General submits that in *CN* the Supreme Court held that the reasonableness standard is always applicable whenever an administrative decision-maker interprets its constituent statute or regulation or a

statute or regulation that is closely connected with its function, unless the decision falls into one of four exceptions, being decisions involving a true question of jurisdiction, a question of law of general importance to the legal system as a whole and outside the expertise of the decision-maker, determination of the respective jurisdiction of two or more administrative tribunals or a constitutional issue. The Attorney General therefore argues that it is no longer appropriate to have regard to the contextual factors mentioned in previous decisions as being relevant to the selection of the standard of review, namely, the presence or absence of a privative clause, the nature of the decision-maker and the assessment of its expertise in respect of the question at issue as compared to the Court's expertise on the issue. Pfizer disagrees and asserts that these factors continue to be relevant and in this case point to the selection of the correctness standard of review.

A. *The Impact of the Previous Case Law applying a Correctness Standard to the Review of Decisions of the Minister of Health under the PMNOC Regulations*

[61] Insofar as concerns the first of these arguments, as Pfizer correctly notes, this Court and the Federal Court of Appeal have previously overturned decisions of the Minister of Health under the PMNOC Regulations and in so doing have afforded no deference to the Minister's decisions. For example, in *Nu-Pharm 1*, both this Court and the Federal Court of Appeal overturned a decision of the Minister issuing an NOC to a generic company that had compared its product to that of another generic company without serving an NOA on the patentee. In overturning the decision to issue the NOC in that case, the Courts held that the Minister had incorrectly interpreted the requirements of sections 5 and 7 of the PMNOC Regulations and therefore set the decision aside. A similar determination was made in *Nu-Pharm Inc. v Merck &*

Co. et al., [1999] FCJ No 1825, 176 FTR 21, aff'd (2000), 5 CPR (4th) 138, [2000] FCJ No 380 (FCA) [*Nu-Pharm 2*]. Both *Nu-Pharm* cases involved situations similar to the present.

[62] The correctness standard has likewise previously been applied in the review of other types of decisions made by the Minister of Health under the PMNOC Regulations (see in this regard *Tazidime* at para 5; *AstraZeneca* at para 25; *Takeda* at paras 26-30).

[63] Pfizer argues that the foregoing authorities mandate that the correctness standard of review be applied in this case as the decisions of the Court of Appeal are binding on me and have settled the issue. Pfizer notes that in the seminal decision of *Dunsmuir v New Brunswick*, 2008 SCC 9, [2008] 1 SCR 190 [*Dunsmuir*], where the Supreme Court of Canada laid out the current approach to standard of review issues, the Court held that a full standard of review analysis is not required in circumstances where the previous jurisprudence has satisfactorily settled the applicable standard to be applied. Pfizer points to paragraphs 57 and 62 in *Dunsmuir*, where Justices LeBel and Bastarache, who wrote for the Court, stated as follows:

> 57 An exhaustive review is not required in every case to determine the proper standard of review. Here again, existing jurisprudence may be helpful in identifying some of the questions that generally fall to be determined according to the correctness standard (*Cartaway Resources Corp.* (Re), [2004] 1 S.C.R. 672, 2004 SCC 26). This simply means that the analysis required is already deemed to have been performed and need not be repeated.
>
> […]
>
> 62 […] the process of judicial review involves two steps. First, courts ascertain whether the jurisprudence has already determined in a satisfactory manner the degree of defence to be accorded with regard to a particular category of question. Second, where the first inquiry proves unfruitful, courts must proceed to an analysis of the factors making it possible to identify the proper standard of review.

[64] Pfizer says that in application of the foregoing, the correctness standard must be applied to the decision of the Minister in this case as the jurisprudence has settled that this is the standard of review applicable to ministerial decisions to issue NOCs under the PMNOC Regulations.

[65] The Attorney General disagrees and argues that the forgoing passages in *Dunsmuir* must be read in light of the subsequent jurisprudence from the Supreme Court of Canada. The Attorney General asserts that this subsequent case law makes it clear that there is at least a presumption that the reasonableness standard should be applied whenever an administrative decision-maker interprets its constituent statute or regulation or a statute or regulation closely connected with its function, unless the decision involves a constitutional issue, a question of general importance for the legal system as a whole that is outside the decision-maker's expertise, the division of jurisdiction between two or more administrative tribunals or a true question of jurisdiction. In support of this argument, the Attorney General relies on *Dunsmuir* at paras 55 and 60, *Alberta (Information and Privacy Commissioner) v Alberta Teachers' Association*, 2011 SCC 61, [2011] 3 SCR 654 [*Alberta Teachers*] at para 39 and *McLean v British Columbia (Securities Commission)*, 2013 SCC 67, [2013] 3 SCR 895 [*McLean*] at para 33.

[66] In light of these pronouncements from the Supreme Court of Canada subsequent to *Dunsmuir*, the Attorney General says that pre-*Dunsmuir* case law mandating the correctness standard of review cannot be said to satisfactorily settle that the correctness standard is applicable where what is at issue is an administrative decision-maker's interpretation of its constituent statute or regulations it is called upon to apply.

[67] I agree with the position advanced by the Attorney General on this point as the case law of the Supreme Court of Canada subsequent to *Dunsmuir* makes it clear that the reasonableness standard is presumptively applicable whenever an administrative decision-maker interprets its constituent statute or a statute or regulation that is closely connected with its function, unless the decision involves a constitutional issue, a question of general importance for the legal system as a whole that is outside the decision-maker's expertise, the division of jurisdiction between two or more administrative tribunals or a true question of jurisdiction.

[68] For example, the deferential standard was applied to the review of: (i) a decision by the Financial Services Tribunal declining to award costs to the appellants out of its pension trust fund on the basis that it lacked the authority to do so (*Nolan v Kerry (Canada) Inc.*, 2009 SCC 39, [2009] 2 SCR 678 at para 34); (ii) a decision by the Patented Medicine Prices Review Board interpreting its enabling legislation (*Celgene Corp v Canada (Attorney General)*, 2011 SCC 1, [2011] 1 SCR 3 at para 34); (iii) the Arbitration Committee's interpretation of a provision in its enabling statute regarding the awarding of costs (*Alliance Pipeline Ltd v Smith*, 2011 SCC 7, [2011] 1 SCR 160 [*Smith*] at para 28); (iv) the Canadian Human Rights Commission's decision that it had the authority under its enabling legislation to award costs in *Canada (Attorney General) v Mowat*, 2011 SCC 53, [2011] 3 SCR 471 [*Mowat*] at paras 15-27; (v) a decision by implication by the Information and Privacy Commissioner of Alberta that it was entitled under its enabling statute to extend the statutory time limit to complete an inquiry (*Alberta Teachers* at para 30); (vi) an implicit decision by the British Columbia Securities Commission interpreting a limitation provision in its home statute (*McLean* at paras 21 -22); and (vii) a decision of the Governor in Council under the *Canada Transportation Act*, SC 1996, c 10 (*CN* at para 55).

[69] In each of these cases the Supreme Court wrote broadly, indicating that there is a presumption that the reasonableness standard applies whenever an administrative decision-maker interprets its constituent statute or a statute closely related to its function (unless one of the foregoing four exceptions applies). In so doing, the Court did not carve out an additional exception for situations where the pre-*Dunsmuir* case law had applied the correctness standard to review of an administrative decision-maker's interpretation of its constituent statute or a statute closely related to its function.

[70] In light of these decisions, in my view, one cannot regard case law that pre-dates them and which mandates the selection of correctness standard as necessarily settling the standard of review in a satisfactory way.

[71] Indeed, the Supreme Court of Canada expressly endorsed this conclusion in *Agraira*, where Justice LeBel, writing for the Court, stated as follows:

> [48] As this Court held in *Dunsmuir*, a court deciding an application for judicial review must engage in a two-step process to identify the proper standard of review. First, it must consider whether the level of deference to be accorded with regard to the type of question raised on the application has been established satisfactorily in the jurisprudence. The second inquiry becomes relevant if the first is unfruitful or if the relevant precedents appear to be inconsistent with recent developments in the common law principles of judicial review. At this second stage, the court performs a full analysis in order to determine what the applicable standard is.

[72] Thus, the decisions in *Nu-Pharm 1* and *Nu-Pharm 2* do not obviate the need for a standard of review analysis in this case because they do not undertake the standard of review analysis mandated in *Dunsmuir* and subsequent Supreme Court of Canada decisions.

B. *The Impact of the Identity of the Decision-Maker*

[73] On the second argument involving the impact of the decision in this case having been made by the Minister of Health (through officials at the OPML branch at Health Canada), I once again agree with the position of the Attorney General and concur that the identity of the decision-maker does not of itself result in the conclusion that the appropriate standard of review is correctness.

[74] There is a line of authority from the Federal Court of Appeal that holds that the presumptive application of the reasonableness standard is inapplicable when a court is asked to review a decision made by a Minister or ministerial delegate under a statutory grant of authority, where the Minister or ministerial delegate has interpreted the statutory provisions being applied. Justice Mainville, writing for the majority in *David Suzuki Foundation v Canada (Fisheries and Oceans)*, 2012 FCA 40, 213 ACWS (3d) 208 [*Suzuki or Georgia Strait*] first enunciated this notion in the following terms (at paras 96-99):

> [96] [The *Dunsmuir*] analytical framework and this presumption must be understood in the context in which they were developed: they concern adjudicative tribunals. The presumption is derived from the past jurisprudence which had extensively considered the standard of review applicable to the decisions of such tribunals. By empowering an administrative tribunal to adjudicate a matter between parties, Parliament is presumed to have restricted judicial review of that tribunal's interpretation of its enabling statute and of statutes closely connected to its adjudicative functions. That presumption may however be rebutted if it can be found that Parliament's intent is inconsistent with the presumption.
>
> [97] The Minister is inviting this Court to expand the above-described *Dunsmuir* analytical framework and presumption to all administrative decision makers who are responsible for the administration of a federal statute. I do not believe that *Dunsmuir*

> and the decisions of the Supreme Court of Canada which followed *Dunsmuir* stand for this proposition.
>
> [98] What the Minister is basically arguing is that the interpretation of the SARA and of the *Fisheries Act* favoured by his Department and by the government's central agencies, such as the Department of Justice, should prevail. The Minister thus seeks to establish a new constitutional paradigm under which the Executive's interpretation of Parliament's laws would prevail insofar as such interpretation is not unreasonable. This harks back to the time before the *Bill of Rights* of 1689 where the Crown reserved the right to interpret and apply Parliament's laws to suit its own policy objectives. It would take a very explicit grant of authority from Parliament in order for this Court to reach such a far-reaching conclusion.
>
> [99] The issues in this appeal concern the interpretation of a statute by a minister who is not acting as an adjudicator and who thus has no implicit power to decide questions of law. Of course, the Minister must take a view on what the statute means in order to act. But this is not the same as having a power delegated by Parliament to decide questions of law. The presumption of deference resulting from *Dunsmuir*, which was reiterated in *Alberta Teachers' Association* at paras. 34 and 41, does not extend to these circumstances. The standard of review analysis set out at paragraphs 63 and 64 of *Dunsmuir* must thus be carried out in the circumstances of this case in order to ascertain Parliament's intent.

[75] This approach has been followed by other panels of the Federal Court of Appeal (see e.g. *Canada (Minister of Citizenship and Immigration) v Tobar Toledo*, 2013 FCA 226, 454 NR 139 [*Toledo*] at para 43 (reasons by Pelletier J.A, concurred by Gauthier and Trudel JJ.A.); *Prescient Foundation v Canada (Minister of National Revenue)*, 2013 FCA 120, 358 DLR (4th) 541 [*Prescient*] (reasons by Mainville J.A., concurred by Gauthier and Pelletier JJ.A.) at para 13; *Bartlett v Canada (Attorney General)*, 2012 FCA 230, 434 NR 241 [*Bartlett*] at para 46 (reasons by Mainville J.A, concurred by Sharlow and Pelletier JJ.A.) and *Sheldon Inwentash and Lynn Factor Charitable Foundation v Minister of National Revenue*, 2012 FCA 136, 432 NR 338 [*Sheldon*] (reasons by Dawson J.A., concurred by Trudel and Stratas JJ.A.) at paras 18-23).

[76] In *Takeda* Justice Dawson writing for the majority stated as follows:

> [113] Application of the presumption of deference to the Minister's interpretation of the data protection regulations is inconsistent with the prior decision of this Court in *Georgia Strait*.
>
> [114] In my view, any departure from such a recent decision creates unacceptable uncertainty. This is particularly so where, in the present case, the issue was not raised. The parties were in agreement that the applicable standard of review is correctness, no one argued that the presumption of reasonableness applied and no one argued that *Georgia Strait* was improperly decided.
>
> [115] Furthermore, the Supreme Court has in the past applied the correctness standard to such decisions. For example, in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, the Court wrote at paragraph 25:
>
> > The outcome of this appeal turns on conflicting interpretations of the NOC Regulations. On a question of legal interpretation, the Minister's opinion is not entitled to deference. The Federal Court of Appeal properly found that the standard of review on the point in issue is correctness.
>
> [116] As well, the Supreme Court has, albeit without discussion of the standard of review, applied a correctness review to the Minister of Citizenship and Immigration's interpretation of a provision of the *Immigration and Refugee Protection Act*, S.C. 2001, c. 27, (*Medovarski v. Canada (Minister of Citizenship and Immigration)*; *Esteban v. Canada (Minister of Citizenship and Immigration)*, 2005 SCC 51, [2005] 2 S.C.R. 539). In *Hilewitz v. Canada (Minister of Citizenship and Immigration)*; *De Jong v. Canada (Minister of Citizenship and Immigration)*, 2005 SCC 57, [2005] 2 S.C.R. 706, at paragraph 71, the Supreme Court accepted the joint submission of the parties that correctness should be applied to a visa officer's interpretation of the *Immigration Act*, R.S.C. 1985, c. I-2. Under the Immigration Act, a visa officer was an "immigration officer stationed outside Canada and authorized by order of the Minister [of Citizenship and Immigration] to issue visas" (subsection 2(1) of the *Immigration Act*). A visa officer was, therefore, a delegate of the Minister.

[77] However, as the Attorney General notes, the Federal Court of Appeal has not unanimously adopted the approach enunciated by Justice Mainville in *Suzuki*. For example, Justice Stratas in his dissenting reasons in *Takeda* concluded that the presumption of deference referred to in *Alberta Teachers* should apply not only to decisions made by adjudicative tribunals but also in the context of ministerial decisions. He wrote as follows:

> [33] I am reluctant to carve out administrative decisions from the *Alberta Teachers' Association* approach merely because the administrative decision-maker is a Minister, as is the case here. For one thing, the *Alberta Teachers' Association* approach aptly handles the breadth of Ministerial decision-making, which comes in all shapes and sizes, and arises in different contexts for different purposes. In addition, Ministerial decision-making power is commonly delegated, as happened here. It would be arbitrary to apply the *Alberta Teachers' Association* approach to decisions of administrative board members appointed by a Minister (or, practically speaking, a group of Ministers in the form of the Governor in Council), but apply the *Georgia Strait* approach to decisions of delegates chosen by a Minister. Finally, although this Court's decision in *Georgia Strait* postdates that of the Supreme Court in *Alberta Teachers' Association*, I consider myself bound by the latter absent further direction from the Supreme Court: see *Canada v. Craig*, 2012 SCC 43 at paragraphs 18-23.

[78] Justice Marc Noël (as he then was), writing for the majority in *Kandola v Canada (Minister of Citizenship and Immigration)*, 2014 FCA 85, 372 DLR (4th) 342 [*Kandola*], adopted the same view as Justice Stratas and held that the Supreme Court's decision in *Agraira* had conclusively determined the issue and therefore that the presumptive application of the reasonableness standard applies to ministerial decisions (at para 40).

[79] Thus, both Justice Stratas in *Takeda* and Justice Noël in *Kandola* found that the presumption of reasonableness applies to ministerial decisions or to decisions made by their delegates. Both, however, went on to note that the presumption may be rebutted by analyzing the

four factors discussed in *Dunsmuir*: (1) the presence or absence of a privative clause; (2) the purpose of the tribunal as determined by interpretation of enabling legislation; (3) the nature of the question at issue; and (4) the expertise of the tribunal.

[80] In light of the division in the Federal Court of Appeal on this issue, I agree with the Attorney General that *Takeda*, *Suzuki*, *Toledo*, *Prescient*, *Bartlett* and *Sheldon* are not binding on me.

[81] Moreover, as Justice Noël noted in *Kandola*, decisions of the Supreme Court of Canada issued subsequent to *Suzuki* and *Takeda* foreclose the application of the correctness standard to decisions of ministerial delegates by reason of the mere identity of the decision-maker.

[82] In this regard, in *Agraira*, the Supreme Court of Canada was faced with a decision of the Minister of Public Safety and Emergency Preparedness denying relief from a determination of inadmissibility on security grounds, which involved the interpretation of the term "national interest" in s. 34(2) of the *Immigration and Refugee Protection Act*, SC 2001, c 27. Despite this, the Court determined that the reasonableness standard of review was applicable. Justice LeBel, writing for the Court, stated as follows:

> [50] The applicability of the reasonableness standard can be confirmed by following the approach discussed in *Dunsmuir*. As this Court noted in that case, at para. 53, "[w]here the question is one of fact, discretion or policy, deference will usually apply automatically". Since a decision by the Minister under s. 34(2) is discretionary, the deferential standard of reasonableness applies. Also, because such a decision involves the interpretation of the term "national interest" in s. 34(2), it may be said that it involves a decision maker "interpreting its own statute or statutes closely connected to its function, with which it will have particular

> familiarity" (*Dunsmuir*, at para. 54). This factor, too, confirms that the applicable standard is reasonableness.

[83] Subsequently, in *CN*, the Supreme Court was faced with the review of an Order by the Governor in Council, who had interpreted section 120.1(1) of the *Canada Transportation Act*. Once again, the Supreme Court held that the reasonableness standard of review was applicable. Justice Rothstein, writing for the Court, found that the *Dunsmuir* framework applies to administrative decision-makers generally, including the Governor in Council, and not just to administrative tribunals. He stated as follows:

> [62] In this case, the Governor in Council was interpreting the *CTA*, legislation closely related to its economic regulation review function. This issue of statutory interpretation does not fall within any of the categories of questions to which a correctness review applies. As such, the applicable standard of review is reasonableness.

[84] Thus, the fact that the decision to issue the NOC to Teva in this case was made by officials at the OPML and involved an implicit interpretation of the PMNOC Regulations does not of itself translate to a need to apply the correctness standard of review as the case law from the Federal Court of Appeal is divided on the issue and the more recent jurisprudence of the Supreme Court of Canada indicates that the reasonableness standard is presumptively applicable to these sorts of decisions.

C. *The Impact of the Decision of the Supreme Court in CN*

[85] In terms of the final principle at issue with respect to the standard of review, the Attorney General argues that in *CN* the Supreme Court of Canada moved its standard of review

jurisprudence forward and determined there is now a firm rule that the reasonableness standard applies to the review of an administrative decision-maker's interpretation of its constituent statute or a statute or regulation closely connected with its function except where the decision involves a constitutional question, a true jurisdictional issue, the determination of the bounds of jurisdiction between two administrative tribunals or a question of law of general importance to the legal system as a whole that is outside the administrative decision-maker's expertise. Thus, according to the Attorney General, unless the decision involves one of the four foregoing types of issues, the reasonableness standard must be applied where the decision-maker interprets its constituent statute or a statute or regulation that is closely connected with its function.

[86] In support of this argument, the Attorney General points to the fact that in *CN*, in determining whether the presumption of reasonableness was rebutted, Justice Rothstein looked only to whether the issue that was determined by Cabinet fell within one of the four foregoing categories to which correctness applies. The Attorney General points in particular to paras 59 to 62 of the decision, where Justice Rothstein wrote as follows:

> [59] The presumption of deference is not rebutted here. The question at issue does not fall within one of the established categories of questions to which correctness review applies. In the present case, there is no issue of constitutionality or competing jurisdiction between tribunals.
>
> [60] This is also not a question of central importance to the legal system as a whole. The question at issue centres on the interpretation of s. 120.1 of the *CTA*. The question is particular to this specific regulatory regime as it involves confidential contracts as provided for under the *CTA* and the availability of a complaint-based mechanism that is limited to shippers that meet the statutory conditions under s. 120.1(1). This question does not have precedential value outside of issues arising under this statutory scheme.

> [61] To the extent that questions of true jurisdiction or vires have any currency, the Governor in Council's determination of whether a party to a confidential contract can bring a complaint under s. 120.1 does not fall within that category. This is not an issue in which the Governor in Council was required to explicitly determine whether its own statutory grant of power gave it the authority to decide the matter (see *Dunsmuir*, at para. 59). Rather, it is simply a question of statutory interpretation involving the issue of whether the s. 120.1 complaint mechanism is available to certain parties. This could not be a true question of jurisdiction or vires of the Governor in Council -- the decision maker under review in this case.
>
> [62] In this case, the Governor in Council was interpreting the *CTA*, legislation closely related to its economic regulation review function. This issue of statutory interpretation does not fall within any of the categories of questions to which a correctness review applies. As such, the applicable standard of review is reasonableness.

[87] The Attorney General argues that the foregoing passage indicates that the Supreme Court abolished the existence of a presumption that the reasonableness standard of review is applicable when an administrative decision-maker interprets its constituent statute or a statute or regulation closely connected with its function (that does not raise one of the four exceptions where correctness applies) in favour of a firm rule that the reasonableness standard is applicable in such circumstances.

[88] Despite the broad manner in which the reasons in *CN* are cast, I disagree that the decision in that case should be read so broadly as establishing a fixed rule that the only way one can rebut the presumption of reasonableness would be if the decision-maker's decision falls into one of the four categories of a constitutional question, a true jurisdictional issue, the determination of the bounds of jurisdiction between two administrative tribunals or a question of law of general importance to the legal system as a whole that is outside the administrative

decision-maker's expertise. So doing would contradict both the approach set out in *Dunsmuir* and detailed in several subsequent Supreme Court cases.

[89] These previous decisions indicate that the inquiry into standard of review does not necessarily end with the determination that the issue being reviewed involves the interpretation of the decision-maker's home statute or a statute or regulation closely connected with its function and does not fall into one of the four foregoing categories to which correctness applies. More specifically, the Supreme Court has indicated in several cases prior to *CN* that the inquiry may need to be pushed further in appropriate cases and may well require consideration of factors such as the presence or absence of a privative clause, the nature of the decision-maker and the assessment of its expertise in respect of the question at issue as compared to the Court's expertise on the issue.

[90] For example, in *Dunsmuir*, itself, Justices Bastarache and LeBel stated on this point at para 54 that guidance may be found in the existing case law and that "[d]eference will usually result where a tribunal is interpreting its own statute or statutes closely connected to its function, with which it will have particular familiarity" [emphasis added]. They continued in the following paragraph, though, to note that where a tribunal has interpreted its home statute, it may nevertheless sometimes be necessary to undertake a contextual analysis. They noted this involves consideration of factors such as (1) the presence or absence of a privative clause; (2) the purpose of the tribunal as determined by interpretation of enabling legislation; and (3) the nature of the question at issue (at paras 55 and 64).

[91] Thereafter, in *Smith*, Justice Fish, who wrote for the Court, confirmed that the standard of review analysis does not necessarily end with the determination that an interpretation of the decision-maker's constituent statute or statute or regulation closely connected with its function does not fall into one of the four categories identified in *Dunsmuir* to which correctness applies. He stated as follows at paras 24 to 26:

> [24] Pursuant to *Dunsmuir*:
>
> > ... the process of judicial review involves two steps. First, courts ascertain whether the jurisprudence has already determined in a satisfactory manner the degree of deference to be accorded with regard to a particular category of question. Second, where the first inquiry proves unfruitful, courts must proceed to an analysis of the factors making it possible to identify the proper standard of review. [para. 62]
>
> Even when resort to these factors is required, it may not be necessary to consider them all (para. 64).
>
> [25] Accordingly, reviewing judges can usefully begin their analysis by determining whether the subject matter of the decision before them for review falls within one of the non-exhaustive categories identified by *Dunsmuir*. Under that approach, the first step will suffice to ascertain the standard of review applicable in this case.
>
> [26] Under *Dunsmuir*, the identified categories are subject to review for either correctness or reasonableness. The standard of correctness governs: (1) a constitutional issue; (2) a question of "general law 'that is both of central importance to the legal system as a whole and outside the adjudicator's specialized area of expertise'" (*Dunsmuir*, at para. 60 citing *Toronto (City) v. C.U.P.E., Local 79*, 2003 SCC 63, [2003] 3 S.C.R. 77, at para. 62); (3) the drawing of jurisdictional lines between two or more competing specialized tribunals; and (4) a "true question of jurisdiction or vires" (paras. 58-61). On the other hand, reasonableness is normally the governing standard where the question: (1) relates to the interpretation of the tribunal's enabling (or "home") statute or "statutes closely connected to its function, with which it will have particular familiarity" (para. 54); (2) raises issues of fact, discretion or policy; or (3) involves inextricably intertwined legal and factual issues (paras. 51 and 53-54).

[92] In *Smith*, Justice Fish determined that the reasonableness standard applied because in addition to the fact that the Arbitration Committee established under Part V of the *National Energy Board Act*, RSC 1985, c N-7 by the Minister of Natural Resources was interpreting its home statute, the issue in question concerned costs, which are "invariably fact-sensitive and generally discretionary" (at para 30). Further, the statute in question provided the Committee authority to award those costs that it determined had been reasonably incurred, language which, according to Justice Fish, "reflects a legislative intention to vest in [the Committee] sole responsibility for determining the nature and the amount of the costs to be awarded" (at para 31). Finally, in awarding costs, the Committee will frequently be required to make determinations where legal issues cannot be easily separated from factual issues, which Justice Fish indicated provided another reason for selecting the reasonableness standard in that case.

[93] To similar effect, in *Mowat*, Justices LeBel and Cromwell, who wrote for the Court, confirmed that the requisite analysis does not stop with the determination that the legal interpretation of the administrative decision-maker's home statute does not fall into one of the four categories set out in *Dunsmuir* to which correctness applies. They stated as follows:

> [15] In *Dunsmuir* and *Canada (Citizenship and Immigration) v. Khosa*, 2009 SCC 12, [2009] 1 S.C.R. 339, the Court simplified an analytical approach that the judiciary found difficult to implement. Being of the view that the distinction between the standards of patent unreasonableness and reasonableness *simpliciter* was illusory, the majority in *Dunsmuir* eliminated the standard of patent unreasonableness. The majority thus concluded that there should be two standards of review: correctness and reasonableness.
>
> [16] *Dunsmuir* kept in place an analytical approach to determine the appropriate standard of review, the standard of review analysis. The two-step process in the standard of review analysis is first to "ascertain whether the jurisprudence has already determined in a satisfactory manner the degree of deference to be accorded with regard to a particular category of question. Second, where the first

inquiry proves unfruitful, courts must proceed to an analysis of the factors making it possible to identify the proper standard of review" (para. 62). The focus of the analysis remains on the nature of the issue that was before the tribunal under review (*Khosa*, at para. 4, per Binnie J.). The factors that a reviewing court has to consider in order to determine whether an administrative decision maker is entitled to deference are: the existence of a privative clause; a discrete and special administrative regime in which the decision maker has special expertise; and the nature of the question of law (*Dunsmuir*, at para. 55). *Dunsmuir* recognized that deference is generally appropriate where a tribunal is interpreting its own home statute or statutes that are closely connected to its function and with which the tribunal has particular familiarity. Deference may also be warranted where a tribunal has developed particular expertise in the application of a general common law or civil law rule in relation to a specific statutory context (*Dunsmuir*, at para. 54; *Khosa*, at para. 25).

[17] *Dunsmuir* nuanced the earlier jurisprudence in respect of privative clauses by recognizing that privative clauses, which had for a long time served to immunize administrative decisions from judicial review, may point to a standard of deference. But, their presence or absence is no longer determinative about whether deference is owed to the tribunal or not (*Dunsmuir*, at para. 52). In *Khosa*, the majority of this Court confirmed that with or without a privative clause, administrative decision makers are entitled to a measure of deference in matters that relate to their special role, function and expertise (paras. 25-26).

[18] *Dunsmuir* recognized that the standard of correctness will continue to apply to constitutional questions, questions of law that are of central importance to the legal system as a whole and that are outside the adjudicator's expertise, as well as to "[q]uestions regarding the jurisdictional lines between two or more competing specialized tribunals" (paras. 58, 60-61; see also *Smith v. Alliance Pipeline Ltd.*, 2011 SCC 7, [2011] 1 S.C.R. 160, at para. 26, per Fish J.). The standard of correctness will also apply to true questions of jurisdiction or *vires*. In this respect, *Dunsmuir* expressly distanced itself from the extended definition of jurisdiction and restricted jurisdictional questions to those that require a tribunal to "explicitly determine whether its statutory grant of power gives it the authority to decide a particular matter" (para. 59; see also *United Taxi Drivers' Fellowship of Southern Alberta v. Calgary (City)*, 2004 SCC 19, [2004] 1 S.C.R. 485, at para. 5).

[94] Likewise, in *Nor-Man Regional Health Authority Inc. v Manitoba Association of Health Care Professionals*, 2011 SCC 59, [2011] 3 SCR 616 [*Nor-Man*], Justice Fish again confirmed this approach. There, the Court was called upon to determine whether a labour arbitrator's application of the doctrine of estoppel should be subject to the correctness or reasonableness standard. As the matter had not been previously ruled upon by the Supreme Court, Justice Fish stated at para 34 that he would adhere in substance to the analytical template set out in *Dunsmuir* and adopted in *Smith*. He indicated that this template involves first asking if the previous jurisprudence has satisfactorily settled the standard of review. That will be the case, he indicated, where the decision involves a constitutional issue, a question of general law that is of central importance to the legal system as a whole and outside the specialized expertise of the decision-maker, a true question of *vires* or an inquiry that involves drawing lines between two or more administrative decision-makers. In such circumstances, the standard of review will be correctness. He next indicated that the reasonableness standard "normally" prevails where the decision involves issues of fact, discretion or policy, inextricably intertwined legal and factual issues or the interpretation of the tribunal's home statute or statutes closely related to its function (at para 36).

[95] Because application of these guidelines did not conclusively settle the issue, Justice Fish went on in *Nor-Man* to undertake a contextual analysis. He noted that "[f]our non-exhaustive contextual factors have been identified in the jurisprudence to guide courts through this exercise: (1) the presence or absence of a privative clause; (2) the purposes of the tribunal; (3) the nature of the question at issue: and (4) the expertise of the tribunal" (at para 40).

[96] More recently, as already cited, in *Agraira*, Justice LeBel, writing for the Court stated:

> [48] As this Court held in *Dunsmuir*, a court deciding an application for judicial review must engage in a two-step process to identify the proper standard of review. First, it must consider whether the level of deference to be accorded with regard to the type of question raised on the application has been established satisfactorily in the jurisprudence. The second inquiry becomes relevant if the first is unfruitful or if the relevant precedents appear to be inconsistent with recent developments in the common law principles of judicial review. At this second stage, the court performs a full analysis in order to determine what the applicable standard is.

[97] To similar effect in *McLean*, Justice Moldaver, who penned the unanimous decision of the Court, stated as follows:

> [20] Before turning to my analysis, I pause to note that the standard of review debate is one that generates strong opinions on all sides, especially in the recent jurisprudence of this Court. However, the analysis that follows is based on this Court's existing jurisprudence - and it is designed to bring a measure of predictability and clarity to that framework.
>
> [21] Since *Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190, this Court has repeatedly underscored that "[d]eference will usually result where a tribunal is interpreting its own statute or statutes closely connected to its function, with which it will have particular familiarity" (para. 54). Recently, in an attempt to further simplify matters, this Court held that an administrative decision maker's interpretation of its home or closely-connected statutes "should be presumed to be a question of statutory interpretation subject to deference on judicial review" *(Alberta (Information and Privacy Commissioner) v. Alberta Teachers' Association*, 2011 SCC 61, [2011] 3 S.C.R. 654, at para. 34).
>
> [22] The presumption endorsed in *Alberta Teachers*, however, is not carved in stone. First, this Court has long recognized that certain categories of questions - even when they involve the interpretation of a home statute - warrant review on a correctness standard (*Dunsmuir*, at paras. 58-61). Second, we have also said that a contextual analysis may "rebut the presumption of reasonableness review for questions involving the interpretation of the home statute" (*Rogers Communications Inc. v. Society of*

> *Composers, Authors and Music Publishers of Canada*, 2012 SCC 35, [2012] 2 S.C.R. 283, at para. 16).

[98] In light of these multiple statements from the Supreme Court, confirming the need for a contextual analysis in appropriate cases, in my view one cannot read the decision in *CN* as changing the law and deciding that there is no longer any place for a contextual analysis in a standard of review case. It would take a much more deliberate treatment of the issue by the Supreme Court than that which is contained in *CN* to effect this result.

[99] In light of the forgoing, I believe the required steps in determining the appropriate standard of review are the following.

[100] First, one must consider whether the previous case law has satisfactorily settled the standard of review to be applied.

[101] 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.

[102] 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.

[103] 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).

[104] 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.

D. *Determination of the Standard of Review in this Case*

[105] I turn now to the application of the foregoing analytical framework in the present case. As noted, the first question involves asking whether the previous jurisprudence has satisfactorily settled the applicable standard of review. I conclude that it has not for three reasons.

[106] First, as discussed above, the previous case law of the Federal Court of Appeal and of this Court, applying a correctness standard of review to decisions of the Minister to issue NOCs under the PMNOC Regulations, does not settle the standard as several of the cases pre-date *Dunsmuir* and none of them undertakes the standard of review analysis that *Dunsmuir* mandates.

[107] Second, the decision made by the Minister does not involve one of the four types of determinations to which the correctness standard applies and no party suggested otherwise. Indeed, the only potentially applicable exception, that of a question of central importance to the legal system as a whole outside the decision-maker's expertise, is clearly inapplicable given the limited scope of the PMNOC Regulations as compared to the breadth of legal issues that come before courts.

[108] Third, the decision at issue is not one of fact or mixed fact and law and does not involve the exercise of a statutory discretion.

[109] Thus, the presumption of reasonableness applies and it becomes necessary to consider whether the presumption is rebutted. This, in turn, requires a contextual analysis.

[110] The first factor the case law identifies as relevant to the contextual analysis is the presence or absence of a privative clause. There is no privative clause in the PMNOC Regulations. While the presence of a privative clause may well be an indicator of the legislator's intent that an administrative decision-maker should be accorded deference, the absence of such a clause is far less relevant as in many cases the reasonableness standard is applicable in the absence of a privative clause (see e.g. *Khosa* at paras 25-26, *Mowat* at para 17 and the non-labour decisions of the Supreme Court post-*Dunsmuir* applying the reasonableness standard of review, in many of which the relevant statutes lacked privative clauses).

[111] The other three contextual factors identified in the case law are the purpose of the tribunal, the nature of the question at issue and the expertise of the tribunal. These factors are interrelated and are aimed at discerning whether the nature of the question being considered is such that the legislator intended it be answered by the administrative decision-maker as opposed to the Court. Indicia of such an intention include the role assigned to the administrative decision-maker under the legislation and the relationship between the question decided and the institutional expertise of the decision-maker as opposed to the institutional expertise of a court.

[112] Consideration of these criteria in this case leads to a conclusion that the presumption of the applicability of the reasonableness standard is rebutted.

[113] The question at issue in this case concerns whether an applicant who files an administrative ANDS based on a licence from another generic company has made a "submission for an NOC" that "directly or indirectly compares" its product to that of the innovator company

whose drug is listed on the Patent List established under the PMNOC Regulations such that the company is caught by section 5 of the PMNOC Regulations. There is nothing in the PMNOC Regulations that indicates that the Governor in Council intended that this issue be left to officials at Health Canada to determine. Indeed, the regulatory and statutory context indicate the converse.

[114] In this regard, the PMNOC Regulations do not afford the Minister of Health discretion to make a decision as to when to issue an NOC but rather are cast in mandatory terms and prevent the Minister from issuing an NOC until the criteria in section 7 of the Regulations are met. Thus, under the PMNOC Regulations, there is no scope for the exercise of discretion or the making of policy determinations by the Minister of Health or Health Canada as to when an NOC may be issued. The fact that Health Canada has adopted a new interpretation of the requirements of the PMNOC Regulations does not equate to a policy determination of the sort that merits deference because the statutory and regulatory context do not afford the Minister a policy-making role under the PMNOC Regulations. Nor do they require the provision of reasons, which often accompanies the exercise of a policy-making function by an administrative decision-maker.

[115] The limited role assigned to the Minister of Health and officials at Health Canada under the PMNOC Regulations may be contrasted with the broader role assigned to them under the FDA Regulations in respect of the issuance of NOCs. Under the FDA Regulations, the Minister and officials at Health Canada are afforded the authority and responsibility to decide whether an NOC should be issued based on Health Canada's expert evaluation of the safety and efficacy of a drug. In the case of an ANDS, this determination calls on the departmental expertise in

evaluating whether drugs are the pharmaceutical and bioequivalent of each other within the meaning of section C.08.002.1 of the FDA Regulations.

[116] On the other hand, under the PMNOC Regulations, no such evaluation is left in the hands of the Minister or officials at Health Canada. Rather, the Governor in Council left the ultimate determination of whether an NOC should be issued under the PMNOC Regulations to this Court as it is the Court that is required to rule on prohibition applications made by innovator companies who wish to forestall the issuance of an NOC to a generic company through an ANDS. The role assigned to this Court under the PMNOC Regulations is inconsistent with application of the reasonableness standard to interpretations of the Minister or officials at Health Canada of the Regulations.

[117] This case, indeed, is somewhat similar to *Rogers Communications Inc. v Society of Composers, Authors and Music Publishers of Canada*, 2012 SCC 35, [2012] 2 SCR 283, in which Justice Rothstein for the majority applied the correctness standard to the review of the Copyright Board's interpretation of its constituent Act on the basis that the Board and the courts shared concurrent jurisdiction under the statute (at paras15 and 19).

[118] Likewise, this case is somewhat similar to *Takeda*. There, Justice Stratas in his dissenting reasons, decided that the Minister's interpretation of the data protection provisions, enshrined in the FDA Regulations, was reviewable on the correctness standard because the presumptive application of the reasonableness standard was rebutted. He based this determination on the fact that the point in issue in that case was purely legal, the Minister had no

particular expertise in legal interpretation and there was nothing in the structure of the legislation or the regulatory regime that suggested that deference should be accorded to the Minister's decision.

[119] Similar reasoning applies in this case.

[120] I therefore conclude that the presumption of the applicability of the reasonableness standard of review is rebutted here and that the correctness standard is applicable to the review of Health Canada's decision to issue an NOC to Teva and to the implicit interpretation of the PMNOC Regulations enshrined in that decision (that is fully enunciated in the amendments to the Guidance Document).

VII. Evaluation of the Correctness of the Decision to Issue the NOC to Teva

[121] Having settled that the correctness standard of review applies to the assessment of the decision at issue in this case, I turn now to consideration of whether the Minister through officials at the OMPL at Health Canada correctly interpreted the PMNOC Regulations in this case.

[122] As noted, the Attorney General argues in the alternative that the interpretation of the PMNOC Regulations enshrined in the amended Guidance Document is correct, even though the Minister had previously interpreted the requirements of the PMNOC Regulations in an opposite fashion.

[123] The Attorney General submits more specifically an administrative submission like the one made by Teva in this case is not a "submission for an NOC" within the meaning of sub-section 5(1) of the PMNOC Regulations for several reasons.

[124] First, the Attorney General argues that one must apply a purposive approach to the interpretation of the PMNOC Regulations and asserts that the purpose of these Regulations is to allow the "early working" by a generic company of a patented drug. In support of this assertion the Attorney General points to the statutory authority for the PMNOC Regulations, contained in section 55.2 of the *Patent Act*, and to judicial pronouncements regarding the scope of the regulation-making power under subsection 55.2(4) of that Act. The Attorney General says that in *Biolyse* and *AstraZeneca* the Supreme Court of Canada recognized that the grant of regulation-making power in subsection 55.2(4) of the *Patent Act* is limited to preventing infringement by those who take advantage of the early working exception to develop a generic version of a patented medicine.

[125] The Attorney General argues that in this case Teva did not take advantage of the early-working exception and, therefore, that under a purposive approach to the interpretation of subsection 5(1) of the PMNOC Regulations it is not necessary to consider the administrative submission made by Teva to be a "submission for an NOC" within the meaning of subsection 5(1) of the PMNOC Regulations. Rather, according to the Attorney General, it was GMP that took advantage of the early-working exception and who filed an ANDS and served an NOA on Pfizer. The Attorney General says that if Pfizer wished to protect its patent rights to the 059 Patent, it ought to have made a prohibition application when it was served with GMP's NOA; the

Attorney General characterizes Pfizer's choice to refrain from doing so as a strategic one as it was aware of the change to the Guidance Document and must be taken to have been alive to the likelihood that GMP would likely licence Teva to produce GMP's exemestane product under Teva's label, given what had occurred with respect to the first NOC that was erroneously issued to Teva. The Attorney General thus argues that under the new interpretation of the PMNOC Regulations at issue in this case, Pfizer had the complete ability to protect its patent but chose not to exercise this right.

[126] Secondly, the Attorney General argues that the conclusion that Teva's administrative drug submission does not come within the scope of subsection 5(1) of the PMNOC Regulations is supported by the wording of the relevant regulatory provisions and the case law, especially when viewed in light of the foregoing purposive approach.

[127] In this regard, the Attorney General notes that the PMNOC Regulations do not define what constitutes a "submission" and that under the FDA Regulations the licence from GMP to Teva would give rise to the need to file a supplemental submission for an NOC under section C.08.003 of the FDA Regulations because there would be changes to the drug's label and name. The Attorney General further says that not all supplemental submissions, within the meaning of section C.08.003 of the FDA Regulations, constitute "submissions" within the meaning of the PMNOC Regulations because this Court and the Federal Court of Appeal have held that supplemental submissions made by innovator companies as a result of minor changes to their filings with Health Canada did not constitute "submissions" under an earlier version of the PMNOC Regulations (relying on *Bristol-Myers Squibb Canada Inc. v Canada (Attorney*

General) (2001), 10 CPR (4th) 318, 199 FTR 142 at paras 13, 19 and 21, aff'd (2002), 16 CPR (4th) 425, 2002 FCA 32; *Ferring Inc. v Canada (Attorney General)* (2003), 26 CPR (4th) 155, 2003 FCA 274 at paras 13-18, leave to appeal refused (2004), 29 CPR (4th) vii, 329 NR 197 (SCC); *Toba Pharma Inc. v Canada (Attorney General)* (2002), 21 CPR (4th) 232, 2002 FCT 927 at paras 28 and 34; *AstraZeneca Canada Inc. v Canada (Minister of Health)* (2004), 36 CPR (4th) 58, 2004 FC 736 at para 39, aff'd (2005), 335 NR 6, 2005 FCA 175 at para 4; *Hoffman-LaRoche Ltd. v Canada (Minister of Health)* (2005), 40 CPR (4th) 108, 2005 FCA 140 at para 25).

[128] In these cases, innovator companies sought to extend their protection under the PMNOC Regulations by filing supplemental submissions for an updated NOC, arguing such filings gave rise to a right to re-list the patent under section 4 of the PMNOC Regulations. The Courts disagreed and found that under a purposive interpretation such supplemental submissions did not constitute "a submission" within the meaning of section 4 of the PMNOC Regulations. The Attorney General says that these cases should apply by analogy here.

[129] Thirdly, the Attorney General argues that this case is on all fours with the decision of Justice Lemieux in *GlaxoSmithKline Inc v Canada (Attorney General)*, 2004 FC 1302, 38 CPR (4th) 27 [*Glaxo*], where Justice Lemieux dealt with the Minister of Health's Name Change Policy and held that administrative new drug submissions filed under that policy did not engage the PMNOC Regulations as such submissions do not constitute "submissions" within the meaning of subsection 5(1) of the PMNOC Regulations. The Attorney General submits that the *Glaxo* decision is the binding authority in this case and that the decision of the Minister to issue the NOC to Teva must therefore be upheld.

[130] Finally, the Attorney General argues that the decisions in *Nu-Pharm 1* and *Nu-Pharm 2* are distinguishable on two bases. First, in those cases, it was clear that the generic company was attempting to circumvent the Regulations. Here, however, GMP and Teva acted in compliance with the Minister's policy. Second, Pfizer had an opportunity to exercise its rights under the Regulations when it received the NOA from GMP. Such an opportunity, however, was not available to the innovator company in the *Nu-Pharm* cases, which arose during the transition period from the previous compulsory licensing system, and the licensor generic company, unlike GMP, was therefore not required to serve the innovator with an NOA.

[131] In assessing the Attorney General's arguments, I concur that it is necessary to interpret the relevant statutory and regulatory provisions through a purposive approach as it is well settled that there is a single correct approach to statutory interpretation, namely, that the words of the provision must be read in "their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament" (see *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 SCR 27 at para 21; *Biolyse* at para 37; and *Agraira* at para 64).

[132] I, however, disagree that a purposive interpretation of the regulatory and legislative provisions in this case leads to the conclusion urged by the Attorney General for several reasons.

[133] First, in my view, the purpose of the PMNOC Regulations is more nuanced than the Attorney General suggests. The Regulations exist not only to allow generic companies to early work patented medicines to develop generic formulations and to have them ready as soon as

possible but, also, to balance these interests with those of the patentee in obtaining protection for innovations that are legitimately patented. The Regulation's recognition of patentees' interests is evident in the provisions that require this Court to issue a prohibition order if it finds a generic company's NOA is justified and which allow the patentee to forestall the entry of the generic version of the drug onto the market until this Court rules on the justification of the NOA.

[134] This balancing of competing interests in the PMNOC Regulations is reflected in the RIAS cited at paragraph 16 of these reasons and in the jurisprudence. Notably, in *Biolyse*, which is the linchpin of the Attorney General's argument in this case, Justice Binnie, writing for the majority, indicated that the purpose of the Regulations is to ensure that generic companies which make a comparison to an innovator drug must comply with subsection 5(1):

> [65] The interpretation offered by BMS of s. 5(1.1) pushes the provision well beyond its stated purpose of preventing generic manufacturers from hiding their reliance on innovator drugs by putting forward as their reference drug another generic manufacturer's product, in circumstances where both generics are simply copies of the innovator drug. If the approval of the generic drug is related to the work of another drug manufacturer in respect of which a patent list has been filed (as in the Nu-Pharm type situations), it will be caught by s. 5(1.1). However, in this case, as stated, the motions judge found that the Minister did not rely on the BMS work. He relied on work performed by Biolyse itself and "on what was known to scientists in the public realm about paclitaxel" (para. 40).
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> [Emphasis added]

[135] In the present case, Teva has made precisely the sort of comparison that Justice Binnie indicated in *Biolyse* fell within the scope of subsection 5(1.1) of the PMNOC Regulations. (The differences between that provision and the current version of subsection 5(1) of the PMNOC Regulations is immaterial to the issues in this case). Thus, the fact that Teva did not seek to take

advantage of the early working exception is irrelevant to the objective of subsection 5(1) to extend protection to the rights of patentees. Therefore, in accordance with the ruling of the Supreme Court in *Biolyse*, requiring Teva to comply with subsection 5(1) of the PMNOC Regulations accords with the purpose of the Regulations.

[136] In short, the Regulations exist to balance the rights of innovators, generic companies and the public, and it is consistent with that balancing exercise and the structure of the Regulations that a company that wishes to enter the market with a generic version of a drug listed on the Patent List be required to address the relevant patents. The situation cannot be likened to that of an innovator company that attempts to re-list a patent through a minor change that requires the filing of a supplemental NDS. Thus, once the purpose of the PMNOC Regulations is properly understood, it supports the conclusion that a company in the position of Teva must comply with subsection 5(1) of the Regulations.

[137] Secondly, I disagree that the *Nu-Pharm* cases are distinguishable. While they arose in a different fact pattern under an earlier version of section 5 of the PMNOC Regulations, neither of these points provides the basis for a principled distinction from the situation in this case. In both *Nu-Pharm* decisions, the Federal Court of Appeal did not limit its decision to the facts before it but, rather, indicated that subsection 5(1) of the PMNOC Regulations exists to require all generic companies who obtain their rights through a licence to address an innovator company's patent on the Patent Register created by the Regulations, whether they make a direct or an indirect comparison to the innovator's product.

[138] In *Nu-Pharm 1*, Justice McDonald, who wrote for the Court of Appeal, stated that section 5 of the PMNOC Regulations:

> [8] […] ensure[s] that a person who seeks a Notice of Compliance for a drug must file an allegation and a detailed statement of its factual and legal basis, and must serve a Notice of Allegation if that person wishes to compare that drug with, or make a reference to, a drug in respect of which a patent list has been submitted. Nu-Pharm can not piggy-back its claim on the Generic Drug Company who relies on the tests of the patentee and then state it need not comply with the Act because the Generic Company did not issue a patent list. The fact remains that although it is one step removed, Nu-Pharm is relying on the tests and other work done by the patentees, whom the Generic Company relied on. While Nu-Pharm claims to be comparing its drug to Generic 1's, it, nonetheless, is, in essence, comparing it to that of the original patentee, because Generic 1 compared its drug to that of the patentee. It is a question of interpretation which requires the Court to construe the words in context so as to be consistent with the purpose of the Act. Thus, in our view, Nu-Pharm cannot circumvent the Regulations by cross-referencing its drug submission to a generic, which filed an Abbreviated Drug Submission.

[139] To similar effect, in *Nu-Pharm 2*, Justice Sharlow, who wrote for the Court of Appeal, noted at para 15 that the issue in that case concerned "whether Regulation 5(1) is engaged by the filing of an ANDS if the Canadian reference product it names is not the subject of a patent list, but the notice of compliance for that Canadian reference product was obtained by comparison to a drug that is the subject of a patent list".

[140] In result, she held that the situation was indistinguishable from *Nu-Pharm 1* as the generic company sought to compare its product directly or indirectly to a patent listed on the Patent Register. She thus concluded that under the holding in *Nu-Pharm 1*, the generic company was required to comply with section 5 of the PMNOC Regulations:

> [30] […] To describe Nu-Pharm's ANDS for Nu-Enalapril as "standing alone" is to distort the facts. Nu-Pharm's actions belie its assertion that it does not wish to compare Nu-Enalapril to Vasotec or refer to Vasotec. Its ANDS for Nu-Enalapril, by using Apo-Enalapril as its Canadian reference product, invites comparison to Vasotec just as surely as if Vasotec were named, because the new drug submission for Apo-Enalapril used Vasotec as its Canadian reference product. In these circumstances, Nu-Pharm cannot deny that it wishes a comparison to be made between Nu-Enalapril and Vasotec. Nor can Nu-Pharm avoid the obligations of Regulation 5(1) by hiding its wish behind a form of ANDS that expressly names only Apo-Enalapril.

[141] In both *Nu-Pharm* cases the generic company, just like Teva, had acquired the right to produce the drug in question under a licence from another generic company. In light of this and given the fact that the Court of Appeal did not limit its reasoning in these cases to the particular facts before it, I believe these cases are binding on me and apply to this case. Just like the generic companies in the *Nu-Pharm* cases, Teva has filed a submission that makes a direct or indirect comparison to AROMASIN and has filed a submission for an NOC. It therefore follows that the Minister was incorrect in issuing the NOC to Teva.

[142] Third, the decision of Justice Lemieux in *Glaxo* that the Attorney General relies on is distinguishable because the fact pattern in *Glaxo* is different as the generic company in that case had complied with subsection 5(1) of the Regulations and had served an NOA on the innovator company in respect of whose product it had undertaken a comparison. It therefore was not required to file an NOA in respect of another company who had a patent for a very similar drug. Due to this, Justice Lemieux concluded at para 56 that "on the facts of [that] case, Apotex [was] not doing an end run on the Regulations. Its NOC [was] based on the NOC which 3M, a patent

holder whose product is on the patent list received from the Minister". Thus, the comments the Attorney General relies on are *obiter dicta* and accordingly are not binding.

[143] Fourth, the cases interpreting the meaning of "submission" in the context of section 4 of the PMNOC Regulations for purposes of listing a patent on the Patent register under an earlier version of the PMNOC Regulations are inapplicable to the issues in this case. Simply put, the concerns about an innovator company's extending its entitlements under the Regulations through administrative filings do not arise in this case.

[144] Here, it is clear that Teva sought an NOC to market a drug in Canada based on the direct comparison of its product to AROMASIN or on an indirect comparison of its drug to AROMASIN by piggy-backing on GMP's comparison. Such comparisons engage subsection 5(1) of the PMNOC Regulations under a purposive interpretation of the requirements of the Regulations because the Regulations strike the required balance between competing interests by requiring generic companies who make such comparisons to address the patents on the Patent Register.

[145] The Federal Court of Appeal has so held in the *Nu-Pharm* cases. As these decisions are indistinguishable, it follows that this application must be granted and the decision of the Minister set aside because Teva did make a submission for an NOC that directly or indirectly compared its product to AROMASIN within the meaning of subsection 5(1) of the PMNOC Regulations. Under section 7 of the Regulations, the Minister of Health could not issue Teva an NOC when it made such a submission until Teva addressed the 059 Patent. Thus, the Minister's decision to

issue Teva the NOC was made in contravention of section 7 of the PMNOC Regulations and must be set aside.

VIII. Costs

[146] The parties submitted that costs should follow the event. I agree that this is appropriate and find they should be based on the mid-point of Column III of Tariff B to the *Rules*. Counsel for the parties indicated that they should be able to concur as to the amount payable and I therefore remit the issue to them. In the event they are unable to agree, the parties may make written submissions as to appropriate quantum of costs within 45 days from the date of this judgment.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. This application is granted;

2. The decision of the Minister of Health granting an NOC to Teva for its exemestane tablets is set aside;

3. Pfizer is entitled to costs at the mid-point of Column III of Tariff B, in an amount to be settled by the parties or determined by the Court in accordance with the procedure outlined in paragraph 146 of these Reasons; and

4. The style of cause is amended to add the Attorney General of Canada as a respondent.

"Mary J. L. Gleason"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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