Federal Court  Cour fédérale

Date: 20130219

Docket: T-599-11
Docket: T-679-11

Citation: 2013 FC 142

BETWEEN:

Docket: T-599-11

NOVARTIS PHARMACEUTICALS CANADA INC.

Applicant

and

APOTEX INC. AND THE MINISTER OF HEALTH

Respondents

and

NOVARTIS AG

Respondent/ Patentee

AND BETWEEN:

Docket: T-679-11

NOVARTIS PHARMACEUTICALS CANADA INC.

Applicant

and

TEVA CANADA LIMITED AND THE MINISTER OF HEALTH

Respondents

and

NOVARTIS AG

Respondent/ Patentee

PUBLIC REASONS FOR JUDGMENT
(Confidential Reasons for Judgment released February 8, 2013)

SNIDER J.

I. Introduction

[1] Novartis AG (Novartis) is the recorded owner of Canadian Patent No. 2,093,203 (the '203 Patent), a patent applied for on April 1, 1993, granted to Novartis on November 26, 2002, and which will expire on April 1, 2013. Novartis Pharmaceuticals Canada Inc. (Novartis Canada), an affiliate of Novartis, sells a drug in Canada with the trademark of GLEEVEC, which is best known as a highly-effective drug for the treatment of chronic myeloid leukemia (CML). The active ingredient in GLEEVEC is imatinib mesylate. Imatinib and its salt, imatinib mesylate, are compounds included in the '203 Patent.

[2] Teva Canada Limited (Teva) and Apotex Inc. (Apotex) wish to sell generic versions of imatinib and they have, separately, taken three steps to enable them to do so. Specifically, each has:

(a) applied to the Minister of Health (the Minister) for a Notice of Compliance (NOC) in respect of orally administered 100 mg and 400 mg tablets containing imatinib, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *PM (NOC) Regulations* or *Regulations*);

(b) served Novartis Canada with a Notice of Allegation (NOA) with respect to the '203 Patent, in which Teva or Apotex, as applicable, alleges that all or certain claims of the '203 Patent are invalid; and

(c) commenced an action against Novartis, seeking a declaration under s. 60(1) of the *Patent Act*, RSC 1985, c P-4 (*Patent Act*) that some or all of the claims of the '203 Patent are invalid (the Teva Impeachment Action in Court File No. T-2021-10 and the Apotex Impeachment Action in Court File No. T-833-11).

[3] In response to each of the NOAs, Novartis Canada filed a Notice of Application requesting that the Court: (a) declare the NOA to be a nullity; or (b) issue an Order of Prohibition in accordance with s. 6(1) of the *PM (NOC) Regulations* preventing the Minister of Health from authorizing the second person to market imatinib until the expiry of the '203 Patent. The two applications are the subject of these reasons for judgment and are referred to as follows:

1. the Teva Prohibition Application filed by Novartis Canada on April 18, 2011 (Court File No. T-679-11); and

2. the Apotex Prohibition Application filed by Novartis Canada on April 8, 2011 (Court File No. T-599-11).

[4] By Order of Prothonotary Tabib dated May 30, 2011, the Teva Impeachment Action, the Apotex Impeachment Action, the Teva Prohibition Application and the Apotex Prohibition

Application were consolidated. All four matters were dealt with in the course of 14 days of evidence and 5 days of argument.

[5] These Reasons for Judgment address the issues raised by the Prohibition Applications. The Impeachment Actions are jointly dealt with in a separate set of Reasons for Judgment and Judgment:

(a) 2013 FC 141 (the Teva Impeachment Action in Court File No. T-2021-10); and

(b) 2013 FC 141 (the Apotex Impeachment Action in Court File No. T-833-11).

[6] Novartis Canada raises two issues in these Prohibition Applications:

1. Are the letters of Teva dated March 7, 2011 and Apotex dated February 18, 2011 proper NOAs under the *PM (NOC) Regulations*; and

2. If so, are the allegations contained in those letters justified?

[7] The second issue identified by Novartis Canada is, in this case, determinative. Because of my decision in the Impeachment Actions that dismisses each of the actions and holds that the claim to imatinib in the '203 Patent is not invalid, it follows that the allegations of invalidity contained in the NOAs cannot be justified. That is a sufficient reason for this Court to issue the

Orders of Prohibition sought by Novartis. I have not repeated those reasons in this decision and refer the reader to that much lengthier decision in 2013 FC 141.

[8] Because of my conclusions that the allegations in the NOAs are not justified, I have concluded that I need not address the propriety of the NOAs. I have, however, included in these reasons enough of the background to provide context to the reader for the question.

II. Statutory Scheme

[9] To situate the reader, I begin with an overview of the drug approval process and the relevant *PM (NOC) Regulations*. Before a pharmaceutical company can market a prescription drug in Canada, it must comply with the provisions of the *Food and Drug Regulations*, CRC, c 870 [*F&D Regulations*] and obtain approval in the form of a Notice of Compliance (NOC).

[10] Section C.08.002(1)(a) of the *F&D Regulations* provides that anyone who wishes to sell a drug in Canada must submit to the Minister of Health (through Health Canada), either a new drug submission (NDS) or an abbreviated new drug submission (ANDS). An NDS is filed by an innovative drug company, or "first person", seeking approval to market a new drug product. In contrast and in very general terms, an ANDS is filed by a generic manufacturer, or "second person", that wishes to market a generic version of a drug that has already been approved. The second person may rely on much of the technical, health and safety information originally filed as part of the NDS by the first person. In other words, it may compare its drug with, or make reference to, a brand name drug (*F&D Regulations*, above at s. C.08.002.1. (1))

[11] An essential element of the regulatory scheme is the "Patent Register". The *PM (NOC) Regulations* allow an innovator who has filed an NDS or a supplement to a new drug submission (SNDS) to submit a list of the associated patents to the Minister for inclusion on the register of patents (Patent Register or Register) (s. 4(1)).

[12] If a patent is listed on the Patent Register, s. 5 of the *PM (NOC) Regulations* provides that the second person, with respect to each patent on the Patent Register, must, in its application for an NOC:

- state that it accepts that the NOC will not issue until the patent expires (s. 5(1)(a)); or

- allege that:

  - the first person is not the patentee or licensee of the listed patent (s. 5(1)(b)(i));

  - the patent has expired (s. 5(1(b)(ii));

  - the patent is not valid (s. 5(1)(b)(iii)); or

  - the second person will not infringe the listed patent (s. 5(1)(b)(iv)).

[13] The second person identifies its election by marking the applicable box on the document entitled "Form V: Declaration Re: Patent List" (Form V) submitted with its ANDS. On the Form V, the second person provides a certification: "*I certify that the information included in this Declaration is accurate and relevant to the Patented Medicines (Notice of Compliance) Regulations*".

[14] If the second person elects to wait for the expiry of the patent, no notice is given to the first person.

[15] Ms. Anne Bowes, Director of the Office of Submissions and Intellectual Property within the Therapeutic Products Directorate of Health Canada, provided very helpful evidence about Health Canada's drug approval procedures. During her testimony, Ms. Bowes advised that Health Canada would commence its review of the ANDS upon receipt of the Form V, even where the second person was electing to await expiry of patents on the Patent Register.

[16] If a second person alleges that an NOC should issue in spite of the listed patents, it must serve an NOA on the first person (*PM (NOC) Regulations*, s. 5(3)). The first person may, within 45 days after service, apply to the Federal Court for an order prohibiting the Minister from issuing an NOC until the expiration of a patent that is the subject of the notice of allegation (*PM (NOC) Regulations*, s. 6(1)). This action triggers a stay that may remain in place for up to 24 months (*PM (NOC) Regulations*, s. 7(1)(e)).

III. Teva and Apotex ANDS and NOA

[17] In these Prohibition Applications, Novartis Canada is the first person, with the '203 Patent listed on the Patent Register. Teva and Apotex are second persons. Since Teva and Apotex compare their proposed imatinib tablets to Novartis's GLEEVEC, they were required to address the '203 Patent by filing Form Vs with their applications.

[18] During the course of their dealings with Health Canada, each of Teva and Apotex amended its Form V, changing its position from one where it would await expiry of the '203 Patent to one where it challenged the validity of the '203 Patent. Novartis Canada's position is that the change of the Form Vs was not permitted by the scheme of the *PM (NOC) Regulations*; in Novartis Canada's view, the NOAs are invalid.

A. *Apotex History*

[19] Apotex filed its ANDS with Health Canada on November 29, 2007 with respect to its proposed Apo-imatinib product. With its ANDS, Apotex included two Form Vs (one for the 100mg strength tablets and one for the 400 mg strength tablets), certified as described above by Dr. Sherman, founder and Chairman of Apotex TX 4, Tab 2). Apotex checked the box on the Form Vs that stated that:

> The Second Person accepts that the Notice of Compliance will not be issued until the declared expiration date for the above patent number [the '203 Patent].

[20] Under cover letter to Health Canada dated February 22, 2011 (TX 4, Tab 4), Apotex sent revised Form Vs for its ANDS in respect of the 100 mg and 400 mg Apo-imatinib tablets. In the revised Form Vs, Apotex checked the two boxes alleging that:

> The ['203 Patent] patent is not valid.
>
> No claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using, or selling the drug for which the submission is filed.

[21] On February 18, 2011, Apotex served its NOA on Novartis Canada as described above. Its key allegation, in very summary form, is that the '203 Patent and each of Claims 1 to 48 thereof, are invalid for (TX 4, Tab 3, section IV.4):

1) Lack of utility and sound prediction;

2) Inutility;

3) Insufficient specification;

4) Claims broader that any invention made or disclosed; and

5) Ambiguity.

[22] On **[Redacted]**, Health Canada advised Apotex that the examination of its submission had been completed on **[Redacted]** and that the NOC would not issue until the requirements of

the *PM (NOC) Regulations* had been met (TX 4, Tab 5). This is commonly referred to as a Patent Hold Letter.

B. *Teva History*

[23] Ratiopharm Inc., predecessor by amalgamation to Teva (TX 26, Tab 3) and referred to as Teva, filed an ANDS with Health Canada on June 30, 2010 with respect to its proposed Apo-imatinib product. With its ANDS, Teva included two Form Vs (one for the 100mg strength tablets and one for the 400 mg strength tablets), certified as described above by Dr. Denike on behalf of Teva (TX 26, Tabs 11-12). Teva checked the box on the Form Vs that stated that:

> The Second Person accepts that the Notice of Compliance will not be issued until the declared expiration date for the above patent number [the '203 Patent].

[24] The Form Vs were re-submitted on July 14, 2010 to correct the Brand Name of the product (TX 26, Tabs 13-14). No change was made to the election at that time.

[25] In further revised Form Vs dated June 10, 2011, Teva purported to amend its election (TX 26, Tabs 18-19). In the revised Form Vs, Teva checked the box alleging that "the ['203 Patent] is not valid".

[26] On March 7, 2011, Teva served its NOA on Novartis Canada as described above. Its key allegations, in very summary form, that the claims of the '203 Patent are invalid for (TX 26, Tab 21):

1) Lack of utility;

2) Insufficient specification; and

3) Claims broader that any invention made or disclosed.

[27] I assume that Teva has not yet received a Patent Hold Letter.

IV. Were the NOAs proper?

[28] In asserting that the *PM (NOC) Regulations* do not permit the amendment of a Form V to change an election, Novartis Canada presents me with an issue of statutory interpretation.

[29] The first question that I must address is whether I should consider this issue. In my view, I should not.

[30] The most important reason is that, in light of my determination that the allegations of invalidity made by Apotex and Teva are not justified, the question is not dispositive. I do not think that it is a wise use of judicial resources to express what would be only *obiter* on this

important question of statutory interpretation. That is better done where the facts give rise to a situation where such a question is determinative.

[31] In addition, it is almost a certainty that the losing parties (or even one of them) to these Prohibition Applications will appeal, thus giving the Court of Appeal the opportunity to consider whether I erred in my conclusion that the NOAs were not justified. If the Court of Appeal determines that I erred in concluding that the NOAs were not justified, the question of the validity of the NOAs would become factually relevant. The Court of Appeal could return the question of the statutory interpretation of the relevant provisions of the *PM (NOC) Regulations* to me for determination. Alternatively, the Court of Appeal could decide to determine this question itself. Beyond a few background facts which are uncontested and which I have carefully set out above, the question before me is a legal one. As such, the Court of Appeal would owe me no deference. By wading into this legal question – which has become purely academic – I would not be assisting either the parties before me or the Court of Appeal.

V. Conclusion

[32] For these reasons, and for the reasons set out in the companion decision on the validity of the '203 Patent, I am satisfied that the allegations of Teva and Apotex are not justified. It follows that NOCs for their generic versions of imatinib should not issue until the expiry of the '203 Patent.

[33] The consolidation of the Prohibition Applications with the Impeachment Actions meant that the Prohibition Applications were dealt with somewhat differently than normally would have been the case. Usually, an application under the *PM (NOC) Regulations* proceeds as an application for judicial review in the Federal Court. Expert and fact evidence is presented by way of affidavits with the other side able to cross-examine on the affidavits. The Court is presented with a mountain of expert and other affidavits, transcripts of cross-examination, memoranda of fact and law and several days of oral arguments by lawyers. Although the prohibition applications are considered to be summary proceedings, the volume of material and the complexity of issues present great challenges to the hearing judge (or, at least this judge). Because of the consolidation in this case, most experts appeared in person to speak to their "reports". The direct and cross-examinations of the experts and fact witnesses, with the ability of the judge to clarify the evidence, was invaluable. I am grateful to all parties and their counsel for their cooperation and for their contributions to this process.

[34] Novartis Canada is entitled to its costs. Ever the optimist (although my optimism is rarely borne out on the issue of costs), I hope that the parties can agree on those costs. If they cannot do so, further written submissions of no more than ten pages may be made within 60 days and reply submissions of no more than five pages within a further 15 days.

POSTSCRIPT

[1] The Confidential Reasons for Judgment were released to the parties on February 8, 2013. Upon release of the Confidential Reasons, the parties were requested to advise the Court of portions of the Reasons for Judgment that they wished redacted for the Public Reasons. On February 14, 2013 and February 15, 2013, in separate letters, counsel for Novartis AG and Novartis Pharmaceuticals Canada Inc. and counsel for Teva Canada Limited advised the Court that there were no portions of the Reasons for Judgment that should be redacted. Counsel for Apotex Inc. made submissions by letter to the Court dated February 15, 2013 requesting certain redactions be made.

[2] These Reasons for Judgment contain redactions made to the Confidential Reasons for Judgment that were issued on February 8, 2013, pursuant to the Amended Protective Order dated December 13, 2011. The redactions were made in accordance with the correspondence received

from the solicitors for Apotex Inc., with which this Court agrees, and are now incorporated in the within Public Reasons for Judgment.

"Judith A. Snider"

Judge

Ottawa, Ontario
Public Reasons – February 19, 2013
Confidential Reasons – February 8, 2013

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Anthony Creber Isabel Raasch John Norman Jennifer Wilkie	FOR THE APPLICANT (T-599-11 and T-679-11)
Andrew Brodkin Daniel Cappe Dino Clarizio	FOR THE RESPONDENT APOTEX INC. (T-599-11)
Jonathan Stainsby	FOR THE RESPONDENT TEVA CANADA LIMITED (T-679-11)

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANT (T-599-11 and T-679-11)
Goodmans LLP Barristers and Solicitors Toronto, Ontario	FOR THE RESPONDENT APOTEX INC. (T-599-11)
Heenan Blaikie LLP Barristers and Solicitors Toronto, Ontario	FOR THE RESPONDENT TEVA CANADA LIMITED (T-679-11)