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Pharma in brief - Canada

FCA finds no failure to mitigate Apotex damages claim against Health Canada for delayed Apo-Trazodone NOC

Case: *Apotex Inc v Her Majesty the Queen,* 2017 FCA 73 (Court File No. A-553-14/A-554-14)
Drug: Apo-Trazodone
Nature of case: Appeal of action for damages in tort and breach of contract
Successful party: Apotex Inc. (in part)
Date of decision: April 6, 2017

Summary

The Federal Court of Appeal allowed Apotex's appeal, in part, from the Federal Court decision that found Apotex was entitled to damages for misfeasance of public office and negligence, finding that Apotex was not required to mitigate its damages by providing Health Canada with evidence of bioavailability of Apo-Trazodone based on a comparison to a Canadian reference product. Apotex had a legitimate business interest in establishing in principle that using a foreign reference product was appropriate. Health Canada's appeal and cross-appeal for errors related to the Federal Court's findings of negligence, misfeasance of public office and breach of a settlement agreement were dismissed.

Background

Apotex filed a submission to Health Canada in January 1988 for approval to sell Apo-Trazodone based on a comparison to a US reference product. At that time, Health Canada's policies on the ability to use a foreign reference product to obtain generic drug approval were unclear. Health Canada did not accept the Apo-Trazodone submission and required testing against a Canadian reference product.

In 1990, Health Canada informed Apotex it would not require a Canadian reference product if Apotex could provide evidence that the foreign product was identical to the Canadian product. Apotex refused, and brought an application to compel the minster to review its submission and issue an NOC. The parties reached a settlement and Apotex discontinued its application.

Pursuant to the settlement agreement, Apotex submitted further bioavailability data to establish equivalency between the US and Canadian reference products. Health Canada continued to refuse to issue the NOC, and Apotex brought a second application, which was dismissed in 1993. The Federal Court held that Health Canada's actions were not "patently unreasonable," but also concluded that Health Canada's refusal to consider Apotex's submission was an unlawful fettering of discretion. The court also held that Health Canada's manner of dealing with Apotex was "maladroit, at times dissembling if not actually misleading," but it was not acting "in bad faith or with malice."

Following additional exchanges with Health Canada, and seven years after filing its original submission, Apotex received its NOC for Apo-Trazodone in February 1995.

Federal Court decision

As we reported, Apotex was successful in its action for damages against Health Canada for lost sales during the period when it should have received its NOC and for the lost ability to be the first generic in the Canadian market for a trazodone product. The Federal Court found that Apotex was entitled to damages for public misfeasance and negligence, but was required to mitigate its damages.

The Court of Appeal upheld the Federal Court on all issues except the finding that Apotex failed to mitigate its damages. The court also commented on whether Health Canada owed Apotex a duty of care outside of the settlement agreement.

Apotex entitled to specific performance to receive NOC based on foreign reference product

The Federal Court of Appeal found that the Federal Court erred in finding the onus of proof has no role to play in assessing mitigation, as the defendant must establish the plaintiff failed to make reasonable efforts to mitigate its losses. The Federal Court also erred in dictating a single reasonable course of action (i.e., using a Canadian reference standard) and failing to consider the reasonableness of Apotex's actual course of conduct.

As a result of these errors, the Federal Court failed to review Apotex's actions to determine whether Apotex made reasonable efforts to mitigate. The Court of Appeal therefore reviewed Apotex' conduct, and held that Apotex had a legitimate interest in specific performance. Between September 1976 and 1995, Apotex could point to four instances when it had received an NOC using a foreign reference product. Apotex had a clear business interest in establishing that foreign reference products were acceptable as a matter of general principle. The Court of Appeal held that where a plaintiff has a substantial and legitimate interest in seeking specific performance of a defendant's obligation, a failure to mitigate is justifiable, and Apotex's choice to pursue litigation was therefore reasonable.

No duty of care owed outside of the settlement agreement

The Court of Appeal rejected Apotex's claim that the Federal Court erred in failing to conduct an analysis of negligence outside of Health Canada's liability arising from the settlement agreement, holding that as the *Food and Drugs Act* and Regulations are neutral on the existence of a *prima facie* duty of care and the legislation is directed to public health and safety through regulation of drug manufacturers, it is difficult to infer that Parliament intended Health Canada to owe a *prima facie* duty of care to drug manufacturers. Requiring Health Canada to be mindful of Apotex's economic interests when exercising its discretion would place Health Canada in a position of conflict between its obligation to Apotex and its duty to the public.

Furthermore, the Court of Appeal found that prior to entering into the settlement agreement, there was not sufficient proximity to establish a duty of care as Apotex's relationship with Health Canada was not distinct from Health Canada's relationship with any other drug manufacturer. Entering into the settlement agreement established the requisite proximity for a duty of care to exist, and policy considerations arising from Health Canada's role as a regulator did not negate this duty.

Link:

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