

PATENTS

INFRINGEMENT

Appeal from decision rendered by Prothonotary dismissing motion brought by appellant seeking dismissal of action commenced in Federal Court (F.C.) by respondents — More particularly, appellant arguing that respondents' action redundant, scandalous, frivolous or vexatious or otherwise abuse of process in accordance with Patented Medicines (Notice of Compliance) Regulations, S.O.R./93-133 (amended Regulations), s. 6.08 — Respondents listing Canadian Patent No. 1341537 ('537 patent) in connection with Neupogen, Neulasta — Appellant intending to market Nivestym, drug biosimilar to Neupogen — Serving notice of allegation (NOA) on respondents — In response, respondents commencing action against appellant under amended Regulations, s. 6(1) — Appellant filing its motion for dismissal of respondents' action — Pursuant to amended Regulations, remedy provided under s. 6 converted from application to prohibit Minister of Health (Minister) from issuing notice of compliance into action for patent infringement — Under former Regulations, s. 6 proceedings only serving to determine whether second person's allegations of non-infringement justified so as to allow Minister to issue Notice of Compliance (NOC) to that second person — Issue whether this change allowing first person to commence s. 6 proceeding under amended Regulations notwithstanding previously unsuccessful s. 6 proceeding under former Regulations — Respondents previously asserting '537 patent against Apotex Inc. (Apotex) by commencing application under former Regulations, s. 6 — F.C. finding that Apotex's allegations of invalidity of '537 patent justified, receiving NOC (F.C. decision) — Notwithstanding F.C. decision, respondents commencing second application against Apotex — F.C. dismissing this application as constituting abuse of process — In present case, appellant's NOA putting forward same allegations of obviousness that F.C. decision found to be justified — In response to NOA, respondents commencing action pursuant to amended Regulations, s. 6(1) against appellant for declaration that making, constructing, using or selling of its drug Nivestym infringing claims of '537 patent — Prothonotary of view, inter alia, that F.C.'s decision could not "simply be grafted on the within action" since regime now provided under amended Regulations distinct from regime under former Regulations — Prothonotary indicating that F.C. decision not determining what is in issue in respondents' action filed under amended Regulations, namely, validity of '537 patent and, if valid, whether appellant's Nivestym infringing any claims of '537 patent — Whether Prothonotary erring in dismissing appellant's motion for abuse of process — Prothonotary not misunderstanding *Sanofi-Aventis Canada v. Novopharm Ltd.*, 2007 FCA 163, [2008] 1 F.C.R. 174 (Sanofi), not committing reviewable error — While correct to say that under former Regulations, by reason of Sanofi, patentee not entitled to second attempt under s. 6(1) against another generic with regard to same issues, question whether this holding true following adoption of amended Regulations — Appellant's action not abuse of process in light of principles enunciated in *Sanofi* — *Sanofi* clear that what it considered abuse of process was fact that Sanofi's second application could possibly give rise to inconsistent judicial decisions on same issues in equivalent proceedings, which could jeopardize credibility of adjudicative process — Purpose of s. 6 application under former Regulations not to determine questions of infringement or validity of patent, but rather question of whether Minister should be prohibited from issuing NOC to generic with respect to product biosimilar to patentee's product — Under former Regulations, patentee could commence proceedings under Patent Act, R.S.C., 1985, c. P-4, s. 55 following dismissal of s. 6 application — Action commenced under amended Regulations, s. 6 deciding essentially same issues as Patent Act, s. 55 action — Appellant wrongly stating that under amended Regulations, patentee failing in respect of application under former Regulations barred from commencing action under amended Regulations, s. 6 because that action constituting abuse of process — Present scenario different from the one in *Sanofi* — Issues to be determined in respondents' s. 6 action, namely, whether appellant's product will infringe '537 patent or whether '537 patent valid, not issues determined by F.C. decision, thus remaining to be determined — Respondents' action not threatening credibility of adjudicative process nor having negative impact on efficient use of scarce judicial resources — Court's decision in *Apotex Inc. v. Pfizer Ireland Pharmaceutical*, 2011 FCA 77

leaving no doubt that commencement of s. 55 action cannot be prevented by reason of decision made under former Regulations, s. 6 — Same conclusion having to be reached in respect of action commenced under amended Regulations, s. 6 — Prothonotary not erring in respect of applicable test — Appeal dismissed.

PFIZER CANADA INC. V. AMGEN INC. (A-24-19, 2019 FCA 249, Nadon J.A., reasons for judgment dated October 4, 2019, 33 pp.)