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Reasonable Request for Samples Required

In the recent decision in *Bayer Inc v Amgen Canada Inc*, Case Management Judge Duchesne of the Federal Court dismissed a request for samples on the basis that Bayer failed to demonstrate that the proposed testing could lead to a result that would assist the trial judge in determining an issue in the proceeding.

Discussion

This decision stems from an action wherein Bayer seeks, among other relief, a declaration that Amgen's making, constructing or selling its Amgen Biosimilar, an intravitreally administered aflibercept solution, would infringe a number of claims of Bayer's 768 Patent. Amgen counterclaimed, seeking, among other orders, a declaration that the 768 Patent's claims are invalid, void and of no force and effect.

In this decision, Bayer sought an order requiring Amgen to deliver for testing representative samples of its cell culture medium and cell culture used in the manufacture of aflibercept for its Amgen Biosimilar. Amgen agreed to produce the cell culture medium samples but refused to produce the cell culture samples. Amgen asserted that Bayer was requesting cell culture samples but had only sought cell culture medium in its written representations, and that these samples were not relevant to the proceeding. The focus of the motion and this decision was whether Amgen should be compelled to produce the cell culture samples.

A moving party seeking to test a sample that is the subject-matter of proceedings under Rule 249 of the *Federal Court Rules* may demonstrate, by way of evidence on a motion, that there is a reasonable possibility that the result of the testing will assist the trier of fact in determining an issue in the proceeding. On the motion Bayer argued that it met the threshold for an order compelling the production of samples. In support of this argument, Bayer relied on statements in Amgen's expert's report that a notional test of a sample existed, however Bayer had neither identified the test itself nor provided evidence of what the test may entail or whether it may produce a result.

Case Management Judge Duchesne considered the interests of Bayer, Amgen and the trial judge, and ultimately concluded that

reliance on a notional and undescribed test does not establish a reasonable possibility of revealing something useful for trial judge.

While acknowledging that claims construction is a matter to be determined by the trial judge, Case Management Judge Duchesne determined that Bayer's request for "cell culture" as opposed to "cell culture media" in their Notice of Motion was intentional. Case Management Judge Duchesne added that regardless of whether the distinction between the two needed to be drawn or not, Bayer failed to discharge its burden.

Case Management Judge Duchesne's order reiterates the threshold required in order to compel samples for testing under Rule 249, reminding parties that reliance by a moving party on a notional and undescribed test is insufficient to establish a reasonable possibility of revealing something useful for the trial judge. A moving party is not required to lead evidence that the proposed tests are the only means to establish its case, disclose the nature of the tests, or even disclose whether it will in fact carry them out. However, the proposed test must be sufficiently identified, and evidence may be provided with respect to whether it may produce a result.

Takeaways

This decision speaks to the importance of accurately identifying what the moving party seeks to compel on a motion. Whatever sample or samples are sought to be compelled, the moving party needs to meet the test under Rule 249 for a Court to order production of the samples.

This decision also aligns with the recent trend that when reasonable requests for relevant samples are made, the responding party often provides the samples on consent. This is reflective of a broader shift under the current *Patented Medicines (Notice of Compliance) Regulations* regime where requests for samples are granted to assist the trier of fact in determining an issue in the action.