

2014 FC 699, 2014 CF 699  
Federal Court

Alcon Canada Inc. v. Apotex Inc.

2014 CarswellNat 2996, 2014 CarswellNat 4494,  
2014 FC 699, 2014 CF 699, 122 C.P.R. (4th)  
109, 244 A.C.W.S. (3d) 181, 459 F.T.R. 255

Alcon Canada Inc. and Alcon Research,  
Ltd., Applicants and Apotex Inc. and  
The Minister of Health, Respondents

Catherine M. Kane J.

Heard: May 12-13, 2014

Judgment: August 8, 2014 \*

Docket: T-1666-12

Proceedings: additional reasons at *Alcon Canada Inc. v. Apotex Inc.* (2014), 2014 CF 794, 2014 CarswellNat 3307, 2014 CarswellNat 2995, 2014 FC 794, Catherine M. Kane J. (F.C.)

Counsel: Gunars Gaikis, Sheldon Hamilton, Tracey Stott, for Applicants, Alcon Canada Inc. et al.

Andrew Brodtkin, Dino Clarizio, Jordan Scopa, for Respondent, Apotex Inc.

No one for Minister of Health

Subject: Civil Practice and Procedure; Evidence; Intellectual Property; Property

#### Table of Authorities

##### Cases considered by *Catherine M. Kane J.*:

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*Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.* (1984), [1985] R.P.C. 59 (Eng. C.A.) — followed

#### Statutes considered:

*Patent Act*, R.S.C. 1985, c. P-4

Generally — referred to

#### Tariffs considered:

*Federal Courts Rules*, SOR/98-106

Tariff B, Table, column IV — referred to

#### Regulations considered:

*Patent Act*, R.S.C. 1985, c. P-4

*Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133

Generally — referred to

APPLICATION for order prohibiting Minister of Health from issuing notice of compliance.

#### Catherine M. Kane J.:

##### 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.

10 Apotex argues that Alcon cannot characterize the '287 as a novel compound with unstated advantages, rather than a selection patent, yet rely on its unstated advantages to support its novelty. If it is novel then it will fail for want of utility because it does not meet its promise.

11 Alcon acknowledges that the '417 application discloses a huge genus of compounds, and that travoprost is included generically in this genus, but argues that the '417 application describes what Alcon refers to as a "functional carve out" of compounds that are not useful due to their side effects. Fluprostenol (and its esters) was carved out, therefore fluprostenol (travoprost) does not fall within the '417 and it is not anticipated or obvious due to the reference in the '417. Alcon also argues that the promised utility of the '287 was soundly predicted.

12 The construction of the claims at issue is not in dispute. However, the determination of the allegations of invalidity is dependant upon the promise of the patent and the inventive concept of the claims, which are in dispute.

## III. The Parties

13 The applicant, Alcon, is a "first person" as described in the *NOC Regulations*. It has listed the '287 Patent in accordance with the Regulations. Alcon obtained a Notice of Compliance [NOC] to sell travoprost, which it does under the brand name Travatan Z, from the Minister of Health.

14 The applicant, Alcon, is the owner of the '287 Patent and this is not contested.

15 The respondent, Apotex, is a "second person" as described in the *NOC Regulations*. In order to sell a generic version of travoprost, as Apo-Travoprost, it must receive a NOC from the Minister of Health. In accordance with the *NOC Regulations*, Apotex served Alcon with a Notice of Allegation [NOA] dated July 25, 2012.

16 In the NOA, Apotex alleges that claims 12, 27, 35 and 46 of the '287 Patent would not be infringed, and that the patent is invalid on the grounds of anticipation, obviousness, and lack of utility (alternative). Apotex also alleges that it does not infringe any valid claim in making, constructing, using or selling its Apotex product.

17 The applicant argues that the allegations advanced by Apotex do not align with its NOA. This issue is addressed later in these reasons.

18 The respondent, the Minister of Health, who has various responsibilities under the *NOC Regulations*, including the issuance of an NOC to a "second person" such as Apotex, took no active role in these proceedings.

#### IV. The '287 Patent Generally

19 Canadian Letters Patent 2,129,287 were applied for by an application deemed to be filed with the Canadian Patent Office on August 2, 1994. The Patent is therefore governed by the provisions of the new *Patent Act*, RSC 1985 c P-4, that governs patents applied for after October 1, 1989.

20 The application was filed under the provisions of the Patent Cooperation Treaty [PCT] and claims priority from a first application filed in the United States Patent Office on August 3, 1993. This is the date upon which the issues of anticipation and obviousness will be determined.

21 The date of filing in Canada, August 2, 1994, is the date upon which the issue of (utility) sound prediction will be determined.

22 The publication date, i.e. the date at which the patent was open to the public for inspection, was February 4, 1995. This is the date that is to be used for the purposes of the construction of the claims.

23 The '287 Patent lists the inventors as Paul W Zinke, Peter G Klimko, John E Bishop, Verney L Sallee, and Louis Desantis Jr, all of the United States of America. Only Peter Klimko provided evidence in these proceedings.

24 The '287 Patent was issued to Alcon Laboratories Inc, US.

25 The term of the '287 Patent, unless declared as invalid, will expire 20 years from the date of the filing of the application in Canada, which is August 2, 2014.

26 There are 54 claims in the '287 Patent, four of which are at issue in this proceeding (Claims 12, 27, 35 and 46). The construction of the claims and the inventive concept of the patent are addressed below.

#### V. The Evidence

27 The evidence in this proceeding was provided in the form of affidavits and transcripts of cross-examinations of experts along with their exhibits. All of the experts were cross-examined. Each party also submitted as evidence the affidavits of law clerks to place documents on the record and attest to facts.

28 The evidence on the record includes the following:

##### *A. For the applicant, Alcon:*

###### *(1) Kingsley Koo:*

29 Kingsley Koo is a law clerk at Alcon's solicitor's office. His affidavit attaches a variety of documents, such as the '287 patent, Apotex's Notice of Allegation, Apotex's prior art references, and the Travatan Z product monograph.

###### *(2) Dr Peter Klimko:*

30 Dr Peter G Klimko is an inventor on the '287 patent. Dr Klimko is a medicinal chemist at Alcon Research, Ltd, in Fort Worth, Texas. He has worked at Alcon since 1993, after earning his PhD in organic chemistry from Texas A&M University in May 1992. He discussed the work conducted by Alcon leading to the filing of the '287 patent, including biological test results. His affidavit reiterates, to a great extent, the contents of the '287 and sets out his role in the development of the patent.

###### *(3) Dr Mitchell deLong:*

31 Dr deLong is an adjunct professor in the department of chemistry at Duke University, and holds a PhD in synthetic organic and medicinal chemistry. He is vice-president of chemistry at Aerie Pharmaceuticals Inc, a company which specializes in the development of ocular drugs. Dr deLong has 20 years experience in medicinal chemistry with prostaglandins and glaucoma treatments. For 13 years, he was a senior scientist at Procter & Gamble, from 1992 to 2005, researching the use of prostaglandins to treat a variety of illnesses.

32 Dr deLong was called upon by the applicant to review the '287 patent and provide an opinion on its construction, as well as utility and novelty. His opinion is detailed, and sets out the person skilled in the art, prior art, and the promise of the patent, among other opinions. He also provides a chemistry primer, explaining prostaglandins,

their therapeutic effects, and the type of drug in issue in this case.

**B. For the respondent, Apotex:**

*(1) Lisa Ebdon:*

33 Lisa Ebdon is a law clerk at the respondent, Apotex's, solicitor's office. Her affidavit attaches a variety of documents, including Apotex's Notice of Allegation, the prior art references, and a copy of the '287 patent.

*(2) Dr Manfred Wolff:*

34 Dr Manfred E Wolff is a pharmacist and a patent agent. He holds a PhD in medicinal chemistry, and is currently president and CEO of Intellepharm Inc. Dr Wolff was asked to comment on the person skilled in the art, and what that person would have understood as the subject matter in the '287 patent, as well as the claims of the patent. He also examines the state of the art and common general knowledge of the skilled person at the relevant date, the inventive concept of the '287 patent, and the difference between the two. His affidavit focuses on anticipation and obviousness. He also commented on the evidence of Alcon's experts.

*(3) Dr Thomas Mittag:*

35 Dr Thomas W Mittag is a professor emeritus of ophthalmology and pharmacology at the Mount Sinai School of Medicine. Dr Mittag was asked to provide an overview of the state of the art as of the relevant date, how the patent would have been understood as of February 4, 1994, as well as to comment on who the skilled person is. He also examined the inventive concept of the claims of the '287 patent, the differences between the state of the art and the inventive concept as of the relevant date, and whether the skilled person would have considered this routine work or inventive. His affidavit focuses on anticipation, obviousness, and utility, in the form of sound prediction.

**VI. Issues**

36 The principal issue is whether to grant an Order prohibiting the Minister of Health from granting a Notice of Compliance to Apotex for its generic product (Apo-Travoprost) until the expiry of the '287 Patent. This determination depends upon whether the allegations raised by Apotex as to the invalidity of the '287 Patent (and non-infringement) are justified.

37 Apotex alleges the '287 patent is invalid on the basis of utility, anticipation, and obviousness.

38 The key area of disagreement between the applicant and respondent (and from which the other issues depend) is the meaning of the patent i.e., what is the promise of the patent and what is the inventive concept (of each claim).

39 The parties also disagree on the characterisation of the '287 patent as a "selection patent". The applicant, Alcon, does not assert that the '287 is a selection patent from the genus in the '417; rather, it argues that it is a novel compound or invention with a promised utility of being useful in the treatment of glaucoma and ocular hypertension.

**A. Alcon's overall position**

40 Alcon markets Travatan Z, which is travoprost, described by Alcon as the isopropyl ester of (+)-fluprostenol, structurally a "16-phenoxy" type of prostaglandin for the treatment of glaucoma.

41 The claims of the '287 Patent at issue (12, 27, 35 and 46) relate to pharmaceutically acceptable esters of fluprostenol for the treatment of glaucoma.

42 Alcon submits that the claims are valid: they were not anticipated by '417 Application; they were not obvious; and, the use of fluprostenol esters for the treatment of glaucoma was soundly predicted.

43 Alcon submits that the '417 references a huge genus of 800 billion compounds, but it only evaluated 11 compounds and only one of those compounds, Compound 4, is a 16-phenoxy (which Alcon submits is the most closely related to fluprostenol). This evaluation revealed that Compound 4 displayed an unacceptable therapeutic profile. Alcon submits that the '417 specifically excludes (or "functionally carves out") from its invention all non-therapeutically useful compounds. Therefore, Compound 4 was not included in the '417 and the '287 could not be anticipated by a compound which was excluded (or "carved out"). Alcon argues that for the same reason, the '287 could not be a selection from the '417.

44 Alcon acknowledges that fluprostenol is within the huge genus of the '417, but it is not referenced in any way in the '417 and was not disclosed.

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