

Federal Court



Cour fédérale

**Date: 20140808**

**Docket: T-1666-12**

**Citation: 2014 FC 699**

**Ottawa, Ontario, August 8, 2014**

**PRESENT: The Honourable Madam Justice Kane**

**BETWEEN:**

**ALCON CANADA INC. and  
ALCON RESEARCH, LTD.**

**Applicants**

**and**

**APOTEX INC. and  
THE MINISTER OF HEALTH**

**Respondents**

**PUBLIC JUDGMENT AND REASONS**  
**(Confidential Judgment and Reasons issued July 15, 2014)**

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## I. OVERVIEW

[1] This application is brought under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended [*NOC Regulations*] by Alcon to prohibit the Minister of Health from issuing a Notice of Compliance to Apotex in respect of its generic product (the Apotex product) until the expiry of Canadian Letters Patent No 2,129,287 (the '287 Patent) on August 3, 2014.

[2] For the reasons that follow, I find that the allegations with respect to the invalidity of the claims at issue for anticipation and obviousness are justified and the allegations with respect to invalidity for lack of utility are not justified.

[3] The application is dismissed with costs to the respondent.

## II. INTRODUCTION

[4] Glaucoma is a disease of the eye resulting in a progressive loss of vision due to increased intraocular pressure ["IOP"], which is the pressure within the aqueous humour of the eye. There is no cure for glaucoma, however, it can be managed by reducing IOP. Such treatment is ongoing or "chronic" and requires the patient to take medication daily, generally for life, to maintain the IOP at a reduced level.

[5] According to the inventors of the '287, drugs were available to treat glaucoma and ocular hypertension prior to the invention of the '287, but they had undesirable effects.

[6] As the experts, Dr deLong and Dr Wolfe, described, prostaglandins [PGs] are a large class of biologically active chemical compounds with many different roles in the body. PGs, and in particular  $\text{PGF}_{2\alpha}$  and their derivatives, were known to reduce IOP since at least the mid 1980s (and Dr deLong suggests as early as 1977).

[7] Although naturally occurring prostaglandins were known to reduce IOP, there were side effects, particularly irritation and hyperemia (blood shot eyes). The goal was therefore to develop a compound that reduced IOP without the side effects. Synthetic prostaglandins also led to side effects, however, various methods may be used to reduce or eliminate the side effects.

[8] Fluprostenol is a PG, more specifically, a synthetic analogue of  $\text{PGF}_{2\alpha}$ , a naturally occurring prostaglandin. Alcon notes that the isopropyl ester of (+)-fluprostenol, known as travoprost, is the active ingredient in Travatan Z marketed by Alcon for the treatment of glaucoma. Apotex seeks to market its own product, Apo-Travoprost, also for the treatment of glaucoma.

[9] Apotex alleges that it does not infringe the claims of the Patent at issue, the '287, because the claims are invalid. Apotex alleges that the patent is a selection patent from the genus of European Patent Application, (EP 0 364 417, referred to as the '417), and that it has not lived up to its promise of the substantial advantages over the '417 and specifically that its utility was not demonstrated or soundly predicted. Apotex alternatively alleges that if the '287 is not a selection patent, but a species patent as Alcon asserts, then it is not novel as it does only what the '417 promised, it is anticipated by the '417, and it is obvious.

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