

Federal Court



Cour fédérale

**Date: 20140501**

**Docket: T-1550-12**

**Citation: 2014 FC 403**

**Toronto, Ontario, May 1, 2014**

**PRESENT: The Honourable Mr. Justice Hughes**

**BETWEEN:**

**BAYER INC. AND BAYER PHARMA  
AKTIENGESELLSCHAFT**

**Applicants**

**and**

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

**Respondents**

**REASONS FOR JUDGMENT AND JUDGMENT**

[1] This is a proceeding commenced by the Applicants Bayer Inc. and Bayer Pharma Aktiengesellschaft (collectively Bayer) under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR / 93-133 (*NOC Regulations*) to prohibit the Minister of Health from issuing a Notice of Compliance to the Respondent Apotex Inc. in respect of its proposed drospirenone + ethinylestradiol product until the expiry of Canadian Letters Patent No. 2,179,728 (the '728 Patent).

[2] The term of '728 Patent, applied for and granted under the provisions of the "new" *Patent Act*, RSC 1985, c. P-4, will expire on December 22, 2014, that is, in approximately seven (7) months time. In another proceeding brought by the same Applicants Bayer et. al. against a different generic pharmaceutical company, Cobalt Pharmaceuticals Company, Federal Court Docket No. T-215-12 (Cobalt Proceeding), I issued Reasons for Judgment and a Judgment, cited as 2013 FC 1061. I determined that Cobalt's allegations as to non-infringement of the asserted claims of the '728 Patent were justified and that the allegations that claims 1, 2, 6 and 7 of the '728 Patent were not patentable because they were directed to a method of medical treatment, were justified.

[3] My decision respecting the '728 Patent is under appeal to the Federal Court of Appeal (A-385-13). I understand that, as of this moment, a Record has been filed with the Court of Appeal as have memoranda of argument of each party, but that no date for the hearing of that appeal has been set. Whether that appeal will be determined before the expiry of the '728 Patent is unknown at this time.

[4] A few weeks before the hearing of the present application was to commence, I held a pre-trial conference with Counsel for the parties. I advised them that I had reviewed the Record in this matter and the memoranda of argument filed by each of the parties Bayer and Apotex in this matter. The Minister of Health has taken no active role in these proceedings. I advised the parties that, based on my review of these materials, I was unlikely to come to any different conclusions in respect of the allegations raised by Apotex in the present application than the conclusions that

I had reached in the earlier Cobalt Proceeding. I invited the parties to consider their position in this matter.

[5] On April 22, 2014 Counsel for Apotex filed a letter with the Court, written on behalf of both Apotex and the Applicants, advising as follows with respect to the '728 Patent:

*The parties will not be making any submissions in Court File No. T-1550-12, it being understood that the application will be dismissed by the Court on the basis of the Reasons for Judgment in Court File No. T-215-12 (the "Cobalt Proceeding").*

[6] Accordingly, I will adopt the Reasons that I gave respecting the '728 Patent in the Cobalt Proceedings (2013 FC 1061) and the determinations that I made as set out in those Reasons. I will dismiss the present application.

[7] The matter of costs arises. The Court has been critical of situations where multiple proceedings have been taken in respect of the same patent under the *NOC Regulations* where a previous determination has been made as to the justification of allegations as to infringement and/or validity. *NOC* proceedings are directed simply as to whether the Minister should be prohibited from issuing a Notice of Compliance to a generic pharmaceutical entity. Other types of proceedings including actions are available to parties challenging the validity of a patent or alleging infringement of a patent. The Court has endeavoured, through its Case Management process, to get those matters to a hearing or trial within a reasonable period of time. There is little need to relitigate a patent under the *NOC Regulations* except where significantly different issues are raised or significantly different new evidence is placed on the record.

[8] The present application was filed before the release of my decision in the Cobalt Proceedings, thus the Applicants cannot be faulted for instituting these proceedings. However, there must be cost consequences for continuing these proceedings after the release of the decision in the Cobalt Proceedings on October 22, 2013, particularly given the imminent expiry of the patent. Shortly after the release of my decision in the Cobalt Proceedings, on October 24, 2013, the solicitors for Apotex sent an e-mail to the solicitors for Bayer inviting them to terminate the present proceedings. Bayer's solicitors responded that they would not.

[9] Accordingly, I will award costs and disbursements to Apotex at the middle of Column IV up to October 25, 2013 and as suggested by Apotex, costs at the middle of Column IV plus 25% thereafter. There is no 25% premium on disbursements. In assessing the fees charged by any expert they shall not exceed the fees charged by senior Counsel for Apotex for a like amount of time.

[10] No costs will be awarded to or against the Minister of Health.

**JUDGMENT**

**FOR THESE REASONS PROVIDED, THIS COURT ORDERS AND ADJUDGES**

**that:**

1. This Application is dismissed;
2. The Respondent Apotex is entitled to costs and disbursements to be paid by the Applicants Bayer as assessed in accordance with the Reasons herein.

“Roger T. Hughes”

---

Judge

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-1550-12

**STYLE OF CAUSE:** BAYER INC. AND BAYER PHARMA  
AKTIENGESELLSCHAFT v APOTEX INC. AND THE  
MINISTER OF HEALTH

**PLACE OF HEARING:** TORONTO, ONTARIO

**DATE OF HEARING:** APRIL 29 & 30, 2014

**REASONS FOR JUDGMENT  
AND JUDGMENT:** HUGHES J.

**DATED:** MAY 1, 2014

**APPEARANCES:**

Peter Wilcox, Lindsay NeidraueAriel Neuer	FOR THE APPLICANTS
Andrew Brodtkin Jenene Roberts	FOR THE RESPONDENT (Apotex Inc.)
No appearance	FOR THE RESPONDENT (The Minister of Health)

**SOLICITORS OF RECORD:**

BELMORE, NEIDRAUER LLP Barristers and Solicitors Toronto, Ontario	FOR THE APPLICANTS
GOODMANS LLP Barristers and Solicitors Toronto, Ontario	FOR THE RESPONDENT (Apotex Inc.)
William F. Pentney Deputy Attorney General of Canada	FOR THE RESPONDENT (The Minister of Health)