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Judicial review of decisions by Minister of Health (respondent) wherein respondent failing to issue notice of compliance (NOC) to applicant in respect of its new drug submission for drug product IDACIO — IDACIO biosimilar of AbbVie Biotechnology Ltd.’s (AbbVie) drug HUMIRA — AbbVie owner of Canadian patents listed in Patent Register in respect of HUMIRA — Applicant sought to address each of listed patents when seeking issuance of NOC, pursuant to *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (NOC Regulations), ss. 7(1),(2) — AbbVie, applicant entering into confidential licensing agreement authorizing applicant to perform certain acts under listed patents — S. 7(2) exempting applicant from meeting certain conditions set out in s. 7(1) — AbbVie expressing forms of consent to respondent on several occasions, including consent to issuance of NOC in accordance with confidential agreement — Respondent’s first decision explained that effective date of consent being sought from AbbVie, prior to issuance of NOC — Second decision confirming that respondent remaining of view that NOC cannot issue until effective date of consent of February 15, 2021, when AbbVie provided consent to all four activities in s. 7(2), i.e. making, constructing, using or selling — Respondent finding that use of word “or” to connect the four activities in s. 7(2) cannot be interpreted in manner leading to absurd result or undermining effective patent enforcement mechanism of NOC Regulations — Applicant of position that consent to any single patent right under subsection 7(2) allowing respondent to issue NOC, respondent’s reading of s. 7(2) contrary to its plain text, inconsistent with its purpose — Whether respondent’s refusal to issue NOC until February 15, 2021, on basis of its interpretation of effective consent under s. 7(2), unreasonable — Whether Court should grant order of *mandamus* if respondent’s decisions unreasonable — *Patent Act*, R.S.C., 1985, c. P-4, s. 55.2(1) providing for “early-working” exception, where subsequent entry drug manufacturers may use patented, innovative drug as it relates to seeking approvals in respect of competing version of that drug — NOC Regulations preventing abuse of exception by setting out conditions under s. 7(1) that must be met prior to issuance of NOC — These conditions not applying where evidence of consent provided by patent owner in accordance with s. 7(2) — Respondent’s decisions unreasonable — Temporal nature of AbbVie’s consent not rendering it ineffective — Consent clear, unequivocal as to patent owner’s intentions — Temporal nature of consent to all four activities not supporting finding that consent only effective as of February 15, 2021 — Respondent circumvented textual reading of s. 7(2) by stating that “or” should be read conjunctively, rather than disjunctively, to avoid absurd result — In circumventing textual analysis, respondent also failing to recognize that consent provided here to all four listed activities in s. 7(2) — Decisions in issue failing to account for entire context, purpose of NOC Regulations, narrowly focusing on enforcement aspect — Dual purpose of NOC Regulations to balance effective patent enforcement over new, innovative drugs with timely market entry of their lower-priced generic competitors — This dual purpose consistent with limited scope of Act, s. 55.2(4) — Interpretation of s. 7(2) that withholds NOC where consent clearly provided by patent owner unreasonable — Choice of patent owner to consent to all four activities at different points in time not amounting to absurdity meriting correction of inclusive disjunctive understanding of word “or” to read as conjunctive “and” — Issuance of NOC on basis of consent provided by patent owner cannot be considered incoherent or incompatible having regard to dual purposes of NOC Regulations, express language of s. 7(2) — No discretion under NOC Regulations to withhold NOC once patent owner providing requisite consent — Appropriate herein to grant order of *mandamus* — Application allowed.

FRESENIUS KABI CANADA LTD. v. CANADA (HEALTH) (T-870-20, T-1048-20, 2020 FC 1013, Manson J., reasons for judgment dated October 29, 2020, 18 pp.)

