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Pharma in brief - Canada

Federal Court grants prohibition order against Apotex's proposed generic tenofovir disoproxil fumarate product

Case:	*Gilead Sciences, Inc v Apotex Inc*, 2016 FC 857 (Court File No. T-1694-14)
Drug:	VIREAD® (tenofovir disoproxil fumarate)
Nature of case:	Prohibition application pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations* (***Regulations***)
Successful party:	Gilead Sciences, Inc. and Gilead Canada, Inc.
Date of decision:	July 21, 2016 - Confidential Reasons; Public Reasons released August 23, 2016

Summary

Gilead Sciences Canada, Inc. markets tenofovir disoproxil fumarate (**TDF**) under the name VIREAD® for the treatment of HIV infection. Apotex sought approval to market a generic TDF product and was required to address Gilead's Canadian Patent No. 2,261,619 (**619 Patent**) under the *Regulations.* By this application, Gilead sought an order prohibiting the minister from approving Apotex's submission until the expiry of the 619 Patent.

The court allowed Gilead's prohibition application. Gilead established that Apotex's anticipation, obviousness, and inutility allegations were not justified.

Background

The 619 Patent relates to tenofovir disoproxil (**TD**, also known as **bis(POC)PMPA**), a prodrug of the nucleotide reverse transcriptase inhibitor tenofovir (also known as **PMPA**). This prodrug increases the oral bioavailability of the parent drug, tenofovir (PMPA). Gilead asserted only claim 32, which claims TD and its salts, tautomers and solvates.

The blinding of experts is a question of relevance, reliability and weight

The parties adopted different approaches towards the treatment of their expert witnesses. Gilead provided the legal framework regarding anticipation, obviousness, and utility to its experts early; Apotex withheld this information until after the experts had drawn their own conclusions on issues such as the promise of the patent, claim construction, and the prior art, but provided its experts with the prior art and common general knowledge. Justice Brown held that the blinding of experts (or lack thereof) may be a factor when determining relevance, reliability and weight, but it is not a matter that goes to admissibility. He preferred some experts on some issues, and other experts on other issues, taking into account the arguments raised by both parties and assessing the appropriate weight to be given to the expert testimony. In general, Justice Brown preferred the expert testimony of Gilead's experts.

Court is not bound by findings on invalidity allegations in previous NOC proceedings

Justice Brown held that the court was not bound by findings on invalidity allegations with respect to the 619 Patent in a previous NOC proceeding. He was not persuaded that he ought to apply comity except in the limited context of patent construction or another question of law.

Court rejects allegations that Claim 32 is invalid for anticipation, obviousness, or inutility

Anticipation. Justice Brown accepted Gilead's evidence that claim 32 was not anticipated by a European genus patent application alleged by Apotex to include TD. He held that there was no disclosure of a carbonate group moiety in the prodrugs described. Justice Brown also rejected Apotex's allegation that claim 32 was an invalid selection from the genus patent application, holding that even if the genus patent application included TD, Gilead's prodrug presented special advantages for efficient oral delivery that were not previously disclosed.

Obviousness. Justice Brown rejected Apotex's allegation that the discovery of the prodrug TD (bis(POC)PMPA) was obvious or obvious to try. He noted that, as argued by the parties, the inventive concept is "the addition of the bis(POC) moiety to PMPA." He held that reaching this inventive concept was a relatively long and arduous process that required an inventive spark and would not have been obvious to the unimaginative and uninventive skilled person.

Utility. Justice Brown held that the promised utility of the 619 Patent is the efficient oral delivery of the parent drug (tenofovir or PMPA) through its prodrug, which has a specific carbonate moiety (yielding TD or bis(POC)PMPA). He held that contrary to Apotex's allegations, efficacy in HIV treatment was a goal — not a promise. The experimental results disclosed in the 619 Patent were sufficient to demonstrate that bis(POC)PMPA efficiently delivered PMPA. Justice Brown also considered additional studies that showed the low bioavailability of PMPA and demonstrated the improved bioavailability of the prodrug (TD) compared to the parent (PMPA).

For these reasons, the court concluded that Apotex's allegations of invalidity were not justified.

Norton Rose Fulbright Canada acted for Gilead in this matter.

Link:

Gilead Sciences, Inc v Apotex Inc, 2016 FC 857