

# \$125-million pharmaceutical damages award undone by hearsay rule

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Over the past several years, Canadian courts have considered claims for damages by generic drug companies kept off the market due to patents asserted by brand-name drug companies under Canada's pharmaceutical patent regulatory scheme (the *Patented Medicines (Notice of Compliance) Regulations*). In one such case, the Federal Court awarded \$125 million in damages (including interest) to Teva for being improperly kept off the market for its generic venlafaxine product. On May 31, 2016, the Federal Court of Appeal allowed an appeal of that decision on the basis that the trial judge had relied on inadmissible hearsay evidence in finding that Teva would be able to supply the market. The Court's judgment in *Pfizer Canada Inc. v. Teva Canada Limited*, 2016 FCA 161, delivered by Justice Stratas, signals a renewed attention to rigorous application of the rules of evidence, and is expected to have wide implications on the conduct of proceedings in the Federal Court.

The case arises under the *Patented Medicines (Notice of Compliance) Regulations*, under which brand-name drug companies may assert patents listed on the Patent Register to prevent approval of generic drug applications. An application under the *Regulations* triggers a 24-month stay preventing approval of the generic drug while the case is pending. Wyeth, now part of Pfizer, had sued ratiopharm, subsequently purchased by Teva, under the *Regulations*, in relation to a patent for its Effexor XR (venlafaxine) product. The patent was found to be improperly listed in association with Wyeth's product. The improper listing resulted in a delay of over 18 months before ratiopharm could enter the market.

The *Regulations* permit a generic company to claim for damages for the time they are kept off the market by an unsuccessful patent proceeding. At trial, Teva (claiming as ratiopharm's successor) was awarded \$125 million in damages, including prejudgment interest, for the delay it experienced before approval of its venlafaxine product.

One issue arising at trial was whether ratiopharm's supplier of raw venlafaxine was able and willing to make and deliver venlafaxine to supply the Canadian market. At trial, Teva led evidence from its Vice-President for Development Management and Regulatory Affairs that the supplier was so willing. He testified that he had received positive indications from a site visit, and he provided testimony in relation to several emails between his subordinates and the supplier. Pfizer objected to the emails as inadmissible hearsay evidence, but the trial judge determined that the evidence would be admitted and weighed appropriately. Although acknowledging that there was no direct witness from the supplier, the trial judge found the Teva evidence to be reliable on the supply issue.

The Federal Court of Appeal dismissed several grounds of appeal raised by Pfizer, but took great issue with the manner in which the hearsay evidence was handled. The Court noted that, as plaintiff, Teva bore the burden of proof in establishing that it could have had access to sufficient product and would have and could have used it. In his reasons, Justice Stratas

noted that some rules of evidence have been liberalized of late, and that:

[83] ... Seduced by this trend towards flexibility, some judges in various jurisdictions have been tempted to rule all relevant evidence as admissible, subject to their later assessment of weight. But according to our Supreme Court, this is heresy. ...

The Court ordered that evidence from the supplier and the Teva subordinates was hearsay evidence and not admissible. Justice Stratas emphasized the right of parties in a civil action to confront evidence presented against their positions, and determined that, "all of the mischief associated with admitting hearsay evidence is present in this case." The Teva witness could not provide direct, first-hand evidence of the operating capacity of the supplier, any constraints they faced or the steps they may have taken. The Court determined that the evidence was neither necessary nor reliable (which could have justified an exception to the hearsay rule), and further noted that hearsay evidence was not admissible to corroborate other evidence, provide evidence of a department head in place of their subordinate or attest to the state of mind of an author of emails that had not been authenticated.

The Court did not reweigh the evidence, instead remitting the matter back to the trial judge on the issue of whether ratiopharm (Teva) would have and could have had access to sufficient quantities of venlafaxine at the relevant time to supply the market, which has a direct impact on the damages to which it may have been entitled. However, in guiding the trial judge in the redetermination, Justice Stratas was prescriptive in the rigour with which the trial judge must identify the evidence relied upon and reasons justifying any inference drawn, with reference to particular jurisprudence on when and how inferences may be made.

In this decision, the Federal Court of Appeal has provided a roadmap for litigants, counsel and trial judges alike for the renewed standard by which trial evidence should be assessed in the Federal Court. The case signals a more careful attention to deliberate application of the rules of evidence, and in particular the rule against admissibility of hearsay evidence. At a minimum, parties before the Federal Court will now be keenly aware of the standards that may be applied by the Court in assessing evidence tendered in support of damages claims.