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The Federal Court Clarifies the Burden of Proof in Summary Trial

In 2022, the use of summary proceedings in patent matters continues at the Federal Court. In *Janssen Inc v Pharmascience Inc*, the Court:

- permitted a summary trial in a PM(NOC) proceeding;
- addressed the burden of proof in summary trial; and
- found that the respondent patentee had proven induced infringement by the moving party defendant.

Background

The underlying proceeding is a patent infringement action brought by Janssen under the *Patented Medicine (Notice of Compliance) Regulations* (SOR/93-133) (the **"**Regulations**"**) in relation to Pharmascience's proposed product, pms-PALIPERIDONE PALMITATE, a generic version of Janssen's INVEGA SUSTENNA® product. On this motion, Pharmascience sought a summary trial on the issue of infringement.

Under the *Federal Courts Rules*, Rule 213 permits a party to bring a motion for summary trial on all or some of the issues raised in the pleadings. The summary trial does not need to determine every issue. The Court has the discretion to hear one or more issues and decide if it is appropriate to deal with any of those issues by way of summary trial.

According to Rule 216(6) and Rule 3, if the Court is convinced that there is sufficient evidence for adjudication, regardless of the amounts involved, the complexities of the issues, and the existence of conflicting evidence, the Court may grant judgment, unless it would be unjust to do so. In addition to the Rules, on a motion for summary trial, the Court will consider:

- the complexity and urgency of the matter;
- any prejudice likely to arise by delay;
- the cost of taking the case forward to a conventional trial in relation to the amount involved;
- whether credibility is a crucial factor and the deponents of the conflicting affidavits have been cross-examined;
- whether the summary trial involves a substantial risk of

wasting time and effort, and producing unnecessary complexity; and

- any other matters which may arise for consideration.

The patent at issue was the subject of a prior decision relating to a different generic defendant: *Janssen Inc v Teva Canada Limited* (**"***Teva Paliperidone***"**).

Appropriate Case for Summary Trial

Pharmascience argued that this case should be determined by way of summary trial because its proposed product is missing an essential element of every claim of the patent at issue. Accordingly, Pharmascience argued that its proposed pms-PALIPERIDONE PALMITATE does not infringe or would not induce infringement of Janssen's Canadian Patent No. 2,655,335. This argument relied on the decision in *Teva Paliperidone*, including the construction given to the patent claims at issue in both proceedings.

Janssen argued that a summary trial was not appropriate because:

- the pending appeal in *Teva Paliperidone* may answer questions of law regarding the test for induced infringement which could bear on the claims construction at play before Justice Manson;
- there were issues of conflicting evidence and credibility; and
- Janssen was prejudiced by not being provided with full discovery of relevant information that lies exclusively within the knowledge of Pharmascience on issues central to this motion.

Justice Manson found that summary trial was appropriate to decide the narrow issue put forward. In particular, the Court determined that there was sufficient evidence for adjudication and that any issues of credibility and conflicting evidence could be determined on the written record before the Court.

Of interest, although the summary trial rules permit *viva voce* evidence, in this case the motion proceeded entirely on a written record. Unlike the recent summary trial decision in *Kobold Corporation v NCS Multistage Inc* where the Court made a determination based on expert reports from only one party (see our discussion here), on this motion the Court had written fact and expert evidence and cross-examination transcripts from all parties which the Court found gave it sufficient information to make its determination.

Two Burdens on Summary Trial

The Court first considered who had the burden of proof on this motion. Pharmascience clearly had the burden on the first step – whether this was an appropriate case for summary trial. However, there was a dispute about the burden when considering the merits at the second step.

Pharmascience argued that the burden on the merits should reflect that of the underlying action—*i.e.,* Janssen bears the civil burden of proof with respect to their allegation of infringement. Janssen argued that the burden was flipped on a summary trial, and that the moving party (Pharmascience) bears the burden of proof of establishing non-infringement.

After reviewing the case law and noting that there was conflicting jurisprudence, Justice Manson determined that on a motion for summary trial:

- The moving party has the burden to demonstrate that summary trial is appropriate.
- The burden and the onus of proof on the merits of the matter (*i.e*., infringement or validity) is that of the underlying action.

Justice Manson explained that the party asserting infringement in the underlying action bears the burden to prove the claim on a balance of probabilities at the motion for summary trial. Similarly, a party asserting validity in the underlying action bears the burden of proof on a balance of probabilities to prove validity at the motion for summary trial. On this motion, it was Janssen's burden to prove infringement on a balance of probabilities.

This finding was notable because, as stated by Justice Manson himself, he had come to the opposite conclusion in the recent *ViiV Healthcare Company v Gilead Sciences Canada, Inc* case, where he held that the moving party defendant bore the burden of proving non-infringement. It appears that, having considered this issue afresh, Justice Manson preferred to adopt the normal civil burden on the merits.

Induced Infringement

Janssen conceded that Pharmascience's product would not directly infringe the patent at issue, such that induced infringement was the only issue for determination.

Justice Manson stated, that while Janssen had the burden to prove infringement, as the Court has found in recent summary judgment motions (see our discussion here), Pharmascience must also put its best foot forward on the issues of non-

infringement.

The test for induced infringement requires:

1. direct infringement by a third party;
2. the inducer influenced the third party to the point that the infringing act would not have occurred without the influence; and
3. the defendant knew that its influence would bring about the infringing act.

The first element requires that the “act of infringement must have been completed by the direct infringer”. The Court determined that prescribing physicians would implement a dosing regime claimed in the patent.

The second element of the inducement test requires that “the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place”. Pharmascience argued that the ultimate dosing decision is based on the physician’s skill and judgment, not the language in the product monograph. Janssen argued that instructions from the alleged inducer as to the use of their product, such as a product monograph in the case of pharmaceuticals, can be the source of the influence even where the instructions are not followed in every instance. The Court determined that Pharmascience’s product monograph will influence at least some prescribers to implement the claimed dosage regime, such that the second element was met.

The third element of the inducement test requires that the inducer have knowledge of its influence. Justice Manson determined that Pharmascience had knowledge that its influence would bring about infringing acts because it was aware that its product monograph contained guidance on implementing the claimed dosage regimen.

Accordingly, the Court determined that Pharmascience would induce the infringement of Janssen’s patent. The Court conclusively decided all issues of infringement raised in the underlying action and stated that it will proceed to trial on the defences of invalidity as pleaded.

Commentary

The Federal Court has continued to use summary proceedings in complex matters in the patent and pharmaceutical space, as we had predicted in our trends to watch for 2022.

There has been discussion among the IP bar of how the Court’s increasing adoption of summary proceedings would

play out in the context of PM(NOC) proceedings. The Regulations require the Court to render a decision within 24 months of the start of the action. Such actions already proceed on a condensed timeline. In this case, the Court allowed the use of summary proceedings in a PM(NOC) proceeding, opening the door in appropriate circumstances. However, there was no explicit reference to this contextual aspect in the Court's analysis of the appropriateness of summary trial. It will be interesting to see if this infringement decision is appealed and how the timing of any appeal would impact, if at all, the timing of the trial on validity issues.

With the increased application of summary proceedings in patent cases, this motion also provided clarification on the burden of proof. The Court's commentary raises interesting questions for a plaintiff to consider when responding to a summary trial brought by the defendant on the basis of non-infringement. It also serves as a reminder to the responding party of the importance of the first step—whether the issue is appropriate for summary trial—since that may be the only step where the moving party bears the burden.

Interestingly, on the issue of induced infringement, this Court came to the opposite result from *Teva Paliperidone*, where the Court had found that Teva would not induce infringement. This decision is a helpful reminder as to the fact-specific nature of the Court's finding of induced infringement, as well as the need for sufficient evidence on this issue be it at trial or summary trial.

While the goal of this type of motion continues to improve efficiency, reduce costs, and save time, these motions remain complex and require extensive evidence. The application of summary proceedings continues to find traction with the Federal Court.