OFFICIAL DECISION RENDERED IN FRENCH; UNOFFICIAL ENGLISH TRANSLATION PREPARED BY FASKEN

COURT OF APPEAL

CANADA
PROVINCE OF QUÉBEC
REGISTRY OF MONTREAL

No.: 500-09-027238-179
(500-17-097879-178)

DATE: January 16, 2019

CORAM: THE HONOURABLE **FRANCE THIBAULT, J.C.A.**
JACQUES DUFRESNE, J.C.A.
MARK SCHRAGER, J.C.A.

JANSSEN INC.
APPELANT – Plaintiff
v.

MINISTER OF HEALTH AND SOCIAL SERVICES
ATTORNEY GENERAL OF QUÉBEC
RESPONDENTS – Defendants

DECISION

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[1] The Appellant appeals a judgment rendered on November 27, 2017 by the Superior Court, district of Montréal (the Honourable Brian Riordan), which dismisses its application for judicial review.

[2] For the reasons given by Justice Schrager, with which Justices Thibault and Dufresne concur, **THE COURT**:

[3] **ALLOWS** the appeal;

[4] **OVERTURNS** the judgment rendered on November 27, 2017 by the Honourable Brian Riordan of the Superior Court, district of Montréal;

[5] **SETS ASIDE** the decision of the Respondent, the Minister of Health and Social Services (the "Minister"), dated February 1, 2017 to end Remicade's coverage;

[6] **ORDERS** as a result that the Minister take the necessary actions to include Remicade on the List of medications established and updated by Regulation of the Minister, in accordance with the recommendations of the Institut national d'excellence en santé et en services sociaux pursuant to the *Act respecting Prescription Drug Insurance*;

[7] **THE WHOLE** with legal costs against the Respondents before both courts.

(s) Mark Schrager, authorized by F. Thibault
FRANCE THIBAULT, J.C.A.

(s) Jacques Dufresne
JACQUES DUFRESNE, J.C.A.

(s) Mark Schrager
MARK SCHRAGER, J.C.A.

M^{tre} Julie Desrosiers
M^{tre} Christian Leblanc
M^{tre} Patricia Hénault
FASKEN MARTINEAU DUMOULIN
For the Appellant

M^{tre} Éric Cantin
MINISTRY OF JUSTICE (DGAJLAJ)
BERNARD, ROY (JUSTICE-QUÉBEC)
For the Respondents

Hearing date: November 13, 2018

[8] The Appellant appeals a judgment rendered on November 27, 2017 by the Superior Court, district of Montréal (the Honourable Brian Riordan), which dismisses its application for judicial review.[1]

1- THE FACTS

[9] Janssen Inc. (the "**Appellant**") is a pharmaceutical company. It has developed and markets Remicade, an innovative biological drug which can be prescribed, for the treatment of arthritis, psoriasis and Crohn's disease, among other indications.

[10] Like traditional medications, innovative biological drugs can be "copied" upon the expiration of their patent. In such a case, the terms biosimilar drugs or subsequent entry biologics ("**SEBs**") are employed.

[11] In Québec, for the cost of a medication to be covered by the province's basic prescription drug insurance plan ("**BPDIP**"), the medication must be added to the List of medications (the "**List**")[2] established and updated by regulation of the Minister of Health and Social Services (the "**Respondent**"), following the recommendations of the Institut national d'excellence en santé et en services sociaux (the "**INESSS**").[3]

[12] When a generic or biosimilar drug is added to the List, it is usually sold at a cost inferior to that of the innovative drug. In such a case, regulation provides that the lowest price method applies; the cost of the innovative drug is reimbursed up to the list price of the generic or biosimilar drug.[4]

[13] The Minister may negotiate with the manufacturer of any medication added to the List a product listing agreement intended to permit payments by the manufacturer to the Minister, including by means of a rebate or discount. The amount of such payments is confidential and never appears on the List, which is otherwise public.[5]

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1 *Janssen inc. c. Ministre de la Santé et des Services sociaux,* 2017 QCCS 6280 [*Judgment rendered*].
2 *Act respecting prescription drug insurance,* CQLR , ch. A-29.01, sections 7, 8 and 60 [*APDI*].
3 Section 60 *APDI.*
4 *Regulation respecting the List of medications covered by the basic prescription drug insurance plan*, CQLR, ch. A-29.01, r. 3, Schedule 1: *List of medications*, last updated November 15, 2018, p. 4, par. 2.2 and 2.2.1 (official version published on the Régie de l'assurance maladie du Québec's website).
5 Sections 60 al. 7, 60.0.1 and 60.0.3 *APDI.*

[14] Since December 7, 2016, the Minister can also suspend or end the insurance coverage of a medication, including when such a listing agreement has been entered into for a competing medication.[6]

[15] Remicade is approved and has been sold in Canada since 2000. Until February 15, 2017, Remicade appeared on the List.

[16] Following the expiration of Remicade's patent, Inflectra, a biosimilar drug, is introduced on the market.

[17] On February 2, 2015, the INESSS recommends the addition of Inflectra to the List, and Inflectra is in fact added to the List the very same day. Reimbursement of Remicade is maintained according to the lowest price method.

[18] As of October 2015, the Appellant takes the necessary steps to negotiate a product listing agreement with the Minister with respect to Remicade. Between October 2015 and August 2016, the Appellant exchanges numerous emails and meets several times with various representatives of the Minister.

[19] In parallel, the Appellant also takes the same steps with the pan-Canadian Pharmaceutical Alliance (the "**pCPA**"), an organization bringing together Canadian provinces and whose objective is to jointly negotiate the price of certain medications. Québec joined this organization in September 2015. The Appellant presents the same offers to the Minister and to the pCPA.

[20] On August 11 and 29, 2016, the Appellant presents to the Minister two offers for a product listing agreement that would have yielded considerable savings to public finances. These offers remain unanswered. The prices offered yield significant savings, estimated at several million dollars according to the calculations submitted by the Appellant for the period ending December 31, 2017. The Respondent does not challenge these figures.

[21] On October 31, 2016, the pCPA informs the Appellant that it will not be engaging in negotiations for a product listing agreement with respect to Remicade. Thereafter, the Minister enters into a product listing agreement with the manufacturer of Inflectra.

[22] On February 1, 2017, the Minister publishes a notice of end of insurance coverage for Remicade (a "**Delisting Notice**"), which reads as follows:

> **End of insurance coverage of a medication**
>
> HAVING REGARD TO section 60.0.4 of the Act respecting prescription drug insurance (chapter A-29.01);

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[6] Section 60.0.4 *APDI*; Bill 92, *An Act to extend the powers of the Régie de l'assurance maladie du Québec, regulate commercial practices relating to prescription drugs and protect access to voluntary termination of pregnancy services*, 41st Leg (Qc), 1st Sess., 2016, sections 44 and 84.

> HAVING REGARD TO the power of the Minister to suspend the insurance coverage of a medication, to end it or to not re-list it, notably when a medication is the object of a listing agreement;
>
> HAVING REGARD TO the power of the Minister to maintain the insurance coverage of a medication as provided in paragraph 3 of section 60.0.4 of the Act respecting prescription drug insurance (chapter A-29.01);
>
> CONSIDERING that Inflectra™, a competitor of Remicade™, was the object of a product listing agreement in accordance with subparagraph 3 of paragraph 1 of section 60.0.4 of the Act respecting prescription drug insurance;
>
> The Minister of Health and Social Services hereby gives notice of the end of the insurance coverage of Remicade™ with respect to adult Crohn's disease, rhumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis, except as an exceptional medication prescribed under the Regulation respecting the List of medications covered by the basic prescription drug insurance plan that will come into force on 15 February 2017 and except with regard to the eligible persons having obtained this medication pursuant to section 6 of that regulation before the coming into force of that regulation.
>
> This Notice will come into force on 15 February 2017.
>
> Québec, February 1, 2017
>
> Original signed by: GAÉTAN BARETTE
> Minister of Health and Social Services

[23] This decision is made without any additional consultation with, or any prior notice to, the Appellant.

[24] In the following weeks, the Appellant files its application for judicial review, which is subsequently dismissed by the Superior Court.

2- JUDGMENT UNDER APPEAL

[25] On the standard of review that applies, the trial judge finds as follows:

> [TRANSLATION]
>
> [27] The appreciation of the standard of review that applies in this case may vary based on the issue analyzed. In any event though, as to whether the Decision is in compliance with the objectives of the APDI, there is general consensus between the parties. It is the standard of correctness that prevails, analyzed from the flexible eye that caselaw favours, as we will see below.

[26] Thereafter, the judge finds that the Minister's Decision is a regulatory act, as the Minister ends the coverage for a medication not by a Delisting Notice, but rather through

updating the List of medications, an act which, under section 60 of the *APDI*, is accomplished by regulation.[7]

[27] The trial judge concurs with the position of the Attorney General of Québec and, based on the Supreme Court decision in *Katz Group Canada Inc. v. Ontario (Health and Long-Term Care)*,[8] defines the normative framework for the judicial review of regulations: the inconsistency of the regulation with the purpose of the act.[9]

[28] In such context, the judge determines that the *APDI*'s objective is to provide the population of Québec with a drug insurance service at the lowest price possible. The Minister pursues this objective through the control and minimization of the costs charged to the government. The judge finds that the application of such a strategy through the pCPA, including through the implementation of a long-term strategy favouring the presence of SEBs on the market, complies with the objectives of the Act.[10]

[29] The trial judge then assesses the relevance of the considerations forming the basis of the decision emanating from the regulatory power, considerations which may also have an impact on the decision's compliance with the objectives of the Act.[11] On this point, the judge does not concur with the Appellant's position wishing to limit this analysis to the aspect of the negotiation of the medications' price. While it is true that the Minister's explanations on paragraph 60.0.4 (3) released at the time of the adoption of the legislative amendment did focus on such aspect, the text of the provision is quite clear with respect to the powers conferred upon the Minister. The judge concludes that this is not an egregious case justifying the declaration of the regulation as *ultra vires*.[12]

[30] The judge rejects the Appellant's claim that the refusal to negotiate with regards to Remicade constitutes a breach of procedural fairness, citing the five meetings held between the parties between October 2015 and August 2016, as well as the letter dated October 31, 2016 from the pCPA advising the Appellant, on behalf of all the provinces, that negotiations with respect to Remicade would not be pursued. The judge finds that the Minister did take into account the Appellant's legitimate expectations, but was not required to meet such expectations.

[31] Finally, and notwithstanding its qualification of the nature of the act and the applicable standard for review, the trial judge considers that the Minister's decision is in no way unreasonable and dismisses the application.[13]

3- QUESTIONS IN DISPUTE

[32] The Appellant submits the following questions:

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7 *Judgment rendered*, *supra*, note 1, par. 28-29.
8 *Katz Group Canada Inc. v. Ontario (Health and Long-Term Care)*, 2013 SCC 64, [2013] 3 SCR 810 [*Katz*].
9 *Judgment rendered, supra*, note 1, par. 30-32 and 50-51.
10 *Id.*, par. 52-58.
11 *Id.*, par. 51.
12 *Judgment rendered, supra*, note 1, par. 59-68.
13 *Id.*, par. 81-82.

1) Did the trial judge err in finding that the decision to remove a medication from the List is a decision of a regulatory nature rather than a decision of an administrative nature?

2) Did the trial judge err in not rendering a decision on one of Janssen's arguments, namely that, in his refusal to negotiate with the Appellant and to follow the pCPA, the Minister bound his decision in advance, made such decision under the influence of a third party, or delegated, contrary to applicable law, his decision-making authority to a third party?

3) Did the trial judge err in finding that the Minister complied with procedural fairness?

4) Did the trial judge err in finding that the Minister's decision was reasonable?

4- DISCUSSION

i) Introduction

[33] When the Court of Appeal sits in appeal of a decision rendered with respect to an application for judicial review, it must follow the analysis process set out by the Supreme Court of Canada in its decision *Agraira v. Canada (Public Safety and Emergency Preparedness*):[14]

> [45] [...] But, before I discuss the appropriate standard of review, it will be helpful to consider once more the interplay between (1) the appellate standards of correctness and palpable and overriding error and (2) the administrative law standards of correctness and reasonableness. These standards should not be confused with one another in an appeal to a court of appeal from a judgment of a superior court on an application for judicial review of an administrative decision. The proper approach to this issue was set out by the Federal Court of Appeal in *Telfer v. Canada Revenue Agency*, 2009 FCA 23, 386 N.R. 212, at para. 18:
>
> > Despite some earlier confusion, there is now ample authority for the proposition that, on an appeal from a decision disposing of an application for judicial review, the question for the appellate court to decide is simply whether the court below identified the appropriate standard of review and applied it correctly. The appellate court is not restricted to asking whether the first-level court committed a palpable and overriding error in its application of the appropriate standard.
>
> [46] In *Merck Frosst Canada Ltd. v. Canada (Health)*, 2012 SCC 3, [2012] 1 S.C.R. 23, at para. 247, Deschamps J. aptly described this process as "'step[ping] into the shoes' of the lower court" such that the "appellate court's focus is, in effect, on the administrative decision" (emphasis omitted).
>
> [47] The issue for our consideration can thus be summarized as follows: Did the application judge choose the correct standard of review and apply it properly?

[14] *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 SCR 559, par. 45-47.

[34] What differentiates the present case is the fact that the Appellant challenges the legal nature of the act taken by the Minister. The issues of procedural fairness and reasonableness of the decision both hinge on that qualification.

[35] Unlike the trial judge, I find that this act is of an administrative nature. Its qualification is subject, as the judge and the parties agree, to a test based on the standard of correctness. For the reasons that follow, I find that the judgment must be set aside and the decision overturned for considerations of procedural fairness.

ii) The legal nature of the act taken by the Minister

[36] The power of the Minister challenged in this case stems from the following section of the *Act respecting prescription drug insurance*:[15]

60.0.4. Le ministre peut suspendre la couverture d'assurance d'un médicament ou d'une fourniture d'un fabricant, y mettre fin ou ne pas réinscrire un médicament ou une fourniture de ce fabricant lors d'une mise à jour de la liste des médicaments, dans les cas suivants :	**60.0.4.** The Minister may suspend the insurance coverage of a manufacturer's medication or supply, end it or not re-enter a medication or a supply of that manufacturer on the list of medications when the list is updated in the following cases:
1° lorsque le fabricant ne respecte pas une des conditions ou un des engagements prévus par règlement du ministre, une disposition d'une entente d'inscription ou une disposition d'un contrat conclu à la suite d'un appel d'offres;	(1) if the manufacturer fails to comply with a condition or commitment prescribed by ministerial regulation, a provision of a listing agreement or a provision of a contract entered into following a call for tenders;
2° lorsque le prix de vente garanti par le fabricant pour un médicament est supérieur au montant maximum payable par le régime général;	(2) if the selling price guaranteed by the manufacturer for a medication is higher than the maximum amount payable by the basic plan;
3° lorsqu'un médicament ou une fourniture concurrent fait l'objet d'une entente d'inscription;	(3) if a competing medication or supply is the subject of a listing agreement;
4° lorsque l'Institut national d'excellence en santé et en services sociaux le lui recommande;	(4) if the Institut national d'excellence en santé et en services sociaux recommends doing so; or
5° lorsqu'il est d'avis que l'intérêt public l'exige.	(5) if the Minister considers that the public interest so requires.
Le ministre suspend la couverture d'assurance ou y met fin au moyen	The Minister suspends or ends the insurance coverage by publishing a

[15] *APDI, supra*, note 2.

d'un avis publié sur le site Internet de la Régie. La suspension ou la fin de la couverture d'assurance s'applique à la date de la publication de l'avis ou à toute date ultérieure que l'avis indique. Un avis y est également publié, le cas échéant, pour indiquer la date de la fin de la suspension. La publication de ces avis leur accorde une valeur authentique. Les avis ne sont pas soumis à l'obligation de publication ni au délai d'entrée en vigueur prévus aux articles 8, 15 et 17 de la Loi sur les règlements (chapitre R-18.1).	notice on the Board's website. The suspension or end of the insurance coverage applies on the date of publication of the notice or on any later date specified in the notice. Where applicable, a notice of the end date of the suspension is also published on the website. Publication imparts authentic value to such notices. The notices are not subject to the requirements concerning publication and date of coming into force set out in sections 8, 15 and 17 of the Regulations Act (chapter R-18.1).
Le ministre peut toutefois, dans un avis de suspension ou de fin de couverture ou lors d'une mise à jour de la liste, maintenir la couverture d'assurance d'un médicament ou d'une fourniture à l'égard des personnes en cours de traitement pharmacologique.	However, the Minister may, in a suspension or end-of-coverage notice or on an updating of the list, maintain the insurance coverage of a medication or supply for persons undergoing pharmacological treatment.
Un médicament pour lequel le ministre a émis un avis de suspension ou de fin de couverture d'assurance ou qui n'a pas été réinscrit à la liste des médicaments est exclu de l'application du sixième alinéa de l'article 60.	A medication for which the Minister has issued a suspension or end-of-coverage notice or which has not been re-entered on the list of medications is excluded from the application of the sixth paragraph of section 60.

[37] Paragraph 60.0.4 of the Act provides that the Minister's power to end the insurance coverage of a medication is exercised by the publication of a regulation. Indeed, the judge observes that, even when the Minister publishes the Delisting Notice on the Régie (de l'assurance maladie) website, it is in fact the regulation which gives effect to the decision to end the coverage of a given medication. Consequently, the trial judge finds that the power exercised by the Minister is of a regulatory nature.

[38] Section 1 of the *Regulations Act* defines the term "regulation" as follows:[16]

1. Dans la présente loi, on entend par :	**1.** In this Act,
[...]	(…)
«règlement» : un acte normatif, de caractère général et impersonnel, édicté en vertu d'une loi et qui, lorsqu'il est en vigueur, a force de loi.	"regulation" means a normative instrument of a general and impersonal nature, made under an Act and having force of law when it is in effect.

[39] Generally, the content and effect of a legislative instrument include the following elements: the instrument embodies a rule of conduct, the instrument has the force of law, and the instrument applies to an undetermined number of persons.[17] In such a context, the act will be legislative in nature where it establishes rules of conduct of a binding nature and modifies the legal order.[18] As Professor Garant explains:[19]

> [TRANSLATION]
>
> A regulation is a normative act to the extent that its role is to create legal rules of conduct, rather than solely individual decisions or decisions of a particular application. A regulation is different from such decisions, as its purpose is to create, essentially and permanently, legal rules of conduct and to establish a new legal order or modify it.

[40] A legal norm is said to be general and impersonal where it applies to an undetermined number of persons; this, however, does not mean a large number of persons. It rather means that the standard applies to [TRANSLATION] "a group of persons defined in abstract and generic terms".[20] Therefore, a regulation should not, in principle, apply specifically to individuals or individual situations.

[41] The registration of medications on the List is provided under section 60 of the Act, which states that "[t]he Minister shall draw up and update periodically [the List], by regulation, after considering the recommendations made by the Institut national d'excellence en santé et en services sociaux [INESSS]".[21]

[42] The INESSS determines the admissibility of the file submitted by the manufacturer. It first assesses the therapeutic value of a medication. Once the INESSS

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16 *Regulations Act*, CQLR, c. R-18.1.

17 *Sinclair v. Quebec (Attorney General)*, [1992] 1 SCR 579, p. 587 [*Sinclair*]. See also *Ruel c. Québec (Éducation),* J.E. 2001-2030, 2001 CanLII 27967, par. 46-51 (C.A.).

18 *Entreprises J.G.N. Michaud inc. c. Régie des alcools, des courses et des jeux*, 2013 QCCA 514, par. 21; *Baillargeon c. Québec (Office des personnes handicapées)*, J.E. 96-1750, 1996 CanLII 5791 (C.A.): [TRANSLATION] the instrument is not regulatory in nature since it does not change the existing legal order.

19 Patrice Garant, *Droit administratif*, 7th Ed., Cowansville, Yvon Blais, 2017, p. 270-271.

20 Pierre Issalys and Denis Lemieux, *L'action gouvernementale – Précis de droit des institutions administratives*, 3rd Ed., Cowansville, Yvon Blais, 2009, p. 518, cited in *Lac-Sergent (Ville de) c. Lapointe*, 2012 QCCA 1935, par. 68.

21 *APDI, supra*, note 2.

considers that the therapeutic value is indeed proven, it then evaluates the fairness of the price of the medication, its cost-efficiency ratio, the consequences of its listing on the various components of the health and social services system, and finally, the appropriateness of listing the medication in light of the plan's purpose. This process is subject to the requirements provided under the *Act respecting administrative justice*.[22]

[43] The List is updated "periodically", meaning that the Minister authorizes a certain number of updates each year, and sets a fixed calendar published on the INESSS website.[23]

[44] The INESSS then provides its recommendation to the Minister to add (or not) the medication to the List, as well as any terms applicable to such listing.[24] However, the *APDI* confers upon the Minister, within the limits of these two boundaries, discretionary authority as to the choice of the medications that may be added to the List.[25] By necessity, these decisions are made one by one, on a case-by-case basis, according to each medication in question. However, the wording of section 60 is unequivocal: the updating of the List is accomplished by the publication of a regulation.

[45] The Respondent submits that the exercise of the delegated statutory power is indivisible. The legislator cannot divide the legislative process into a number of discrete steps, and then claim that such process lacks a legislative character.[26] I do not agree on this point. Here, the very nature of each listing decision is administrative. We must distinguish the periodic update of the List by regulation from the Minister's individual decisions regarding the medications listed or removed from the List.[27]

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22 *Act respecting the Institut national d'excellence en santé et en services sociaux*, CQLR, c. 1-13.03, sections 5(8), 7 and 53 [*Act respecting INESSS*]. For illustration purposes, see the terms established by INESSS: INESSS, "Evaluation Process and Criteria" at inesss.qc.ca, June 2017, online: https://www.inesss.qc.ca/index.php?id=39 (page consulted on November 26, 2018).

23 INESSS, "List Update Schedule in 2018" online at: https://www.inesss.qc.ca/en/themes/medicaments/drug-products/manufacturer-information-centre/list-update-schedule-in-2018.html (page consulted on November 26, 2018). Certain decisions note the "periodic" and non-continuous nature of the updates: *Apotex inc. c. Québec (Procureur général) (Ministre de la Santé et des Services sociaux)*, 2012 QCCS 1742, par. 9 and 21; *Genpharm Inc. c. Legault*, J.E. 2003-1398, 2003 CanLII 47975, par. 16 (C.A.).

24 *Act respecting INESSS*, *supra*, note 22, section 5(8); Institut national d'excellence en santé et en services sociaux, *Evaluation of drugs for listing purposes – A change of approach*, July 2018, p. 21-23.

25 *Nu-pharm inc. c. Québec (Ministre de la santé et des services sociaux)*, J.E. 2000-1857, 2000 CanLII 10218, par. 40 (C.A.) *[Nu-pharm]*.

26 *Sinclair, supra*, note 17 p. 589.

27 See a similar reasoning from the Ontario Court of Appeal in *Ontario (Minister of Health) v. Apotex Inc.*, 60 OR (3d) 209, 2002 CanLII 42002 (ON CA), par. 35.

[46] This interpretation of the process can be found in the wording of the statute. For instance, section 60.0.1 states that:

60.0.1. Le ministre peut, avant d'inscrire un médicament à la liste des médicaments, conclure une entente d'inscription avec le fabricant de ce médicament. Une telle entente a pour objet le versement de sommes par le fabricant au ministre au moyen notamment d'une ristourne ou d'un rabais qui peut varier en fonction du volume de vente du médicament.	**60.0.1.** The Minister may, before entering a medication on the list of medications, make a listing agreement with its manufacturer. The purpose of such an agreement is to provide for the payment of sums by the manufacturer to the Minister in particular by means of a rebate or discount which may vary according to the volume of sales of the medication.
Le prix du médicament indiqué sur la liste ne tient pas compte des sommes versées en application de l'entente d'inscription.	The price of the medication indicated on the list does not take into account the sums paid pursuant to the listing agreement.

The entering of an agreement is the result of one or more administrative acts which may influence the preparation of the List (regulatory act).

[47] Paragraph 60.0.0.1 of the *APDI* provides for the possibility of a call for tenders by the Minister to identify a supplier for a given medication and to establish the prices and listing conditions. This is an individual act which ultimately affects the determination of the contents of the List.

[48] The *APDI* also provides that the Régie de l'assurance maladie is entitled to make changes to the List without following the regulatory process in cases where it authorizes the substitution of a medication which is out of stock (section 60.1 of the *APDI*), and where it updates the information relating to a medication (price drop, change of therapeutic class) or to the manufacturer (change of manufacturer), or where it corrects a manifest clerical error or any other error of form (section 60.2 of the *APDI*). Therefore, not every change made to the List can be considered to be the result of a regulatory power.

[49] Foremost, the acts provided in section 60.0.4 of the *APDI* do not meet the requirement of general and impersonal provisions. Paragraphs 60.0.4 (1) and (2) of the *APDI* confer upon the Minister a power to sanction, to be exercised from time to time and on a case-by-case basis. This qualification is determined by the nature of the power; these are acts specific to the application of a statute rather than the creation of a rule of law.

[50] We do not have before us a regulation which, despite its general wording and normative terms, applies only to one person due to factual circumstances. Such a regulation will be valid as long as it is not adopted in bad faith or with a discriminatory

intent.[28] In this case, the List (or the regulation) targets, by its definition, a series of particular cases.

[51] A parallel can be drawn with the administrative power of the Minister provided under sections 63 and 65 of the *APDI* to withdraw the accreditation of a drug manufacturer who fails to comply with the agreed upon conditions or commitments. Such a decision entails the exclusion from the BPDIP of all the medications produced by such manufacturer.[29] In such a case, the decision is made following an inquiry by the Régie and may be contested before the Administrative Tribunal of Québec.[30] Considering the significant consequences such a situation entails for the manufacturer, the latter also has the opportunity to participate in the inquiry[31] and to present its observations to the Minister prior to the decision being made.[32] The Minister's decision shall only take effect once the period for bringing a proceeding has expired.[33] The decision will be reflected in the next update of the List.[34] Once again, the elements of the decision are administrative acts, despite the List being published and embedded in a regulation.

[52] Paragraph 3 of section 60.0.4 is the case at hand. The delisting decision mentioned finds its source in another individual decision, namely to decision to enter into a product listing agreement with a competitor of Remicade. The comments regarding paragraphs 1 and 2 of section 60.0.4 apply in this instance. These are individual acts, rather than the application of a general and normative rule.

[53] With due respect for the trial judge, these individualized effects undeniably lead to the conclusion that the delisting of Remicade by the Minister was indeed an act that is administrative rather than regulatory in nature.

iii) Did the Minister bind his decision in advance?

[54] The Appellant considers that the Minister has bound his decision to the pCPA's position and therefore did not exercise his discretionary power. The Appellant claims that the trial judge has erred in not deciding on this matter, which constitutes a determining error, as it would have been sufficient to decide on the case.

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28 *Phaneuf c. Corporation du Village de St-Hugues*, (1936) 61 B.R. 83; *Sillery (Cité) c. Canadian Petrofina Ltd.*, [1968] B.R. 854 (C.A.), confirmed in *Canadian Petrofina Ltd. v. City of Sillery*, [1970] SCR 533; *Montréal v. Arcade Amusements Inc.*, [1985] 1 SCR 368; *Bertrand c. Charny (Ville)*, J.E. 97-740, 1997 CanLII 10427 (C.A.) : [TRANSLATION] "it is possible for a norm of general application to apply to only one person. In such a case, the criteria to examine is no longer the distinction created by the regulation, but the good faith of the Administration"; *Veilleux c. Pièces d'autos Roch Drouin inc.*, J.E. 99-921, 1999 CanLII 13805 (C.A.); *Ste-Anne-de-Bellevue (Ville) c. Papachronis*, J.E. 2000-1490, 2000 CanLII 29960 (C.A.).

29 Sections 60 al. 2, 63 al. 1-2 and 65 *APDI*

30 Sections 63, 65 and 68 *APDI*

31 *Novopharm Ltd. c. Rochon, ès qualités Ministre de la Santé et des Services sociaux*, J.E. 98-2158, 1998 CanLII 11249, par. 35-53 (S.C.).

32 Section 67 *APDI*

33 Sections 69-70 *APDI*

34 Section 63 al. 2 *APDI*

[55] The Appellant claims that the Minister, in the case at hand, has simply failed to exercise his discretionary power, as he gave precedence to the pCPA when he made his decision under the *APDI*. The Appellant notes that the Minister's representative asserted in his sworn statement that he could no longer negotiate with the Appellant due to the fact that the province of Québec had joined the pCPA. He also told the Appellant on numerous occasions that the Minister would follow the pCPA's decision.

[56] Administrative law generally requires a statutory power to be exercised by the very person upon whom it has been conferred.[35] It is therefore necessary for there to be some limit on the extent to which the exercise of such discretionary power can be bound, even "fettered",[36] by the adoption of an inflexible policy, by a directive, or by other means. The existence of discretion implies the absence of a rule dictating the result in each case; the essence of discretion is that it can be exercised differently in different cases.[37] Each case must therefore be looked at individually, on its own merits. Anything which requires that the Minister exercise his discretion in a particular way may illegally limit the ambit of its power. The conclusion that a decision results from a case of fettering on the decision maker's discretionary power necessarily entails the conclusion that the decision is unreasonable.[38]

[57] However, the Minister may adopt a general policy guiding him in the exercise of his discretionary power. Any decision maker faced with a large volume of discretionary decisions – as is the case in the situation before us, where the Minister must manage the coverage under the BPDIP – will necessarily adopt such a policy. This practice is legally acceptable, as long as each case is still assessed individually on its own merits.[39]

[58] According to section 60.0.1 of the *APDI*, the Minister may negotiate a product listing agreement with a drug manufacturer. The Minister may also withdraw insurance coverage for a medication appearing on the List by virtue of section 60.0.4 of the *APDI*. No provision of the Act imposes or prescribes a specific way for the Minister to negotiate with pharmaceutical manufacturers. Similarly, the Minister may refer to a policy adopted by another administrative entity when deciding to exercise his own discretion.[40]

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35 *The Queen v. Harrison*, [1977] 1 SCR 238, p. 245-246; reiterated in *Comeau's Sea Foods Ltd. v. Canada (Minister of Fisheries and Oceans)*, [1997] 1 SCR 12, par. 28; *Québec (Procureur général) v. Loyola High School*, 2012 QCCA 2139, par. 107.

36 Jones de Villars, *Principles of Administrative Law*, 6th Ed., Toronto, Carswell, 2014, p. 206.

37 *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817, par. 52 [*Baker*].

38 *Alberta (Director of Assured Income for the Severely Handicapped) v. Januario*, 2013 ABQB 677, par. 35-37; *Stemijon Investments Ltd. v. Canada (Attorney General)*, 2011 FCA 299, par. 22, 24 and 59-60; *Québec (Procureur général) c. Atocas de l'érable inc.*, 2013 QCCA 1794, par. 78-79; *Québec (Procureur général) c. Germain Blanchard Ltée*, 2005 QCCA 605, par. 84.

39 *Maple Lodge Farms v. Government of Canada*, [1982] 2 SCR 2, p. 6-7; *Nu-pharm*, *supra*, note 25, par. 42, 55-56.

40 *Innisfil Township v. Vespra Township*, [1981] 2 SCR 145, p. 160, 173, 175 and 176 [*Innisfil*]; Pierre Issalys and Denis Lemieux, *L'action gouvernementale – Précis de droit des institutions administratives*, 3rd Ed., Cowansville, Yvon Blais, 2009, p. 222; Jones de Villars, *Principles of Administrative Law*, 6th Ed., Toronto, Carswell, 2014, p. 208.

[59] Whether the policy on which the Minister relies to justify the exercise of his discretionary power is internal or emanates from another administrative entity, it must be relevant to the purpose for which the discretion was granted under the enabling statute. Failing that, the exercise of the power delegated shall be deemed invalid.[41]

[60] The *APDI*'s purpose is to ensure that all persons have "a reasonable and fair access to the medication required by their state of health".[42] In the pursuit of this objective, "[a] policy respecting medications shall be drawn up by the Minister […] in particular by means of [the BPDIP], and, subject to the availability of financial resources".[43] In doing so, the Minister strives to achieve "the implementation of effective and efficient strategies and actions".[44] As the trial judge notes, the legislator provides the Minister with the tools necessary to [TRANSLATION] "ensure the control and minimization of the costs charged to the government for the medications in question".[45] The power to negotiate product listing agreements and the power to end coverage for a medication registered on the List are two examples of such tools.

[61] With this in mind, in September 2015 the province of Québec joined the pCPA, which collectively negotiates the price of certain drugs. The Appellant is aware of this.

[62] By their very nature, biological drugs are sold at prices higher than those of traditional drugs. The pCPA is currently engaged in a reflection on these products and the means to encourage competition and the introduction of SEBs on the market. As the trial judge observes, this position is in line with the province of Québec's concerns, which gave itself new powers under section 60.0.4 of the *APDI* in order to, among other things, achieve such objective.[46]

[63] The Appellant argues that the Minister bound his negotiations with the Appellant, as well as his decision to delist Remicade, to the process and decision of the pCPA. I do not agree on this point.

[64] While it is perfectly legitimate to negotiate the prices of medications through a concerted action to ensure the long-term efficiency of policies relating to sectors impacting several jurisdictions, such as the universal Canadian health insurance plan, the Minister nevertheless maintains jurisdiction. The Minister will not be deemed to be exercising his discretionary power under the influence of a third party unless he deems himself bound to follow an opinion, a recommendation or a decision having no normative value under the law.[47]

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41 *Innisfil*, *supra*, note 40; Pierre Issalys and Denis Lemieux, *L'action gouvernementale – Précis de droit des institutions administratives*, *supra*, note 40, 2009, p. 108; Jones de Villars, *Principles of Administrative Law*, *supra*, note 40, p. 210-211.

42 Section 2 al. 1 *APDI.*

43 Section 51 *APDI.*

44 *Ibid.*

45 *Judgment rendered, supra*, note 1, par. 53.

46 *Judgment rendered, supra*, note 1, par. 58.

47 Pierre Issalys and Denis Lemieux, *L'action gouvernementale – Précis de droit des institutions administratives*, *supra*, note 40, p. 123-124, 128 and 245-246.

[65] On April 1, 2016, the pCPA publishes a negotiation policy relating to SEBs and biological drugs providing that any negotiation undertaken for such medications will be examined solely by the pCPA: “Determination of whether or not to proceed with negotiations with the requesting manufacturer will be made at the discretion of the pCPA”. The Minister seems to be following this directive rigorously.

[66] On August 11, 2016, the Appellant submits to the Minister the offer it intends to present to the pCPA. The Minister’s representative indicates at that time that he is not in a position to negotiate directly with the Appellant, as a parallel action is underway with the pCPA. The representative confirms, in his sworn statement, that [TRANSLATION] “from the moment when the pCPA refused, in [its] decision of October 31, 2016, to negotiate an agreement with [the Appellant for Remicade], the Minister could no longer negotiate directly with [the Appellant]”. At the discovery stage, he explains that, following the negotiation and joint entering of a letter of intent between a manufacturer and the pCPA, it is up to each province to implement internally the conditions negotiated therein. [TRANSLATION] “[However] there is no second round of negotiations. We [the provinces] must adapt the whole in light of each province’s own reality. But the negotiation is carried out at the level of the letter of intent.”

[67] The Minister’s representative also confirms at the discovery stage that the Appellant’s offers were in fact assessed by the Minister [TRANSLATION] “in the global dynamic of the issue of biosimilars, and not in isolation.” He specifies:

> [TRANSLATION]
>
> A Well, we’ve seen it, the proposal, but it did not align with the objectives in terms of the position of the pan-Canadian Alliance, which Québec is part of [...]

[68] It appears from the foregoing that the Minister exercised his negotiation power through the pCPA. It also appears from the file that the Appellant nevertheless met with various Minister representatives individually, in order to present its detailed offers, and that the Minister had in fact all of the information required to make a decision with respect to the product listing agreement sought by the Appellant.

[69] The trial judge describes in the evidence five meetings held between the ministry’s representatives and the Appellant between October 2015 and August 2016. The Appellant’s representatives were given, during those meetings, the opportunity to present and explain two product listing agreement offers with respect to Remicade. The judge notes that the offer presented on August 29, 2016 is identical to that presented to the pCPA. The latter informed the Appellant by letter dated October 31, 2016, on behalf of all of the provinces, that it would not continue negotiations with respect to Remicade, and included its reasons for deciding so. In addition, the Appellant was informed by the pCPA that if one of the provinces were interested in pursuing negotiations for Remicade, the file would come back to the pCPA. Below is the text as quoted by the judge:

Dear Mr. Halyk:

Thank you for submitting the unsolicited proposal for Remicade dated August 12th, 2016. The proposal has now been reviewed by all pCPA (APP) jurisdictions. The pCPA Office has collated feedback from the jurisdictions and would like to notify you, on behalf of the pCPA, that the pCPA will not be engaging Janssen in negotiations for Remicade at this time. For clarity, this is the consensus decision of all pCPA jurisdictions.

We would like to share some of the feedback received on your proposal for your information:

● pCPA noted the proposal was contingent on certain components (mainly securing first-line listing status).

● The proposal does not align with pCPA's Subsequent Entry Biologies (SEBs) (PBU) First Principles regarding transparent price reductions.

● pCPA is interested in pursuing additional cost effective product options in this therapeutic space.

● pCPA understands that the motivation behind the submitted proposal and willingness for Janssen to now offer value is due to the introduction of competition from a SEB. In order to promote an environment that supports optimizing value on drug expenditures, the pCPA remains committed to encouraging a competitive environment that includes SEB market growth as communicated in the SEBs First Principles.

● According to PMPRB's Market intelligence Report, Canada has been paying a very high price for Remicade. Remicade accounted for nearly 40% of the Canadian market for biologic DMARDs and has been priced close to 50% more per patient than the class average. The market share for Remicade was much lower in the PMPRB7 countries, ranging from 12% to 23% in 2015, with a median list price 25% less than in Canada. This price difference translates into $224 million in drug sales or 1.0% of the entire Canadian pharmaceutical market.

In view of this, the pCPA is not interested at this time in engaging Janssen in negotiations for Remicade. For clarity, this decision means that the jurisdictions will keep the current individual product listing agreements (PLA) for Remicade in their respective jurisdictions at this time.

In accordance with the current process, should any jurisdiction wish to re-consider negotiation for Remicade in the future, the file will come back to the pCPA table for further discussion through the pCPA Office. The manufacturer is kindly requested to communicate with the pCPA Office directly and not approach individual jurisdictions - if Janssen Inc. is later able to submit an offer that can provide the value required by participating jurisdictions.

If you have any questions or wish to discuss this matter, please contact myself or [...] (416) [...]; email: [...]@ontario.ca.

(Emphasis added)

[70] The judge finds that the pCPA's letter is clear and comprehensive. As indicated, the fact that the Appellant refuses to accept that the pCPA speaks for Québec does not change the fact that the Appellant was heard directly by the ministry and its agent, the pCPA.

[71] A too-stringent application of the principle that such decision is invalid could fetter the accomplishment, by the Minister, of his mandate stemming from the *APDI*. The alignment of the Minister with the pCPA's position is aimed at achieving, in the long term, a more efficient and productive negotiation process between the provinces and the manufacturers, that have in this relationship the balance of power.[48] The *APDI* grants discretion, but does not determine the way in which the Minister is to negotiate with manufacturers in the exercise of such discretion.

[72] The structure put in place by the ministry stems from the Minister's decision to take part in a process allowing him to exercise his discretionary power in a way to achieve the objectives of the Act. More specifically, the Minister decided to contribute his negotiation power to that of an alliance backed by the purchasing power of all of the Canadian provinces brought together. What is more, considering the method of participating in the negotiation process commenced by the pCPA and described above, we are far from a situation where the Minister has abdicated a decision-making power. Particularly, and with all due respect, the Appellant's position leads to the absurd conclusion that such an arrangement would be impossible without a specific legislative amendment authorizing a province to join such an alliance. Such a result is contrary to one of the Act's ultimate purpose, namely the securing of attractive prices for the Québec population. Adhering to a collective negotiation process is far from renouncing a decision-making power. On the contrary, it is a sensible way of exercising such power.

[73] The final decision to end insurance coverage for Remicade, once negotiations through the pCPA were concluded, presents similar considerations.

[74] With a view to favouring healthy competition and reducing the cost pressures on the BPDIP, Québec's orientation with respect to SEBs is similar to that of the pCPA: [TRANSLATION] "[in] terms of public finances, it is important to encourage the introduction on the market of SEBs in preference to brand-name biologics". This concern of the Québec authorities is also clear from the INESSS' notices of recommendation for Inflectra, which suggest to limit in time the application of the lowest price method for the reimbursement of Remicade.

[75] With the adoption of section 60.0.4 of the *APDI* on December 7, 2016, the Minister gave himself the tools necessary to implement that orientation. He can therefore prefer providing insurance coverage to SEBs over the branded products, thus favouring their entry on the market by the implementation of a reimbursement plan that emphasizes their use. In accordance with the *APDI*'s purpose, this possibility is in alignment with the Minister's efforts to control the costs of medication and ensure the sustainability of the BPDIP.

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[48] Pierre Issalys and Denis Lemieux, *L'action gouvernementale – Précis de droit des institutions administratives, supra*, note 40, p. 226.

[76] Although the representative of the Minister confirms that the decision taken "[TRANSLATION] is a result of the application of pCPA's global biosimilar policy", the Appellant has not convinced me that the Minister applied this orientation in an inflexible manner or that such orientation has dictated the exercise of his discretion, nor that the decision was subject to the dictates of the pCPA. As indicated by the Respondent, the Minister had on hand all useful information for his decision, which decision, we must say, falls within the exercise of a discretionary power under the larger notion of public interest.

[77] Once again, the position of the Appellant results in an impass where the Minister would be barred from participating in a cooperative intergovernmental program to better attain the objectives of a law that he is mandated to apply.

Procedural fairness

[78] Although I am not of the opinion that the Minister bound his decision to that of the pCPA, I am of the opinion that, in the circumstances, the decision to delist Remicade was taken without complying with procedural fairness. Here is my explanation.

[79] Classically, "the duty to act fairly has two components: the right to be heard (the *audi alteram partem* rule) and the right to an impartial hearing (the *nemo judex in sua causa* rule)".[49] The nature and extent of the duty may vary with the specific context. The Supreme Court identifies five factors to take into consideration when determining the applicable degree of protection:[50]

> 5. The content of the duty of fairness on a public body varies according to five factors: (1) the nature of the decision and the decision-making process employed by the public organ; (2) the nature of the statutory scheme and the precise statutory provisions pursuant to which the public body operates; (3) the importance of the decision to the individuals affected; (4) the legitimate expectations of the party challenging the decision; and (5) the nature of the deference accorded to the body: [...]

[80] The power to delist a medication is an important tool afforded to the Minister in the pursuit of a reasonable and fair access to medication for the Quebec population. It stems from a global perspective aimed at reducing the cost pressures on the BPDIP. The Minister and his advisors' expertise and his elevated position in the decision-making hierarchy to which power is granted by the *APDI* favour increased restraint when facing the decision of delisting a medication.[51]

[81] Considering the above, I consider that the procedural fairness principles relevant to the situation required a minimal degree of fairness: giving sufficient notice to the

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[49] *Therrien (Re)*, 2001 SCC 35, [2001] 2 SCR 3, par. 82 [*Therrien*].

[50] *Therrien*, *supra*, note 49, par. 82 mentionning *Baker*, *supra*, note 37, par. 23-28; *Congrégation des témoins de Jéhovah de St-Jérôme-Lafontaine v. Lafontaine (Village)*, 2004 SCC 48, [2004] 2 SCR 650, par. 5, [*Congrégation*].

[51] *Mount Sinai Hospital Center v. Québec (Minister of Health and Social Services)*, 2001 SCC 41, [2001] 2 SCR 281, par. 58 [*Mount Sinai*].

Appellant that such a decision will be taken; provide the Appellant with the possibility of presenting its observations relevant to the decision; and finally, justify the decision taken.[52]

[82] The adequacy of the reasons is evaluated in the particular context, taking into account both what is expressed and what is implied:[53]

> Reasons are not to be reviewed in a vacuum – the result is to be looked at in the context of the evidence, the parties' submissions and the process. Reasons do not have to be perfect. They do not have to be comprehensive.

Therefore, the inadequacy of the reasons does not, in and of itself, allow the quashing of a decision.[54]

[83] Let's look at the context of the Minister's decision. Except for the reference to section 60.0.4 (3) of the *APDI* and the agreement entered into for Inflectra, no reason was given in the Delisting Notice published on February 1, 2017. According to the Respondent's attorney, relying on the sworn statement of the representative of the Minister, the decision to delist Remicade was based on a long-term savings decision, to favour SEBs that, according to the Minister, have only managed to penetrate the market marginally in the year since their entry. These reasons were not communicated to the Appellant – the Minister's notice makes no mention of them.

[84] On October 31, 2016, the pCPA advised that although the negotiations with the Appellant were completed, its agreements with all the jurisdictions (including Québec) remain in place. The parties had five meetings between October 2015 and August 2016 and the last unit price offered by the Appellant to the Minister would have yielded considerable savings to public finances. In such circumstances, elementary procedural fairness required a notice, or else, the calling of a meeting with the Minister to disclose the reasons for the delisting, and giving the Appellant the possibility of answering.

[85] A court of law sitting in review is not in a good position to evaluate the reasonableness of the Minister's decision to delist.[55] However, considering that last communication from the pCPA, the negotiations over several months and the policy of refunding the lowest price, a prior notice and the possibility of being heard would have

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[52] *Imperial Oil Ltd. v. Quebec (Minister of the Environment)*, 2003 SCC 58, [2003] 2 SCR 624, par. 38; *Congrégation*, *supra*, note 50, par. 5; *Mount Sinai*, *supra*, note 51, par. 58; *Baker*, *supra*, note 37, par. 18-28.

[53] *Newfoundland and Labrador Nurses' Union v. Newfoundland and Labrador (Treasury Board)*, 2011 SCC 62, [2011] 3 SCR 708, par. 18 [*Newfoundland and Labrador Nurses' Union*], citing *Public Service Alliance of Canada v. Canada Post Corp.*, 2010 FCA 56 (confirmed in *Public Service Alliance of Canada v. Canada Post Corp.*, 2011 SCC 57, [2011] 3 SCR 572).

[54] *Newfoundland and Labrador Nurses' Union*, *supra*, note 53, par. 14.

[55] *Cardinal c. Québec (Ministre de la Santé et des Services sociaux)*, 2014 QCCA 2275, par. 6; *Montréal (Ville de) c. Montréal-Ouest (Ville de)*, 2009 QCCA 2172, par. 40; *Montréal (City) v. Montreal Port Authority*, 2010 SCC 14, [2010] 1 SCR 427, par. 37 "The decisions challenged by the appellant relate to the management of federal Crown property. They involve acts of administration in respect of which the courts should, as a general rule, remain deferential. I readily acknowledge that it is not the role of judges to manage Crown property."; *Bellefleur c. Québec (Procureur général)*, J.E. 93-1569, 1993 CanLII 4067 (C.A.), p. 107-109.

been appropriate as regards the principle of procedural fairness. This omission justifies, in this case, overturning the decision of the Minister.

[86] As a result of this conclusion, it is not necessary to examine the last argument raised, namely the reasonableness of the decision.

[87] For all of these reasons, I propose that the appeal be granted, overturning the judgment of the Superior Court, setting aside the decision of the Respondent to cease coverage of Remicade and ordering the Minister to take the necessary measures as a result and, more particularly, as regards the inclusion of Remicade on the List, the whole with legal costs, before both courts.

(signed) Mark Schrager, J.C.A.

MARK SCHRAGER, J.C.A.