



## JUDGES AND COURTS

See also: *Food and Drugs*

Appeal from Federal Court decision (2019 FC 904) upholding Minister of Health's refusal to grant data protection for appellant's SPRAVATO drug on basis SPRAVATO not "innovative drug" eligible for such protection — Minister determining that SPRAVATO's medicinal ingredient variant of medicinal ingredient in previously approved drug — Basing decision in part on Federal Court of Appeal's interpretation of relevant regulation in *Takeda Canada Inc. v. Canada (Health)*, 2013 FCA 13, [2014] 3 F.C.R. 70 — Appellant asking Court herein to revisit *Takeda*, to conclude differently with respect to proper interpretation of regulation in issue — Canada's data protection regime contained in *Food and Drug Regulations*, C.R.C., c. 870 as amended by *Regulations Amending the Food and Drug Regulations (Data Protection)*, SOR/2006-241 (Data Protection Regulations) — Data Protection Regulations stating that data protection provided to "innovative drugs" — "Innovative drug" defined in Data Protection Regulations, s. C.08.004.1(1) as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph" — Majority in *Takeda* determined, *inter alia*, open to Governor in Council to decide, as matter of policy, that salts, esters, enantiomers, solvates, polymorphs not sufficiently different so as to be considered "new chemical entities" — Dissenting opinion in *Takeda* found that Minister's interpretation of s. C.08.004.1(1) too literal, running counter to context surrounding, purpose of Data Protection Regulations — SPRAVATO treatment for major depressive disorder — Medicinal ingredient thereof esketamine hydrochloride, enantiomer of ketamine hydrochloride — Appellant's primary argument in present case that majority decision in *Takeda* wrongly decided, that Court should reinterpret s. C.08.004.1(1) in manner espoused by minority — Main issue whether *Takeda* should be followed — *Stare decisis* doctrine provides that decisions from same level of court should be followed unless compelling reason not to do so — Appellant not showing "exceptional circumstances" in this case justifying departure from majority decision in *Takeda* — No admissible evidence herein that economic, social or political circumstances underlying *Takeda* have changed since that case decided — Fact that dissenting Judge in *Takeda* member of panel herein not changing anything — No panel of Court sitting in appeal of other panels — *Stare decisis* providing that judges should follow prior decisions, even when disagreeing with them — Appeal dismissed.

JANSSEN INC. V. CANADA (ATTORNEY GENERAL) (A-252-20, 2021 FCA 137, Mactavish J.A., public reasons for judgment dated July 12, 2021, 24 pp.)