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June 7, 2016

The Rules of Evidence Still Apply in PMNOC Section 8 Cases

It's no surprise to litigators that some courts tend to be relaxed with the rules of evidence in civil cases. In many contexts, courts are prepared to admit inadmissible hearsay evidence and simply address evidentiary concerns by noting that such evidence may be given less weight. That type of approach was often taken in cases under section 8 of the *Patented Medicine (Notice of Compliance) Regulations*.

However, in the recent case of *Pfizer Canada Inc. v. Teva Canada Limited (Venlafaxine)*, the Federal Court of Appeal confirmed that the rule against admitting hearsay still applies in section 8 cases, and the Court returned the case to the trial judge with directions to exclude certain inadmissible hearsay evidence.

Under the *PMNOC Regulations*, a brand pharmaceutical manufacturer can bring a proceeding to prohibit the Minister of Health from issuing regulatory approval to a another pharmaceutical manufacturer's generic version of the brand product on the basis that the generic's product would infringe the brand pharmaceutical manufacturer's patent. However, if the brand pharmaceutical manufacturer's proceeding is ultimately dismissed or discontinued, the brand is liable to the generic for damages under section 8 of the *PMNOC Regulations* for the profits that the generic lost due to the brand manufacturer pursuing the proceeding.

The *Venlafaxine* case was an action brought by Teva Canada Limited against Pfizer Canada Inc. for damages pursuant to section 8 in relation to Teva's lost sales of its generic version of Venlafaxine, which Pfizer had marketed in Canada as Effexor. As in every section 8 case, the Federal Court had to construct a "but-for world": namely, but for Pfizer commencing its prohibition proceeding against Teva, what profits would Teva have made in connection with the sale of Venlafaxine?

One of the issues that Federal Court had to address in *Venlafaxine* was whether Teva would have been able to obtain sufficient active pharmaceutical ingredient (API) from its supplier, Alembic Pharmaceuticals, to supply the Venlafaxine market. Teva did not lead any evidence from Alembic employees, but instead led evidence of Alembic's ability to supply through one of Teva's former employees. That former

employee testified both to his own observations of Alembic's ability to supply API (which was not objected to), but also to information as to Alembic's capacity that was provided to him by others.

Pfizer objected to the admission of the latter category of evidence for the truth of its contents. However, the Federal Court admitted such evidence and the Court ultimately concluded that Teva could have obtained sufficient API from Alembic to be able to supply the market.

On appeal, the Federal Court of Appeal held that the trial judge had erred in admitting the employee's second-hand evidence as to Alembic's capacity to manufacture API.

The Federal Court of Appeal characterized the trend of some courts to "rule all relevant evidence as admissible, subject to their later assessment of weight" as "heresy". The Court of Appeal went on to hold that although evidence could be provisionally admitted, a trial judge would have to conclude that the evidence was properly admissible under the laws of evidence before relying on it.

These laws of evidence include the rule that hearsay evidence is presumptively inadmissible. The Federal Court of Appeal held that the admission of hearsay evidence distorts the truth seeking process by undermining the ability of an opposing party to effectively test the truth of that evidence on cross-examination:

> To be effective, cross-examination must be able to test many aspects of witnesses' testimony – their observation, perception, memory and narration of events or facts, their accuracy in recounting or perceiving them, and their sincerity and honesty as witnesses.
>
> All of these vital objectives are lost when witnesses testify second-hand about an event. When that happens, only their sincerity and honesty about what they were told can be tested. The person who actually knows first-hand about the event or fact is out of court, shielded from any testing of their observation, memory, accuracy, sincerity or honesty.

In the result, the Federal Court of Appeal returned the matter to the trial judge for redetermination, without any reliance on the inadmissible hearsay evidence of Teva's former employee as to Alembic's capacity to manufacture API.

The Federal Court of Appeal's decision is critical in reminding trial judges and lawyers that the rules of evidence still apply, even in the context of constructing the "but-for world" of section

8 cases. As in all cases, the “but-for world” must be built based on evidence from individuals with direct knowledge, so that such evidence can be properly tested on cross-examination.