Federal Court continues to breathe life into motions to dismiss proceedings under the *Patented Medicines (Notice of Compliance) Regulations*

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In amended reasons released on May 26, 2016, the Federal Court in *Janssen Inc. v. Celltrion Healthcare Co. Ltd*[1] (*Janssen*) granted a motion to dismiss an application for a prohibition order in respect of the drug INFLECTRA (infliximab). Although under appeal, this decision reflects the Court's continued willingness to dismiss proceedings brought under the *Patented Medicines (Notice of Compliance) Regulations* (the Regulations) where it is plain and obvious that an applicant will not succeed in showing, within the constraints of a proceeding under the Regulations, that a patent will be infringed.

Janssen is reminiscent of the recent decision in *Bayer Inc. v. Pharmaceutical Partners of Canada Inc*[2], where the Federal Court also dismissed an application filed under the Regulations because it was clear the applicant could not show that a use patent would be infringed. The *Janssen* and *Bayer* cases signal that, on a motion to dismiss, the Federal Court will assess critically whether an applicant benefiting from the Regulations' 24-month stay will be able to make its case within the procedural constraints of the Regulations – particularly where the patent at issue relates to how a proposed product will be used.

The decision

Celltrion has held a market authorization (NOC) for INFLECTRA for use in the treatment of rheumatoid arthritis since 2014. In 2015, Celltrion filed a Supplementary New Drug Submission (SNDS) with the Minister of Health for a new use of INFLECTRA in the treatment of inflammatory bowel diseases (the IBD Indications). Janssen commenced an application under the Regulations against Celltrion, to which Celltrion responded by filing a motion to dismiss under section 6(5)(b) on the ground that INFLECTRA's use for the IBD Indications could not infringe the patent at issue (the 630 Patent).

Janssen asserted that the issue was whether INFLECTRA could be used to infringe the claims of the 630 Patent, and not whether the new use proposed in the SNDS would infringe the claims. Janssen argued that INFLECTRA would infringe the 630 Patent because it was indicated for the treatment of rheumatoid arthritis. The Court, however, rejected this argument, holding that the Regulations make specific reference to the use of the drug for which the SNDS is filed. The rheumatoid arthritis indications did not come into play because Celltrion's SNDS related to only the IBD Indications.

The Court granted Celltrion's motion, holding that the 630 Patent covered only rheumatoid arthritis. The Court found that no expert evidence was needed to construe the claims of the

630 Patent because the claims, on their face, only addressed rheumatoid arthritis, and not the IBD Indications. Therefore, the Court concluded that Celltrion's SNDS could not infringe the claims of the 630 Patent because INFLECTRA's new indications fell outside the scope of the claims at issue.

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1 *Janssen Inc. v. Celltrion Healthcare Co. Ltd.*, 2016 FC 525 (Prothonotary Aalto) (*Janssen*).

2 *Bayer Inc. v. Pharmaceutical Partners of Canada Inc.*, 2015 FC 388 *aff'd* 2015 FC 797 *aff'd* 2016 FCA 13 (*Bayer*).