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Policing Scope Creep: Relevance in Canadian Pharma Disputes for Section 8 Damages

In Canada, a generic pharmaceutical company can commence an action for damages under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (the *"Regulations"*), if it successfully defends a patentee's claims in an earlier section 6 prohibition proceeding. Section 8 actions are often complex, requiring a determination of the alleged loss suffered by assessing a "but-for world" where the generic would have received regulatory approval and commenced sales at an earlier date, but for having been blocked by the operation of the *Regulations*. Depending on the drug(s) and patent(s) at issue, there may be several independent section 8 actions against a patentee, each started by a different generic plaintiff (see our previous post). When distinct section 8 actions are commenced pertaining to the same drug(s), patent(s), and patentee(s), issues as to relevance and scope of each action may arise.

This issue was recently canvassed on a motion to compel involving the drug abiraterone, used to treat prostate cancer, and Canadian patent 2,661,422 (the "422 Patent). In the recent decision of *Pharmascience Inc v Janssen Inc* (*"Abiraterone"*), the Court addressed several issues pertaining to relevance in discovery including settlement agreements and waiver. In this blog we highlight three aspects of the decision as it relates to section 8 proceedings and the Court's efforts to focus the scope of issues in dispute.

Background

The 422 Patent has been the subject of considerable litigation in Canada, both under the previous and current version of the *Regulations*. Most recently in 2019, Janssen commenced prohibition proceedings under the current version of the *Regulations* against each of Apotex, Pharmascience ("PMS"), and Dr Reddy's relating to their respective abiraterone products. Those actions were heard together and collectively dismissed after the Court found the 422 Patent invalid (*Janssen Inc v Apotex Inc*, 2021 FC 7; aff'd 2022 FCA 184). Each of Apotex, PMS, and Dr Reddy's then commenced section 8 actions against Janssen for damages. Janssen entered consent judgments with both Dr Reddy's and Apotex. The proceeding with PMS remains ongoing.

In *Abiraterone*, PMS was seeking an order by way of motion, to compel Janssen to answer various questions from discovery and produce related documents, particularly as it related to the actions with Apotex and Dr Reddy's. A common theme amongst the three aspects of the decision described below is PMS' unsuccessful attempts at pursuing issues in discovery beyond the scope of its own action into those of other parties.

Settlement Agreements

On the motion, PMS was seeking production of settlement agreements PMS believed Janssen may have entered into with Apotex and Dr Reddy's to resolve those respective section 8 actions. The Court refused to order production based on settlement privilege.

The Court emphasized that it "has long been recognized as a policy interest worth fostering that parties be encouraged to resolve their private disputes without recourse to litigation, or, if an action has been commenced, encouraged to effect a compromise without resort to trial" and that settlement privilege "is an effective tool to ameliorate the 'stubbornly endemic delays', expense and stress of litigation".

While there was no evidence of any agreement with Dr Reddy's or Apotex on the motion, the Court found it "self-evident" that should such agreements exist, they, and the negotiations leading up to them, would be protected by settlement privilege. The Court highlighted the lack of precedent, stating that the parties were unaware, as was the Court, of a decision where a defendant in a section 8 action was obliged to disclose settlement agreements reached with other parties in other section 8 proceedings relating to the same drug.

The Court also dismissed PMS' argument that Janssen waived its settlement privilege by having plead that had PMS received regulatory approval in the but-for world, several other generics

would have also entered the market. The Court held that Janssen was not relying on the fact that, in the real world, it reached a settlement with Apotex and Dr Reddy's, or the terms of any such agreement, only that certain agreements would have been concluded in the hypothetical but-for world. There was no waiver of privilege.

Cooperation Agreements

PMS also moved for production of purported cooperation agreements. PMS believed that Apotex and Dr Reddy's were assisting Janssen in the PMS section 8 action. PMS argued that if there were cooperation agreements in place, then those agreements would be relevant to the weight to be attributed to any evidence about the actions of Apotex and Dr Reddy's in the but-for world (such as the willingness and ability of Apotex and Dr Reddy's to enter the abiraterone market, as asserted by Janssen).

PMS argued that as a general principle, cooperation agreements must be disclosed. The Court dismissed this argument, distinguishing the authorities referred to by PMS, particularly on the basis that they did not address a cooperation agreement with a non-party as in this instance. While in multi-party litigation, agreements between various parties within the same action may change the adversarial relationship and significant unfairness could result from a lack of disclosure, the same is not the case with non-party agreements. The Court held that PMS could not force production and information about any cooperation agreements. In this regard the Court found the questions dealing with cooperation agreements were properly refused. The Court also held that in any event, PMS could ask questions on cross-examination at trial as to the circumstances leading to the testimony, including whether the evidence was voluntary or truly compelled by subpoena.

Alleged Waiver of Solicitor-Client Privilege

The Court was also seized with considering the issues of an alleged waiver of solicitor-client privilege and found there was no such waiver. In the context of discovery questions relating to the but-for world, Janssen was asked who would have decided to reach a settlement (or not) with Dr Reddy's in the but-for world. In response to the question Janssen answered that the decision would have been made with advice from two in-house counsel. PMS argued on the motion that since Janssen did not settle with Dr Reddy's in the real world, by necessary implication, these in-house counsel would have given different advice to guide Janssen to make a different decision on whether to settle and on what terms, and therefore, Janssen was relying on that advice in its defence. While not contesting

that the information was privileged, PMS argued Janssen had waived privilege in providing the discovery answer.

The Court emphasized that solicitor-client privilege is “fundamental to the proper functioning of our legal system and a cornerstone of access to justice”. The Court found that as a sophisticated corporation, it was expected Janssen would seek legal advice prior to or as part of its strategy. However, Janssen was not relying on the legal advice from in-house counsel it received in the real world as part of its defence of what would happen in the but-for world. As held by the Court, a “purely narrative reference to the giving of legal advice does not constitute waiver” and in this instance, Janssen was not “holding out what its lawyers said to justify actions, strategies or conduct”.

Conclusion

The *Abiraterone* decision offers useful guidance to patentees and generics as to the scope and relevance of issues in section 8 proceedings, particularly since as of the date of this post, no section 8 action has proceeded to trial since the amendments to the *Regulations* in 2017. Limiting non-party agreements and the potential for waiver about the but-for world sets important boundaries. The decision also highlights the active role of the Court to focus the issues in dispute in section 8 proceedings. As held by the Court: “Not that long ago, the conduct of discoveries and related motions was largely in the hands of the parties. Discoveries probed the furthest reaches of relevance, and discovery motions could stretch out over multiple days. Parties, lawyers, and the Court alike complained about the inefficiencies, both in terms of time and money. Fortunately for everyone involved, those days are long over”.