

## Pharma in brief - Canada

### Sound prediction of patent utility disclosure requirements remain in flux: Federal Court dismisses gatifloxacin prohibition application

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<b>Case:</b>	<i>Allergan Inc. v Apotex Inc.</i> , 2016 FC 344
<b>Drug:</b>	ZYMAR <sup>®</sup> (gatifloxacin)
<b>Nature of case:</b>	Prohibition application pursuant to section 6 of the <i>Patented Medicines (Notice of Compliance) Regulations</i> , SOR/93-133 (the <b>Regulations</b> )
<b>Successful party:</b>	Apotex Inc.
<b>Date of decision:</b>	April 1, 2016

#### Summary

Allergan Inc. (**Allergan**) markets gatifloxacin ophthalmic solution in Canada under the name ZYMAR<sup>®</sup> for use in the treatment of bacterial infection. In response to a notice of allegation (**NOA**) from Apotex Inc. (**Apotex**) alleging invalidity of Canadian Patent No. 2,307,632 (the **632 Patent**) pertaining to gatifloxacin, Allergan instituted an application for a prohibition order under section 6 of the *Regulations*. Justice Zinn dismissed Allergan's application, finding the invention disclosed in the 632 Patent to be obvious and lack utility.

#### Background

The 632 Patent contains ten claims; in this proceeding, Allergan asserted only claim 10. Claim 10 covers an aqueous liquid pharmaceutical composition in the form of eye drops wherein the pH of the composition is within the range of 5 to 8 which comprises gatifloxacin or its pharmaceutically acceptable salt in an amount of 0.1 to 1.0 w/v% and disodium edetate (**EDTA**) in an amount of 0.01 to 0.1 w/v%.

#### No disclosure of factual basis for a sound prediction of utility

Apotex argued that the promised utility of claim 10 included the same advantages that formed part of the inventive concept, discussed below. The Court agreed, preferring Apotex's evidence and its reading of the patent as a whole over Allergan's argument that the advantages were mere goals, not promises.

As Claim 10 covered many compositions, including compositions that were not tested by the inventors, Zinn J held that this was a case of sound prediction, not demonstrated utility. The Court declined to follow recent jurisprudence in the Federal Court holding that the factual basis for a sound prediction of utility need not be disclosed in the patent itself, other than in new-use patents. The Court also accepted Apotex's evidence that the data contained in the 632 Patent did not provide a factual basis for a sound prediction that the entire range of EDTA concentrations specified by claim 10 would prevent precipitation of gatifloxacin crystals.

As a result, the Court held that Apotex's inutility allegation regarding claim 10 was justified.

## The combination of gatifloxacin and EDTA was obvious

Referring to the specification as a whole, Zinn J accepted that the inventive concept of claim 10 was an aqueous composition containing gatifloxacin and EDTA in the amounts specified, useful for one of: increasing the corneal permeability of gatifloxacin; preventing precipitation of gatifloxacin crystals; and preventing colouration of the gatifloxacin solution (the **Advantages**).

The Court accepted Apotex's evidence that although the skilled person would not have known with absolute certainty that the claimed combination would yield these Advantages, "each was known to some degree and was not an unexpected consequence of the combination". The skilled person would therefore have had more than a fair expectation of success that "combining gatifloxacin with EDTA would produce an effective ophthalmic compound" with the Advantages, and the skilled person would have "had good reason to pursue the known options within his or her technical grasp", i.e. the combination of gatifloxacin and EDTA.

For these reasons, Apotex's obviousness allegation regarding claim 10 was justified.

## Blinded expert evidence preferred

The Court preferred the evidence of Apotex's blinded expert affiant over that of other expert affiants who had previously given evidence in proceedings regarding the corresponding US patent.

Justice Zinn held that because certain affiants had prior knowledge of the 632 Patent and the positions of the parties when offering their opinions, their evidence was to be given less weight on issues of construction and obviousness than that of Apotex's one "blinded" expert. The Court also held that the blinded expert's experience was most closely related to the evidence.

## Appeal sought

Following release of the confidential reasons on 22 March 2016, Allergan appealed the Court's judgement in this case (Court File No. A-96-16).

## Link to decision:

[Allergan Inc. v Apotex Inc., 2016 FC 344](#)

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