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Pharma in brief - Canada

Federal Court dismisses prohibition application relating to naproxen and esomeprazole magnesium tablets

Case:	*AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2017 FC 142
Drug:	VIMOVO® (naproxen and esomeprazole magnesium tablets)
Nature of case:	Prohibition application pursuant to section 6 of the *Patented Medicines (Notice of Compliance Regulations)*, SOR/93-133 (the ***Regulations***)
Successful party:	Mylan Inc. (**Mylan**)
Date of decision:	February 7, 2017

Summary

AstraZeneca Canada Inc. markets VIMOVO® (naproxen and esomeprazole magnesium tablets) in Canada to treat pain, inflammation and various medical conditions. Mylan sought approval for a generic version of VIMOVO® and was opposed by AstraZeneca and Pozen Inc., which asserted Canadian Patent No. 2,449,098 (the **098 Patent**) under section 6 of the *Regulations*. Mylan's allegations included invalidity on the basis of obviousness, lack of utility and overbreadth. The court found that Mylan's allegations of obviousness were justified and dismissed the application. Given his findings on obviousness, Justice Diner held that there was no need to address utility or overbreadth.

Background

The 098 Patent claims a dosage form that provides the sequential release of an acid inhibitor followed by a non-steroidal anti-inflammatory drug (**NSAID**). The patent also claims use of this dosage form to treat pain, inflammation and other medical conditions.

Obviousness

Justice Diner found the difference between the inventive concept and the state of the art to be the application of a sequential release profile in an NSAID-proton pump inhibitor (**PPI**) co-formulation, where part or all of the PPI would be released immediately, with a delayed release of the NSAID at a higher pH. Given his findings on the state of the art, including that NSAID-PPI combination therapies were well known and that a tablet with an enterically coated NSAID core surrounded by a gastroprotective compound was marketed at the time, he held that bridging this difference did not require any degree of invention.

Obvious to try analysis

Justice Diner also concluded that the inventive concept of the 098 Patent was obvious to try as (i) there were a limited number of predictable solutions that were more or less self-evident to the skilled person (including the marketed tablet having an enterically coated NSAID core surrounded by a gastroprotective compound), (ii) only a limited amount of effort was required to achieve the inventive concept and (iii) there was a strong motivation from the prior art to combine an NSAID with a PPI in a single fixed-dose combination having a sequential release profile. Justice Diner also

disagreed that there would be no incentive to try something if it has no known inventive benefit, holding that the newness of an idea does not prevent such an idea from also being obvious. He held that a contextual approach should be used when assessing motivation, rather than focusing on whether the motivation was specific or general.

Expert witnesses

Justice Diner rejected both parties' allegations that the experts for the other side were not impartial, holding that the evidence presented did not meet the burden of showing that an expert was unable or unwilling to fulfill his or her duty to the court. He also held that the blinding of experts does not necessarily produce a more reliable outcome, citing Justice Locke's previous decision in *Shire Canada Inc v Apotex Inc*, 2016 FC 382 (reported here). He found that the preparation of witnesses by both parties was acceptable and no evidence should be excluded on this basis.

Link to decision:

Astrazeneca Canada Inc v Mylan Pharmaceuticals ULC, 2017 FC 142

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