



[2022] 4 F.C.R. D-3

PATENTS

Application for judicial review of Minister of Health (Minister) decision finding that through transfer of ownership, respondent Biosimilar Collaborations Ireland Limited (BCIL), as successor second person on new drug submission (NDS) could adopt notice of allegation (NOA) of predecessor second person, BGP Pharma ULC doing business as Viatris Canada (Viatris) — Minister found that with transfer, BCIL obtained benefits of *Patented Medicines (Notice of Compliance) Regulations* (Regulations), SOR/93-133, s. 5, including prior service of NOA under subsection 5(3) — NOA at issue precursor to proceeding under Regulations, s. 6(1) involving two Canadian patents listed on Patent Register in association with medicine aflibercept and its related drug product EYLEA — Viatris filed NDS seeking notice of compliance (NOC) for EYLEA biosimilar known as YESAFILI — Served applicant Bayer Inc. (Bayer) with NOA alleging non-infringement, invalidity of two listed patents for EYLEA — Bayer commenced Regulations, s. 6(1) action, naming Viatris as defendant — Ownership of NDS for YESAFILI subsequently transferred to BCIL — Minister of view that BCIL should be made a defendant in docket T-1241-22, other Regulations, s. 8.2 actions that had been commenced in respect of NDS for YESAFILI, for purpose of Minister's administration of Regulations, s. 7 — Applicants seeking order quashing, setting aside Minister's decision, declaration that BCIL cannot adopt steps previously taken by Viatris to comply with Regulations, s. 5, declaration that BCIL had not complied with requirements of s. 5 — Applicants asserting that decision unreasonable because: (1) it falls outside Regulations, is not supported by principles of statutory interpretation; (2) it contemplates premature issuance of NOC to successor second person; (3) it frustrates applicants' express right to be able to renounce 24-month stay — Further contending that respondents' fear of prolonging 24-month stay not justified, not supporting decision — Whether Minister's decision that successor second person can adopt NOA served under Regulations, s. 5(3) by its predecessor unreasonable or incorrect — Decision transparent, intelligible, justified, consistent with scheme, objectives, purpose of Regulations — Applicants' arguments not persuasive — Regulations creating patent linkage regime that ties regulatory approval of generic medicines to protection of patent rights — Objective of Regulations to "balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors" — Dual purpose of Regulations, balance it seeks to achieve reflected in its overall scheme — NOA not act of infringement, as pre-approval regulatory activities of second person exempt from infringement — Transfer of NOA implicit from scheme of Regulations, its underlying policies, including those relating to associated review and handling of drug submissions under *Food and Drug Regulations*, C.R.C., c. 870 — As matter of policy, change in name of manufacturer during review of NDS not changing filing date of submission, successor manufacturer not required to refile submission or to address any patents added to Patent Register between date NDS filed, date successor second person assumed ownership of NDS — Drug submission process continues uninterrupted under successor manufacturer, regardless of whether change of name due to merger, buyout, or transfer of rights in drug — Upon transfer of ownership of NDS, successor manufacturer becomes second person under Regulations, their predecessor ceases to be second person — Allowing successor second person to adopt NOA served by its predecessor is consistent with handling of change in ownership after review of NDS — Transfer of rights to BCIL result of administrative change of ownership over drug product — If NOA served on first person, the new second person need only notify first person of its new name in order to ensure transparency — Interpretation of Regulations requiring successor second

person to re-serve same NOA on first person would be contrary to objectives of Regulations, balance set out in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 — Nothing in Minister's decision or Regulations, s. 8 confirming whether second person may recover damages for period that it is not second person — Applicant's interpretation ignoring express balance that scheme of Regulations intended to protect as any additional time the subsequent entry version was kept off market due to restarted 24-month stay would not be result of early working but rather because of administrative change alone — Minister not erring in finding that scheme of Regulations, mechanism of handling submissions under *Food and Drug Regulations* supporting view that NOA, its service would be transferred to BCIL — Reasonable for Minister to find that successor second person would not be issued NOC in some intervening period before change made to named defendants in pending action commenced under Regulations, s. 6(1) in respect of predecessor's NOA — *Federal Courts Rules*, SOR/98-106, rr. 104, 107 allowing successor second person to be added as defendant to action — Application dismissed.

BAYER INC. V. BGP PHARMA ULC (VIATRIS CANADA) (T-1178-23, 2023 FC 1325, Furlanetto J., reasons for judgment dated October 3, 2023, 25 pp.)