Federal Court of Appeal | Cour d'appel fédérale

Date: 20210712

Docket: A-252-20

Citation: 2021 FCA 137

CORAM: **STRATAS J.A**
RENNIE J.A.
MACTAVISH J.A.

BETWEEN:

JANSSEN INC.

Appellant

and

ATTORNEY GENERAL OF CANADA
(MINISTER OF HEALTH)

Respondent

Heard by online video conference hosted by the Registry on June 15, 2021.

Judgment delivered at Ottawa, Ontario, on July 12, 2021.

PUBLIC REASONS FOR JUDGMENT BY: MACTAVISH J.A.

CONCURRED IN BY: STRATAS J.A.
RENNIE J.A.

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PUBLIC REASONS FOR JUDGMENT

This is a public version of confidential reasons for judgment issued to the parties. The two are identical, there being no confidential information disclosed in the confidential reasons.

MACTAVISH J.A.

[1] The Minister of Health refused to grant data protection for Janssen Inc.'s SPRAVATO drug on the basis that it was not an "innovative drug" eligible for such protection. This was because SPRAVATO's medicinal ingredient was a variant of a medicinal ingredient in a drug that had been previously approved by the Minister.

[2] The Minister based her decision, in part, on this Court's interpretation of the relevant regulation in *Takeda Canada Inc. v. Canada (Health)*, 2013 FCA 13, [2014] 3 F.C.R. 70 *[Takeda]*. There, this Court held that salts, esters, enantiomers, solvates and polymorphs of previously approved medicinal ingredients are variations of those ingredients and, as such, do not fall within the definition of "innovative drug" for the purpose of the governing regulation. The Minister's decision in the present case was upheld by the Federal Court in a decision reported as 2020 FC 904.

[3] Janssen asks us to revisit *Takeda*, and to come to a different conclusion with respect to proper the interpretation of the regulation in issue. However, Janssen has not shown that the circumstances of this case would justify reconsideration of this Court's decision in *Takeda.* Nor has Janssen shown that new evidence should be admitted on this appeal, or that the Federal Court erred in its application of the reasonableness standard of review to the remainder of the issues raised by Janssen. Consequently, I would dismiss the appeal.

I. The Regulations in Issue

[4] Canada's data protection obligations arose out of its commitments under the *North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 289 (entered into force 1 January 1994) [*NAFTA*], the *Canada-European Union Comprehensive Economic and Trade Agreement*, 30 October 2016 (entered into force provisionally 21 September 2017) and the *Agreement on Trade-Related Aspects of Intellectual*

Property Rights, 15 April 1994, 1869 U.N.T.S. 299 (entered into force 1 January 1995 [*TRIPS*], [collectively "the Agreements"].

[5] After the Minister rendered the decision in issue in this appeal, *NAFTA* was replaced by the *Canada-United States-Mexico Agreement*, 30 November 2018, Can T.S. 2020 No. 5 (entered into force 1 July 2020) [*CUSMA*]. The significance of this development will be discussed later in these reasons.

[6] The Agreements required that signatories protect data provided to governmental authorities by innovative drug manufacturers to establish the safety and efficacy of drugs containing new chemical entities where the origination of that data required considerable effort. The treaties do not define the phrase "new chemical entity".

[7] Canada's data protection regime is contained in the *Food and Drug Regulations*, C.R.C., c. 870, as amended by the *Regulations Amending the Food and Drug Regulations (Data Protection)*, S.O.R./2006-241 [Data Protection Regulations]. The Data Protection Regulations state that data protection will be provided to "innovative drugs". "Innovative drug" is defined in subsection C.08.004.1(1) of the Data Protection Regulations as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph".

[8] The Data Protection Regulations protect manufacturers of innovative drugs who submit undisclosed data in support of applications for approval from unfair commercial use of their clinical data by others (such as manufacturers of generic drugs) for a specified period of time: *Takeda*, above at para. 6. Under the Data Protection Regulations, an "innovative drug" is entitled to eight years of data protection, with an additional six months being granted if the drug has been the subject of clinical trials involving the pediatric population.

[9] Prior to the enactment of the Data Protection Regulations, one of the impediments to the ability of generic drug manufacturers to obtain the approvals necessary to market generic drugs was the existence of unexpired patents. Since the enactment of the Data Protection Regulations, generic drug manufacturers cannot obtain approval for their generic drugs until the period of market exclusivity of the innovative drug expires, even where there is no patent protection for that drug: *Takeda*, above at para. 7.

II. The Decisions in *Takeda*

[10] As noted earlier, subsection C.08.004.1(1) of the Data Protection Regulations was interpreted by this Court in *Takeda*. In order to situate the issues raised by Janssen in this appeal, it is therefore first necessary to have an understanding of the *Takeda* decision.

(a) The Minister's Decision

[11] In *Takeda*, the Minister of Health refused to list a drug called DEXILANT, used in the treatment of gastroesophageal reflux disease, on the Register of Innovative Drugs, and to provide data protection to Takeda under section C.08.004.1 of the Data Protection Regulations. The Minister granted regulatory approval for DEXILANT, but rejected Takeda's request for data protection on the basis that DEXILANT was not an "innovative drug". The Minister came to this conclusion because the medicinal ingredient in DEXILANT was an enantiomer of a medicinal ingredient that had been previously approved by the Minister, and was thus a variation of a previously approved medicinal ingredient.

(b) The Federal Court's Decision

[12] Takeda sought judicial review of the Minister's decision in the Federal Court, focusing its submissions on the meaning of the word "variation" in the definition of "innovative drug". Takeda argued that the five categories of substances listed in the subsection—namely salts, esters, enantiomers, solvates and polymorphs—were only examples of what might be considered "variations" of medicinal ingredients.

[13] Reviewing the Minister's interpretation of subsection C.08.004.1(1) on the correctness standard, the Federal Court dismissed Takeda's application, substantially agreeing with the Minister's interpretation of the subsection.

(c) This Court's Decision

[14] The Minister argued in this Court that, based on a literal reading of subsection C.08.004.1(1), the five categories of substances listed therein (i.e. salts, esters, enantiomers, solvates and polymorphs), cannot qualify as "innovative drugs", and thus cannot benefit from data protection.

[15] In contrast, Takeda submitted that the words "variation ... such as a[n]...enantiomer" did not mean that all enantiomers are "variations", and that a contextual and purposive interpretation of the term "variation" should be adopted. Takeda was of the view that subsection C.08.004.1(1) protects clinical and pre-clinical data necessary for regulatory approval, if generating that data required "considerable effort".

[16] Takeda's appeal to this Court was dismissed by a majority of this Court.

(i) The Majority Decision

[17] Applying the correctness standard of review, Justices Pelletier and Dawson held that the Governor in Council, in the exercise of its discretion, had determined that salts, esters, enantiomers, solvates and polymorphs of previously approved medicinal ingredients are variations of those ingredients, and, as such, do not fall within the definition of "innovative drug". Reading the definition in its ordinary, grammatical sense, an "innovative drug" is one that

contains a medicinal ingredient not previously approved by the Minister and is not a variation of a previously approved medicinal ingredient: *Takeda,* above at paras. 119-123.

[18] Citing the Regulatory Impact Analysis Statement that accompanied the Data Protection Regulations, the majority observed that proponents for the innovative drug industry had requested that the scope of data protection be expanded to include product variations that have different safety and efficacy profiles from the original product, such as metabolites, enantiomers, salts and esters. This request had, however, been rejected. The Governor in Council focused instead on whether data protection should be extended to enantiomers and the like, concluding that it should not. According to the majority, this was a choice on the part of the Governor in Council that had to be respected: *Takeda*, above at paras. 127-128.

[19] The majority further held that the Governor in Council would have created an incoherent scheme if the enumerated examples of variations were, in some unarticulated circumstances, not considered variations of approved medicinal ingredients. It was open to the Governor in Council to decide, as a matter of policy, that salts, esters, enantiomers, solvates and polymorphs were not sufficiently different so as to be considered "new chemical entities", and it was a matter for the Governor in Council to remedy if the Data Protection Regulations were under inclusive.

(ii) The Dissent

[20] In his dissenting judgment, Justice Stratas concluded that Takeda's interpretation of subsection C.08.004.1(1) was to be preferred. He found that the Minister's interpretation of the

provision was too literal, and that it ran counter to the context surrounding, and the purpose of the Data Protection Regulations.

[21] According to Justice Stratas, a drug that contains an enantiomer of a previously approved medicinal ingredient is not automatically excluded from data protection under subsection C.08.004.1(1). The listed substances in the definition of "innovative drug" were simply examples of substances that may be "variations", depending on the circumstances surrounding the data that had to be submitted in order to obtain regulatory approval.

[22] In particular, if regulatory approval for the drug required the submission of confidential data generated by considerable effort, and the medicinal ingredient in the drug is "new" in the sense that it has qualities of safety and efficacy that are materially different from a previously approved medicinal ingredient, then it is not a "variation" of that previously approved medicinal ingredient.

[23] Justice Stratas accepted that the inclusion of the words *"such as"* before the listed categories injected an element of uncertainty into the matter. However, if it were intended that all substances falling within those five categories were automatically "variations", then "variations" would have been defined as "*any* salt, ester, enantiomer, solvate or polymorph" or "*all* salts, esters, enantiomers, solvates or polymorphs".

[24] Justice Stratas held that the Minister's interpretation of subsection C.08.004.1(1) in other cases confirmed the view that the subsection is open-ended, and that the controlling idea was

whether or not a medicinal ingredient was a “variation”, and not whether the medicinal ingredient fell within the five listed categories of substances. According to Justice Stratas, considerable effort in testing, and difference or newness lay at the heart of the concept of what is and is not a minor variation under subsection C.08.004.1(1).

[25] Finally, Justice Stratas found that two particular aspects of *NAFTA* and *TRIPS* ensured that innovators got data protection only where there was a benefit to the public: the innovator must have engaged in “considerable effort” in generating the data, and a “new chemical entity” must be present. Those two factors altered the risk/reward equation for innovators, created appropriate incentives, and ensured that data protection was afforded only where the risk undertaken merited it. Subsection C.08.004.1(1) must embody those concepts in order to implement the relevant provisions of *NAFTA* and *TRIPS*. The Minister’s interpretation did not take the purpose of the treaties and the Data Protection Regulations into account, which was to encourage research and development of new medicines by protecting data created with considerable effort.

[26] Takeda sought leave to appeal from this Court’s judgment in *Takeda*, but was denied leave by the Supreme Court of Canada: leave to appeal to SCC refused, 35276 (13 June 2013).

III. Janssen’s SPRAVATO Drug

[27] SPRAVATO is a treatment for major depressive disorder [MDD], administered by way of a nasal spray. According to Janssen, SPRAVATO addresses a significant unmet need on the

part of patients who suffer from MDD, who have not responded to at least two other antidepressant medications.

[28] The medicinal ingredient in SPRAVATO is esketamine hydrochloride. It is undisputed that esketamine hydrochloride is an enantiomer of ketamine hydrochloride, and that products containing ketamine hydrochloride have previously been approved by the Minister for use as injectable general anaesthetics.

[29] Janssen asserts that considerable effort went into the development of SPRAVATO. The clinical development program required to establish the safety and efficacy of SPRAVATO in MDD involved an eight-year program, and 29 clinical studies involving thousands of patients with MDD. These included nineteen Phase I studies, four Phase II studies and six Phase III studies.

IV. The Decision Regarding Data Protection for SPRAVATO

[30] In December of 2018, Janssen filed a New Drug Submission [NDS] with the Office of Submissions and Intellectual Property [OSIP], an office under the Resource Management and Operations Directorate within the Health Products and Food Branch of Health Canada. OSIP, on behalf of the Minister, is responsible, in part, for the administration of drug-related intellectual property regimes. Janssen was seeking data protection for SPRAVATO, and asking that it be added to the Register of Innovative Drugs.

[31] Following an extensive review process, OSIP determined that SPRAVATO was not eligible for data protection pursuant to subsection C.08.004.1(1) of the Data Protection Regulations on the basis that esketamine hydrochloride was an enantiomer of ketamine hydrochloride—a previously approved medicinal ingredient. As such, esketamine hydrochloride was not an "innovative drug" and was therefore ineligible for such protection. In May of 2020, the Therapeutic Products Directorate of the Health Products and Food Branch did issue a Notice of Compliance for SPRAVATO, approving it for marketing and sale in Canada.

[32] Janssen argued that SPRAVATO was eligible for data protection because it provides a novel therapeutic mechanism of action for treating MDD, a new indication, a new route of administration, a new dosage form and a new strength, as compared to previously approved drugs containing ketamine hydrochloride. However, OSIP observed that this very argument had been rejected by the majority in *Takeda*, above at paras. 127-128.

[33] OSIP thus concluded that as an enantiomer of a previously approved drug, SPRAVATO was not entitled to data protection, despite it having a different safety and efficacy profile from previously approved drugs.

[34] OSIP also considered Janssen's argument that the data it had submitted in its NDS should be assessed in order to determine whether it was the product of considerable effort. OSIP held that the question of whether data submitted by an innovator involved "considerable effort" is only relevant once it had been determined that the medicinal ingredient in the drug had not been previously approved. Having determined that esketamine hydrochloride was a variation of a

previously approved medicinal ingredient, OSIP found that it was unnecessary to determine whether the data submitted in the NDS involved "considerable effort": citing *Takeda*, above at paras. 125 and 126.

[35] Consequently, Janssen's request for data protection was rejected.

V. The Federal Court's Decision

[36] Janssen sought judicial review of OSIP's decision in the Federal Court, arguing that the decision was unreasonable, notwithstanding the fact that it accorded with the majority decision of this Court in *Takeda*.

[37] Relying on the Supreme Court's decision in *Carter v. Canada (Attorney General)*, 2015 SCC 5, [2015] 1 S.C.R. 331 at paragraph 44, Janssen argued that the Federal Court could reconsider the Federal Court of Appeal's interpretation of "innovative drug" in *Takeda* "where a new legal issue is raised or there is a change in the circumstances or evidence that fundamentally shifts the parameters of the debate": Federal Court decision at para. 20.

[38] Janssen identified the release of the Supreme Court's decision in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, 441 D.L.R. (4th) 1, with its emphasis on ensuring that legislation is interpreted in the proper statutory scheme, consistent with Canada's international obligations, as a "new legal issue" warranting a reconsideration of the interpretation of the Data Protection Regulations.

[39] The Federal Court rejected this submission, noting that there was nothing new in ensuring that legislation is interpreted in a manner consistent with Canada's international obligations, and that the majority in *Takeda* was well aware of Canada's international obligations underpinning the provisions of the Data Protection Regulations.

[40] Janssen also argued that the evidence in this case differs significantly from the evidence that was before this Court in *Takeda*. In *Takeda*, the same company had developed both the original and the purportedly new drug, both of which were used in the same manner for the same indication, and that none of these facts are present in this case. Janssen submitted that the facts in *Takeda* involved exactly the kind of "mere variation" that the exception to the definition of "innovative drug" was designed to catch, and that the situation here is markedly dissimilar.

[41] The Federal Court agreed that there were factual differences between *Takeda* and this case, but there was nothing in *Takeda* that suggested that the interpretation of the Data Protection Regulations was based on, or was influenced by those facts, and that the factual differences between the two cases were not such that the Federal Court could refuse to follow *Takeda*. Consequently, Janssen's application for judicial review was dismissed.

VI. Janssen's Arguments on this Appeal

[42] Janssen's primary argument is that the majority decision in *Takeda* was wrongly decided, and that we should reinterpret subsection C.08.004.1(1) of the Data Protection Regulations in the manner espoused by Justice Stratas in his minority decision.

[43] While accepting that OSIP's decision was reviewable on the reasonableness standard, Janssen submits that the Federal Court erred in finding that OSIP's decision in this case met the post-*Vavilov* reasonableness standard. Even though it was bound by the majority decision in *Takeda*, Janssen says that OSIP should nevertheless have explained why that decision was wrong, as it resulted in an outcome that did not accord with the purpose of the Data Protection Regulations.

[44] Finally, Janssen contends that we should admit new evidence on this appeal with respect to the repeal of *NAFTA* and the coming into force of *CUSMA*.

VII. Should We Admit New Evidence on this Appeal with respect to *CUSMA*?

[45] Dealing with its last issue first, Janssen seeks leave to present fresh evidence regarding the impact that *CUSMA* should have on the interpretation question at issue in this case. It submits that even if we were to find that OSIP's decision was reasonable at the time it was made, the appeal should still be granted as the decision is no longer reasonable, as the basis on which the Minister based her decision no longer exists.

[46] Janssen points out that under *CUSMA*, Canada agreed to provide protection to "new pharmaceutical products", which are specifically defined as products that do not contain a chemical entity that has previously been approved. Janssen notes that OSIP explicitly found that the medicinal ingredient in SPRAVATO had not been previously approved in a drug in Canada, and that this would qualify SPRAVATO for data protection under *CUSMA*.

[47] In support of this argument, Janssen seeks to adduce evidence that it made a second request for data protection for SPRAVATO in November of 2020, and that OSIP has declined to deal with that request pending the outcome of this appeal. Janssen notes that the Minister has taken the position here that it would be improper for this Court to consider *CUSMA* on this appeal. Janssen says that the Minister is essentially trying to have it both ways: refusing to deal with Janssen's second request for data protection on the basis that it wants to see what this Court decides, while, at the same time, urging the Court not to consider *CUSMA* at all.

[48] I do not accept Janssen's arguments.

[49] The test for fresh evidence to be admitted on an appeal is set out in *Palmer v. The Queen*, [1980] 1 S.C.R. 759, 106 D.L.R. (3d) 212. *Palmer* provides that (1) evidence should generally not be admitted if, by due diligence, it could have been adduced in the Court below; (2) the evidence must be relevant in the sense that it bears upon a decisive or potentially decisive issue in the trial; (3) the evidence must be credible in the sense that it is reasonably capable of belief; and (4) it must be such that if believed it could reasonably, when taken with the other evidence adduced in the Court below, be expected to have affected the result.

[50] It is true that the exchange of letters between Janssen and OSIP were not in existence when this matter was before the Federal Court and could not therefore have been considered by that Court. However, the underlying argument—that the Data Protection Regulations should be interpreted in light of *CUSMA*—could have been made at the time that Janssen's application for judicial review was heard in the Federal Court.

[51] *CUSMA* was finalized on December 10, 2019 and came into force on July 1, 2020. Janssen served and filed its application record in the Federal Court on July 17, 2020, and its application was heard in the Federal Court on August 31, 2020. While *CUSMA* was referenced in Janssen's memorandum of fact and law as one of the several treaties that imposed obligations on Canada and limited the Minister's interpretation of the Regulations, Janssen did not make substantive submissions that *CUSMA* had changed the data protection regime and the interpretation of section C.08.004.1 of the Data Protection Regulations.

[52] *CUSMA* was also mentioned at the hearing in the Federal Court: see Federal Court decision at para. 5. It does not, however, appear that Janssen made the argument that it seeks to advance here with respect to the implications that *CUSMA* may have for the Data Protection Regulations, nor has Janssen explained why it could not have advanced its arguments with respect to *CUSMA* in the Federal Court.

[53] The second *Palmer* factor is whether the evidence is relevant, in the sense that it bears upon a decisive or potentially decisive issue in the court below. This requires a consideration of the nature of the proceedings in the Federal Court and in this Court.

[54] The task of the Federal Court was not to decide whether esketamine hydrochloride should be entitled to data protection. Its task was to determine whether OSIP's decision to refuse data protection for SPRAVATO was reasonable, based on the record before it. To make this determination, the Court had to examine OSIP's decision in light of the factual and legal constraints that were on OSIP: *Vavilov*, above at para. 68.

[55] OSIP rendered its decision on April 25, 2019, more than a year before the coming into force of *CUSMA* and the exchange of correspondence between the parties. Consequently, the agreement and the documents could have had no bearing on OSIP's decision with respect to SPRAVATO, and they were not relevant to the task that the Federal Court had to perform.

[56] On an appeal from a decision of the Federal Court in an application for judicial review, this Court's task is to determine first, whether the Federal Court identified the correct standard of review, and second, whether it properly applied that standard: *Agraira v. Canada (Public Safety and Emergency Preparedness*), 2013 SCC 36, [2013] 2 S.C.R. 559, at paras. 45-47. This is often described as this Court "stepping into the shoes" of the Federal Court, focusing on the administrative decision.

[57] Rather than asking us to determine whether the Federal Court properly identified and applied the reasonableness standard of review to OSIP's decision, however, Janssen is asking us to make an entirely new decision based on a new international instrument that was not in force at the time that the administrative decision under review was made. This Court is acting on appeal from a judicial review of an administrative decision, based on the facts and the law that existed before the administrative decision-maker at that time. In circumstances such as these, we are restricted to a reviewing capacity. We have no power to act as if we were the administrative decision-maker ourselves, considering new issues, new facts and new law. Accordingly, the new evidence with respect to *CUSMA* will not be admitted.

[58] The Minister refused to consider the data-protection issue in light of *CUSMA*. It may still be possible for Janssen to apply to the Federal Court for judicial review of that refusal, if it has not done so already.

VIII. Did the Federal Court Err in Finding OSIP's Decision to be Reasonable?

[59] I agree with the parties that the Federal Court correctly identified reasonableness as the standard of review to be applied to OSIP's decision. The question for determination is thus whether it properly applied that standard in finding that the decision to deny data protection to SPRAVATO was indeed reasonable.

[60] Janssen submits that the Federal Court erred in finding that OSIP's decision satisfied the post-*Vavilov* reasonableness standard. The Court failed to apply a purposive approach to the Data Protection Regulations and the definition of "innovative drug", failed to consider the effort required to develop SPRAVATO, and failed to consider the evidence demonstrating the substantial differences between SPRAVATO and ketamine hydrochloride. These failures, along with OSIP's narrow and literal reading of the majority decision in *Takeda*, all render the decision unreasonable.

[61] While asserting that it is not arguing that the reasons provided by OSIP for its decision were insufficient, Janssen says that in cases such as this, where the determinative issue involves a question of statutory interpretation, the decision must comply with the rationale, purview and constraints of the statutory scheme, including the treaties.

[62] Janssen accepts that OSIP was bound by the majority decision in *Takeda*. Moreover, while submitting that there are some factual differences between this case and *Takeda*, Janssen concedes that these differences are not significant enough to allow *Takeda* to be distinguished from the present case.

[63] Janssen submits, however, that OSIP should nevertheless have provided reasons explaining how it was that the outcome of its decision in this case was reasonable, given that the application of the majority decision in *Takeda* results in an outcome that does not accord with the purpose of the Data Protection Regulations. OSIP should also have explained why the interpretation of subsection C.08.004.1(1) of the Data Protection Regulations articulated in Justice Stratas' dissenting reasons was to be preferred.

[64] In other words, Janssen says that it was incumbent on OSIP to essentially re-do the analysis that was carried out by this Court in *Takeda*.

[65] I do not accept Janssen's argument.

[66] The reasons provided by OSIP for rejecting Janssen's request for data protection for SPRAVATO are clear. Its central finding was that esketamine hydrochloride, the medicinal ingredient in SPRAVATO, is an enantiomer of ketamine hydrochloride, a previously approved medicinal ingredient. In accordance with the majority decision in *Takeda*, such variations are not eligible for data protection. As a result, Janssen's request for data protection was refused.

[67] The use of precedent has been described as "a foundational principle of the common law": Robert J. Sharpe, *Good Judgment: Making Judicial Decisions* (Toronto: University of Toronto Press, 2018) at 168. In according with the doctrine of *stare decisis*, lower courts and administrative tribunals must follow decisions of higher courts unless the case under consideration can be distinguished on its facts. This provides for "consistency, certainty, predictability, and sound judicial administration": *David Polowin Real Estate Ltd. v. Dominion of Canada General Insurance Co.* (2005), 76 O.R. (3d) 161, 255 D.L.R. (4th) 633 at para. 119.

[68] Thus, where a decision of a higher court reflects a considered view of the law and is intended to provide guidance to lower courts, it will be seen as binding on those lower courts, even where there is a dissenting opinion: The Honourable Justice Malcolm Rowe & Leanna Katz, "A Practical Guide to *Stare Decisis*", (2020), Windsor Rev. Legal Soc. Issues 1 at 9. This Court's decision in *Takeda* most certainly satisfies these requirements.

[69] It was thus entirely reasonable for OSIP to follow the interpretation of the Data Protection Regulations articulated in the majority decision in *Takeda*. Indeed, absent some tenable basis for distinguishing it on the facts, it would have been unreasonable for it not to do so. Furthermore, having found that this case was not distinguishable from *Takeda* on its facts, it follows that it was reasonable for the Federal Court to dismiss Janssen's application for judicial review.

[70] This takes us to Janssen's argument that we should revisit this Court's interpretation of the Data Protection Regulations in *Takeda* and adopt the minority reasoning of Justice Stratas.

IX. Should *Takeda* be Followed?

[71] Janssen submits that the majority decision in *Takeda* was wrongly decided, and that we should interpret subsection C.08.004.1(1) of the Data Protection Regulations in the manner espoused by Justice Stratas in his dissent. In support of this contention, Janssen advances similar arguments to those that were before the Court in *Takeda*.

[72] The aspect of the doctrine of *stare decisis* discussed in the previous section of these reasons involved the vertical convention—that is, the principle that lower courts and tribunals must follow the decisions of higher courts. However, *stare decisis* also includes a horizontal convention, which provides that decisions from the same level of court should be followed unless there is a compelling reason not to do so: Rowe and Katz, above at 6-7.

[73] As this Court observed in *Miller v. Canada (Attorney General)*, 2002 FCA 370, 220 D.L.R. (4th) 149, while it is open to this Court to overrule its prior decisions, "the values of certainty and consistency lie close to the heart of the orderly administration of justice in a system of law and government based on the rule of law": at para. 8. As a result, one panel of this Court ought not to come to a different conclusion from a different panel, merely because it is of the view that the first decision was wrongly decided: *Miller*, above at para. 8.

[74] The Court went on in *Miller* to state "in the interests of certainty and consistency, sound judicial administration requires that, save in exceptional circumstances, a Court of intermediate

appellate jurisdiction should follow its prior decisions. The Court is responsible for the stability, consistency and predictability of the law": *Miller*, above at para. 9.

[75] What are the "exceptional circumstances" that would warrant one panel of this Court departing from a decision of another panel? A prior decision may be overruled where that decision "is manifestly wrong, in the sense that the Court overlooked a relevant statutory provision, or a case that ought to have been followed": *Miller*, above at para. 10.

[76] That is not the situation here. All of the members of the panel in *Takeda* were well aware of the governing jurisprudence, legislation and international instruments, as well as the relevant principles of statutory interpretation. Both the majority and the minority decisions are thorough and carefully reasoned. While the majority may not have made express reference to the *North American Free Trade Agreement Implementation Act*, S.C. 1993, c. 44, it was well aware of the fact that the Data Protection Regulations were intended to implement Canada's obligations under *NAFTA* and *TRIPS*: see *Takeda*, above at para. 129. And while the majority may not have referred to section 12 of the *Interpretation Act*, R.S.C., 1985, c. I-21, neither did Justice Stratas, with the result that this is not a reason for preferring one decision over the other.

[77] Thus, Janssen has not shown "exceptional circumstances" in this case that would justify a departure from the majority decision in *Takeda*.

[78] However, Janssen says that this is not the end of the matter. It refers to the decisions of this Court in *Tan v. Canada (Attorney General)*, 2018 FCA 186, [2019] 2 F.C.R. 648 and *Bank*

of Montreal v. Li, 2020 FCA 22, 443 D.L.R. (4th) 688 which observe that the Supreme Court has taken a more liberal approach to issues of *stare decisis* in recent years. The Court has held that the certainty and predictability of *stare decisis* must sometimes give way where the economic, social and political circumstances underlying a decision have changed. There are two responses to this argument.

[79] The first is that this approach has most often been taken by the Supreme Court in cases involving the *Canadian Charter of Rights and Freedoms, s. 7, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (U.K.), 1982, c. 11*: see, for example, *Canada (Attorney General) v. Bedford*, 2013 SCC 72, [2013] 3 S.C.R. 1101, and *Carter v. Canada*, above. The second is that, in any event, there is no admissible evidence before us that the economic, social or political circumstances underlying the *Takeda* decision have changed since that case was decided in 2013.

[80] We are, however, faced with an unusual situation in this case that bears comment. That is, Justice Stratas, the dissenting judge in *Takeda*, is a member of this panel. Does this change anything? The short answer is no.

[81] As Justice Stratas observed during the hearing, he wrote his dissenting opinion in *Takeda* because he believed that it was right, and he still thinks that his interpretation of the Data Protection Regulations is the preferable one. That does not, however, open the door for him to try to achieve a majority decision in this case.

[82] Every panel of this Court speaks for the Court, and no panel of the Court sits in appeal of other panels: *Apotex Inc. v. Eli Lilly Canada Inc*., 2016 FCA 267 at para. 2. As Rowe and Katz observe, *stare decisis* provides that judges should follow prior decisions, even if they disagree with them: above at 13. Indeed, in *Knuller (Publishing, Printing and Promotions) v. D.P.P.* [1972] 2 All E.R. 898, 3 W.L.R. 143, Lord Reid of the British House of Lords found himself in a similar position to that of Justice Stratas in this case. Lord Reid reluctantly followed an earlier decision from which he had dissented, stating "[o]n reconsideration I still think that the decision was wrong … But I think that however wrong or anomalous the decision may be it must stand … unless or until it is altered by Parliament": at 903. The same may be said here.

X. Conclusion

[83] For these reasons, I would dismiss Janssen's appeal, with costs fixed in the amount of $2,850.00, inclusive of disbursements and GST.

"Anne L. Mactavish"
J.A.

"I agree.
David Stratas J.A."

"I agree.
Donald J. Rennie J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-252-20
STYLE OF CAUSE:	JANSSEN INC. v. ATTORNEY GENERAL OF CANADA (MINISTER OF HEALTH)
PLACE OF HEARING:	HEARD BY ONLINE VIDEO CONFERENCE HOSTED BY THE REGISTRY
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PUBLIC REASONS FOR JUDGMENT BY:	MACTAVISH J.A.
CONCURRED IN BY:	STRATAS J.A. RENNIE J.A.
DATED:	JULY 12, 2021

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