



PATENTS

Motion by defendant seeking to amend its statement of defence in underlying action under *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 6(1), to include allegations not found in its notice of allegation (NOA) — Proposed amendments seeking to add additional prior art references to support allegations of obviousness in respect of asserted patents; additional grounds of invalidity based on anticipation, inutility, overbreadth, ambiguity, insufficiency — Underlying action involving three patents listed for medicinal ingredient lurasidone hydrochloride — Plaintiffs arguing abusive to allow proposed amendments — Asserting that scheme of Regulations restricting allegations of invalidity raised in defence to action for infringement under section 6(1) — Defendant arguing that amendments to Regulations no longer limiting generic to issues raised in their NOA; instead action governed by pleadings, intended to parallel regular patent infringement action — Whether proposed amendments should be allowed — Amendments should not be refused outright on basis that arguments, prior art sought to be raised not in defendant's NOA; rather, amendments must be considered under principles relating to pleading amendments, with respect to their impact in present proceedings — Significant amendments made to Regulations in 2017 converting right of innovator under s. 6(1) to bring application to prohibit Minister from issuing notice of compliance (NOC) to generic into right to bring action for patent infringement as against generic — NOA precursor not to application but action intended to determine patent infringement, validity, for which statement of defence will be filed, counterclaim may be provided — Right to bring action intended to be final — Delivery of NOA intended to facilitate early consideration of issues *likely* to be raised in litigation, not to circumscribe or limit issues, arguments that may be raised in proceeding, defined by pleadings themselves — Amendments proposed here having to be considered under principles set out for pleading amendments in *Federal Courts Rules*, SOR/98-106 — *Federal Courts Rules*, r. 75 providing that Court may at any time, allow party to amend document on such terms as will protect rights of parties — As threshold issue, motion to amend pleading not allowed unless amendment having reasonable prospect of success when considering chance of success in context of law, litigation process — If proposed amendment having reasonable prospect of success, consideration given to other factors consonant with interests of justice, e.g. timeliness of motion to amend, extent to which proposed amendments delaying expeditious trial of matter — Here, amendments proposed already in play in other s. 6(1) action for lurasidone hydrochloride, involving third party generic; having reasonable chance of success — Proposed amendments not vulnerable to being struck as abuse of process — Amendments raised not impacting plaintiffs' choice to assert infringement — Principles of fairness, common sense, that justice be done favouring allowing amendments into proceeding — Motion allowed.

SUNOVION PHARMACEUTICALS CANADA INC. V. TARO PHARMACEUTICALS INC. (T-671-20,
2021 FC 37, Furlanetto J., reasons for order dated January 11, 2021, 21 pp.)