Federal Courts Reports
Recueil des décisions des Cours fédérales

FOOD AND DRUGS

Judicial review of respondent's decision refusing to accept applicant's abbreviated new drug submission (ANDS) for drug containing two medicinal ingredients, tenofovir alafenamide hemifumarate (TAF), emtricitabine — Respondent concluding that applicant's ANDS prohibited by data protection provisions of *Food and Drug Regulations*, CRC, c. 870 — Under those provisions, manufacturer may not file ANDS for new drug "on the basis of a direct or indirect comparison between the new drug and an innovative drug" for defined period — TAF, emtricitabine antiretroviral agents used in treatment of HIV/AIDS — Both agents found in two products marketed by respondent Gilead Sciences Canada Inc: DESCOVY, GENVOYA — Respondent considering GENVOYA "innovative drug" under data protection provisions because TAF had not been previously approved in drug when GENVOYA approved — DESCOVY, approved subsequently, not innovative drug — Applicant's ANDS comparing its drug to DESCOVY; therefore, arguing not making comparison to innovative drug, that data protection provisions not preventing it from filing its ANDS — Respondent's reasons for refusing applicant's ANDS under data protection provisions considering intent of ANDS, which was to implement certain trade agreements — Respondent finding agreements requiring protection of TAF during data protection term, such that DESCOVY "protected" under GENVOYA period of data protection because also containing TAF — Also noting that Gilead's submission for DESCOVY relying on comparative bioavailability studies for DESCOVY compared to GENVOYA — Respondent finding such reliance further supporting position that DESCOVY protected under same data protection term as GENVOYA — Whether respondent's conclusion that applicant's submission could not be accepted for filing until expiry of data protection term for GENVOYA reasonable — At issue was application of *Food and Drug Regulations*, s. C.08.004.1 [10] — Applicant filing ANDS seeking notice of compliance for its NAT-EMTRICITABINE-TENOFOVIR tablets, which product to be generic version of DESCOVY— Applicant's ANDS identifying DESCOVY as Canadian reference product (CRP), as defined in Regulations, s. C.08.001.1, seeking approval in accordance with s. C.08.002.1 — Respondent stating that consistent with intent of Regulations, s. C.08.004.1 to protect new chemical entities, drugs containing TAF, such as DESCOVY, benefitting from same period of data protection — Conclusion that data protection provisions barring applicant's ANDS based on (i) its assessment of intent of Regulations, obligations set out in NAFTA, TRIPS (ii) its assessment that fact DESCOVY approval relied on data for GENVOYA further supporting position — Respondent finding that data protection provisions triggered by applicant's comparison to DESCOVY — Applicant arguing that respondent broadening definition of "innovative drug" to include other drugs with same medicinal ingredient — While mechanism used in data protection provisions that of "market exclusivity", based on existence of "innovative drug," generic version of innovative drug not only product that can trigger market exclusivity protection as applicant arguing — Test under Regulations is not reliance on innovator's data but rather whether comparison made, direct or indirect, between generic manufacturer's new drug, innovative drug — Respondent not addressing triggering question in analysis before reaching conclusion — Only trigger for "no-file" prohibition is direct or indirect comparison to innovative drug — To conclude that product line extension or other drug containing same new medicinal ingredient "necessarily" invokes data protection, regardless of whether it entails such comparison, divorcing analysis from regulatory scheme as promulgated — Respondent addressing reliance on data for GENVOYA in approval of DESCOVY — Despite respondent's mischaracterization of obligations in trade agreements or intent of Regulations, s. C.08.004.1 as being to "protect new chemical entity", while trade agreements providing for obligation to protect *data* filed to obtain approval of drug containing new chemical entity rather than for protection of new chemical entity itself, language used not rendering respondent's decision unreasonable — Respondent elsewhere in decision

appropriately referring to obligations under treaties as being to protect undisclosed test or other data of pharmaceutical product that utilizes new chemical entity — On overall review of decision, respondent not misunderstanding nature of treaty obligations or intent of regulations — While respondent's statement that comparison to DESCOVY constituting indirect comparison to GENVOYA not clear, passage at issue can be read as respondent making determination that applicant's ANDS indirectly comparing its drug to GENVOYA — Respondent finding on facts of case that new drug submission for DESCOVY made comparison to new drug submission for GENVOYA; that applicant's submission comparing its drug to DESCOVY thereby making "direct or indirect comparison" to GENVOYA, innovative drug — Such conclusion reasonable in light of record, history, context of proceeding, relevant factual, legal constraints on decision — While respondent's reasoning not containing all arguments, statutory provisions, or other details reviewing judge would have preferred, not standard on which Court having to assess decision nor basis for setting decision aside — With respect to term "direct or indirect comparison" to innovative drug, presumption of consistent expression rebutted in this case — Phrase "direct or indirect comparison" in Regulations, s. C.08.004.1 must be read differently than phrase "directly or indirectly compares" in *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (PM(NOC) Regulations) — However, while data protection provisions, PM(NOC) Regulations arising in similar contexts, each having different purposes, different regulatory language, different regulatory, case law contexts — Structure of PM(NOC) Regulations supporting interpretation that direct or indirect comparison in question referring only to "other drug" while context of Regulations, s. C.08.004.1 suggesting very use of "direct or indirect comparison" designed to deal with any comparison to "innovative drug" — Even though similar language appearing in data protection provisions, PM(NOC) Regulations, different meaning must be given to each to reflect their respective regulatory contexts — Respondent's interpretation of Regulations, s. C.08.004.01(3) reasonable — Considering both contextual issues raised by respondent, additional arguments raised by applicant, clear that interplay of text, context and purpose leaving room for single reasonable interpretation: "direct or indirect comparison" to innovative drug that forms trigger for data protection provisions may include manufacturer's comparison to drug product that in turn was compared to innovator product for approval — Given respondent's finding that applicant compared its product to DESCOVY, that approval of DESCOVY based on comparison to GENVOYA, very data supporting its innovative drug status, outcome that applicant's ANDS could not be accepted for filing inevitable — Application dismissed

NATCO PHARMA (CANADA) INC. V. CANADA (HEALTH) (T-1353-19, 2020 FC 788, McHaffie J., reasons for judgment dated July 24, 2020, 50 pp.)