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Pharma in brief - Canada

Federal Court comments on the admissibility of 'but for' world s. 8 evidence and rejects generic pipefill claim

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Case: *Eli Lilly Canada Inc et al v Teva Canada Limited*, 2017 FC 88
Drug: ZYPREXA® (olanzapine)
Nature of case: Action pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party: Teva Canada Limited
Date: April 4, 2017 (public reasons)

Summary

The Federal Court established the parameters to calculate Teva Canada Limited's damages for being delayed from entering the olanzapine market, clarified evidentiary issues on fact witnesses and hearsay, and rejected Teva's argument that its damages should include a pipefill adjustment.

Teva sought damages from Eli Lilly Canada Inc. pursuant to section 8 of the *Regulations*, as compensation for having been prevented from coming to market in 2006-2007 with a generic version of ZYPREXA® (olanzapine). ZYPREXA® is a medication primarily used to treat schizophrenia. Justice O'Reilly applied the legal framework set out in *Apotex Inc v Sanofi-Aventis*, 2012 FC 553 for determining the amount of compensation, if any, owed under section 8 of the *Regulations*, to determine the factual findings necessary for calculating Teva's damages.

Construction of the hypothetical world

The court considered two major evidentiary issues when construing the but-for world: (i) whether fact witnesses could testify about what they thought would or would not have happened in the but-for world; and (ii) the admissibility of hearsay evidence.

Fact witness testimony: The court agreed with Lilly that the opinions of fact witnesses are not admissible. Justice O'Reilly recognized jurisprudence that allows fact witnesses to, in a limited way, give evidence about a company's "general intentions in the hypothetical world" and "the general steps it took to prepare itself for entry into the market." Justice O'Reilly suggested that for some fact witnesses, they could be asked about what they did in the real world and then asked whether they knew of any reason why they would have acted differently in the but-for world. He held that some of the evidence from Teva's witnesses went into inadmissible opinion territory.

Use of hearsay evidence: The court also agreed with Lilly that hearsay evidence cannot be admitted unless it falls within a recognized hearsay objection or meets the criteria of necessity and reliability. The court rejected the admissibility of two pieces of evidence: (1) a Deloitte report containing information about Teva's trade-spend rate on its venlafaxine product; and (2) documents purporting to contain information about the rebates and other incentives that Teva would have paid to pharmacies. The court held that the Deloitte report had an unknown author and the details surrounding the report's preparation were not in evidence. Similarly, Teva did not call the author of the rebate documents as witnesses. The court relied instead on *viva voce* evidence from Teva's witnesses as to its trade-spend.

Applying the Ramipril analysis

Period of liability: The court found that the relevant period is from March 3, 2006, (the date Teva would have received its Notice of Compliance in the but-for world) to June 5, 2007 (the date the prohibition application was dismissed). Lilly argued the start date of the relevant period should be March 22, 2007, because, among other reasons, in the real world Teva filed a Notifiable Change to change the process of making olanzapine from process 1 to process 2. Teva could not have sold material containing olanzapine made using process 2 until after the Notifiable Change was approved on March 22, 2007. Justice O'Reilly rejected this argument, and held that while the evidence showed that Teva could not have marketed its product with process 2 API prior to March 22, 2007, it equally demonstrated that Teva could have sold olanzapine tablets containing process 1 API as of March 3, 2006.

Size of market: The parties agreed that the size of the olanzapine market in the but-for world would have been the same as it was in the real world. Entry of a generic manufacturer into the market would not have affected the overall olanzapine market.

Generic share of the market: The parties agreed on the methodology for determining the generic portion of the olanzapine market but disputed the speed with which Teva could have entered in each province, which depends on the date the generic could have obtained approval and listing on the provincial formularies. The court preferred the evidence of Teva's regulatory expert on the likely formulary listing dates for each province.

Teva's share of the market: The court rejected Lilly's assertion that Teva would have had to share the generic olanzapine market with another generic company, given that Lilly's real-world behaviour of continuing to pursue generics even after its proceeding against Teva was dismissed and there was no evidence at trial that the other generic was even in a position to come to market in 2006.

Real amount of Teva's losses: The court considered two issues: (i) should the calculation of Teva's losses include compensation for so-called pipefill and (ii) how much should Teva's losses be reduced to account for the monies it would have paid to pharmacies and other retailers of its product?

- **Pipefill:** Justice O'Reilly concurred with Lilly's expert, and held that pipefill does not represent lost sales during the liability period. He found that the preceding authorities on this issue were somewhat ambiguous on the issue, as in none of those cases was the issue seriously contested or a quantum specifically calculated. As only losses suffered during the liability period are compensable under the *Regulations*, Justice O'Reilly reasoned that a figure representing pipefill should not be added to Teva's losses.

- **Trade-spend:** The court was satisfied that in the 2006-2007 time frame, Teva's trade-spend would have been lower for generic olanzapine than it would have been for its other products, as Teva would have been the sole generic on the market during the relevant period.

Link to decision:

Eli Lilly Canada Inc et al v Teva Canada Limited, 2017 FC 88

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