Federal Court  Cour fédérale

Date: 20180216

Docket: T-1668-10

Citation: 2018 FC 185

Ottawa, Ontario, February 16, 2018

PRESENT: The Honourable Mr. Justice Locke

BETWEEN:

ASTRAZENECA AKTIEBOLAG,
ASTRAZENECA CANADA INC. and
ASTRAZENECA UK LIMITED

Plaintiffs/
Defendants by Counterclaim

and

APOTEX INC. and
APOTEX PHARMACHEM INC.

Defendants/
Plaintiffs by Counterclaim

ORDER AND REASONS

I. Introduction

[1] This decision concerns crossed motions by the parties on how this patent infringement action should proceed. Before outlining the parties' respective positions, it is helpful to have some background.

[2] In February 2007, Apotex Inc. (Apotex) initiated steps to obtain permission to market a generic version of a pharmaceutical product marketed by AstraZeneca Canada Inc. (AstraZeneca) as Nexium. As part of this process, Apotex had to address 10 patents that AstraZeneca had identified on the patent list associated with its product under the *Patent Medicines (Notice of Compliance) Regulations*, SOR/93-133 (since amended) [the *Regulations*]. Apotex did this by serving AstraZeneca with seven notices dated January 17, 2008, alleging, for various reasons, that the listed patents should not impede Apotex from obtaining a notice of compliance (NOC) required for access to the market. In response to Apotex's notices of allegation, AstraZeneca commenced seven separate applications under the *Regulations* on March 7, 2008, each seeking to prohibit the Minister of Health from granting Apotex an NOC. These applications were all eventually discontinued or dismissed. Apotex obtained its NOC on June 17, 2010. Its generic product is called Apo-Esomeprazole.

[3] In October 2010, AstraZeneca and two affiliates (AstraZeneca Aktiebolag and AstraZeneca UK Limited) commenced the present action against Apotex and Apotex Pharmachem Inc. (Pharmachem) alleging infringement of Canadian Patent No. 2,139,653 (the 653 Patent) and Canadian Patent No. 2,193,994 (the 994 Patent). This action is referred to hereinafter as the Infringement Action. In the context of the Infringement Action, AstraZeneca and its two affiliates are referred to as the plaintiffs, and Apotex and Pharmachem are referred to as the defendants.

[4] A few months later, in March 2011, Apotex commenced a separate action (Federal Court No. T-389-11) under s. 8 of the *Regulations* against AstraZeneca seeking compensation for the

alleged loss it suffered during the period that it was kept off the market by operation of the *Regulations*. This separate action is referred to hereinafter as the Section 8 Action.

[5] The Infringement Action was bifurcated to carve out the following issues: (i) any experimental and regulatory use exemption, (ii) the quantum of any damages or profits, and (iii) all issues pertaining to the 994 Patent. This left the parties to proceed to a first trial essentially on the 653 Patent alone. Since it was not disputed that Apo-Esomeprazole falls within the scope of the claims in issue of the 653 Patent, the only issues in dispute in the first trial in the Infringement Action concerned the validity of the 653 Patent.

[6] The trial was conducted before Justice Donald J. Rennie (then of this Court) from September to November 2013. The 653 Patent validity issues in dispute were (i) utility (or lack thereof), (ii) novelty (or anticipation), and (iii) inventiveness (or obviousness). Justice Rennie issued his decision (2014 FC 638) on July 2, 2014. He found that the 653 Patent had the required novelty and inventiveness, but that it was invalid because it lacked utility. The basis for the finding of lack of utility was that the 653 Patent makes a promise of a certain therapeutic benefit that had not been demonstrated, and could not be soundly predicted, at the date the patent was filed.

[7] The plaintiffs appealed to the Federal Court of Appeal (FCA) arguing that Justice Rennie had misconstrued the promise in question. For their part, the defendants argued that Justice Rennie had erred in finding that the 653 Patent was novel and inventive. The FCA dismissed the appeal concerning lack of utility, and found it therefore unnecessary to consider the issues of

novelty and inventiveness that the defendants had raised. Accordingly, Justice Rennie's decision stood unaltered.

[8] The plaintiffs then sought leave to appeal to the Supreme Court of Canada (SCC), which leave was granted. The appeal to the SCC was heard in November 2016.

[9] In May 2017, after the SCC hearing but before its decision, the Section 8 Action went to trial before me. The same trial was also to rule on issues pertaining to the 994 Patent in the Infringement Action, but the parties settled those issues.

[10] Recognizing that the decision of the SCC concerning the validity of the 653 Patent could have a profound effect on both the Section 8 Action and the Infringement Action, it was agreed during the trial that (i) I would not issue a decision regarding the issues at trial until after the SCC had issued its decision, and (ii) if the SCC were to reverse the FCA on the validity of the 653 Patent, I would give the parties an opportunity to make supplemental submissions.

[11] The SCC issued its decision (2017 SCC 36, the SCC's Decision) on June 30, 2017. The SCC ruled that the Promise Doctrine that had been applied by Justice Rennie is not the correct approach to determine the utility of a patent. The SCC allowed the appeal, set aside the decisions of Justice Rennie and the FCA, and declared that the 653 Patent is not invalid for lack of utility.

[12] Following the SCC's Decision, the parties disagreed on its effect and on how to proceed in both the Section 8 Action and the Infringement Action. The plaintiffs took the position that the

validity of the 653 Patent had been fully and finally confirmed by the SCC, and that in the absence of any other non-infringement allegation, infringement of the 653 Patent was confirmed. As regards the Infringement Action, the plaintiffs argued that the matter should therefore proceed directly to a reference to determine the quantum of damages/profits. As regards the Section 8 Action, AstraZeneca argued that I would be in a position to render a decision upon receiving supplemental submissions.

[13] For its part, the defendants took the position that the SCC had merely set aside the finding that the 653 Patent was invalid for lack of utility. They argued that other grounds of invalidity remained in issue. Specifically, the defendants argued that the reversal on the utility issue meant that the FCA should have considered the other validity issues that it had determined were unnecessary to consider: novelty (or anticipation) and inventiveness (or obviousness). The defendants also noted that the SCC's Decision accepted that the problem of overpromising which was formerly addressed in the Promise Doctrine is indeed a mischief, and that such mischief can be addressed based on other grounds of invalidity. Accordingly, the defendants urged that the parties should be given an opportunity to address these other validity issues with additional evidence and argument.

[14] In August 2017, the defendants filed a motion with the SCC seeking (i) amendment of the SCC's judgment to remand certain 653 Patent validity issues to the Federal Court and others to the FCA, and (ii) a re-hearing before the SCC. The SCC dismissed that motion without reasons.

[15] Following a series of trial management conferences, I set a date of January 11, 2018 for supplemental oral submissions in the Section 8 Action. After hearing those supplemental submissions, I dismissed Apotex's claim in the Section 8 Action for reasons that may be found at 2018 FC 181 (my Section 8 Decision).

[16] With regard to the Infringement Action, I made arrangements for the parties to file their respective motions that are the subject of the present decision. The hearing of those motions took place on January 12, 2018.

II. Motions

[17] The plaintiffs' motion seeks a declaration that the defendants have infringed the 653 Patent, and directing the quantification of their damages or the defendants' profits by a reference. The reference would concern infringement of the 653 Patent and the 994 Patent (this patent is now the subject of a separate declaration of infringement that was included in my Section 8 Decision), and would include consideration of any experimental and regulatory use exemptions as well as determination of rates and terms of pre-judgment and post-judgment interest. The plaintiffs also seek a declaration that they are entitled to elect between their damages and the defendants' profits after discovery. The plaintiffs also seek dismissal of the defendants' counterclaim. Finally, the plaintiffs request that the trial of the reference be scheduled for 15 days in February, March or April 2020.

[18] The defendants oppose the plaintiffs' motion and make their own motion seeking to re-open the trial that began in May 2017 to permit the question of overpromising in the 653 Patent to be adjudicated in light of the SCC's Decision.

[19] Despite the overlap in the issues addressed in the parties' respective motions, they were dealt with separately both in writing and orally. Accordingly, I address them separately in these reasons.

III. Analysis of the Plaintiffs' Motion

[20] The plaintiffs' argument in favour of their motion is relatively straightforward, and much as described in paragraph [12] above: with the validity of the 653 Patent now finally determined and no other non-infringement issues in dispute, the plaintiffs are entitled to a declaration of infringement of the 653 Patent, and the next step is to determine the quantum of damages/profits. Likewise, there are no non-infringement issues in dispute with regard to the 994 Patent (except those related to experimental and regulatory use exceptions), so it too is ready for determination of the quantum of damages/profits.

[21] With regard to the plaintiffs' request for a declaration that they are entitled to elect between their damages and the defendants' profits, the plaintiffs note that this issue was fully addressed in closing submissions before Justice Rennie in 2013. Because of his finding that the 653 Patent was invalid, he did not rule on this issue. However, the plaintiffs argue that the submissions made in 2013 are equally applicable today.

[22] With regard to pre-judgment and post-judgment interest, the plaintiffs assert that they are entitled to both, and request that the rates and terms thereof be determined in the reference.

[23] As alluded to above, the defendants oppose proceeding to a reference at this stage. They argue that some issues of validity of the 653 Patent remain in dispute. They note that the SCC did not declare the 653 Patent valid or infringed. They also note that, likewise, neither Justice Rennie nor the FCA declared the 653 Patent valid or infringed. The defendants argue that the plaintiffs' motion is improper because it effectively asks this Court to vary the SCC's judgment by granting relief that it did not grant. The defendants argue that the plaintiffs should have made a motion directly to the SCC to get the relief it seeks in this motion.

[24] The defendants also argue that the plaintiffs' motion seeks to vary Justice Rennie's judgment by granting additional relief that he did not grant, such as the right to elect between their damages and the defendants' profits after discovery, and the right to pre-judgment and post-judgment interest.

[25] With regard to the 994 Patent, the defendants oppose a reference on two grounds. Firstly, though the parties have agreed on the terms of a judgment, no formal judgment has yet issued. Of course, with the issuance of my Section 8 Decision, this ground of opposition no longer applies.

[26] The second ground asserted by the defendants for opposing a reference in respect of the 994 Patent is that the parties agree that Apotex never made any commercial sales of Apo-

Esomeprazole made by the process that infringes the 994 Patent. Though this fact does indeed appear to be undisputed, it is equally clear that the plaintiffs assert nevertheless that they are entitled to damages/profits in respect of non-commercial dealings with Apo-Esomeprazole. Though the defendants may eventually be shown to have no liability for infringement of the 994 Patent, it would not be appropriate, in my view, to decide that issue at this stage.

[27] In the alternative, the defendants favour re-opening the trial to give the parties an opportunity to address the remaining 653 Patent validity issues with additional evidence.

[28] In response to the defendants' argument that the plaintiffs seek to vary the SCC's Decision, the plaintiffs assert that they are asking for the SCC's Decision to be applied, not varied. Accordingly, as indicated in my Section 8 Decision, I have approached the SCC's Decision with a view to interpreting it, not varying it.

[29] The defendants' position that there remain other invalidity issues in dispute was addressed in my Section 8 Decision. There, I concluded that the validity of the 653 Patent was finally decided by the SCC, and that there remains no other validity issue to debate. I also stated that any doubt that might have remained about the SCC's intent in its decision concerning the validity of the 653 Patent was resolved by the dismissal of Apotex's motion to the SCC. I apply the same reasoning here as in my Section 8 Decision.

[30] Moreover, since it was never disputed that Apo-Esomeprazole falls within the scope of the claims of the 653 Patent, there remains no issue on infringement.

[31] It follows that the plaintiffs are entitled to a declaration that the defendants have infringed the 653 Patent. In light of this declaration, as well as the declaration concerning infringement of the 994 Patent in my Section 8 Decision, the next step is to quantify the damages/profits to which the plaintiffs are entitled.

[32] With regard to the plaintiffs' request that I declare that they are entitled to elect between their damages and the defendants' profits after discovery, I recognize that this issue was argued before Justice Rennie in 2013, but not decided. Even though I have been provided with substantially the same arguments as were made before Justice Rennie, I accept the defendants' argument that certain circumstances have changed since 2013; not least the SCC's Decision that the Promise Doctrine is not good law. Such circumstances may or may not be relevant to the issue of the plaintiffs' right to elect an accounting of the defendants' profits but, in my view, it would be preferable for the parties to have the opportunity to argue the issue in full before the judge who will decide it. I see no important reason that the parties should not proceed on the basis that the right to elect profits will be considered as part of the reference, after discovery on both damages and profits.

[33] Just as with the right to elect profits, Justice Rennie's judgment did not provide for pre-judgment or post-judgment interest because he found the 653 Patent invalid. The defendants again urge me not to award interest at this time, in part because of certain changed circumstances. As with the right to elect profits, I conclude that it would be preferable for the parties to have the opportunity to argue this issue before the judge who will decide it.

[34] Finally, with regard to the plaintiffs' request that a trial date be set, it is my view that this is a matter better dealt with by the case management judge who can also address the scheduling of steps leading to trial.

IV. Analysis of the Defendants' Motion

[35] Having decided to grant the substance of the plaintiffs' motion, and having concluded that there remain no issues concerning the validity of the 653 Patent to debate, there is no point in re-opening the trial as the defendants urge.

[36] The defendants argue certain grounds on which I have the discretion to re-open the trial. The plaintiffs dispute these grounds, and much of the time spent on this motion was devoted to the question of whether I have any discretion to exercise. I need not decide this question because, even if I have discretion to re-open the trial, I decline to exercise that discretion for the reasons discussed herein and in my Section 8 Decision.

V. Conclusions

[37] I have concluded that the plaintiffs are entitled to a declaration that the defendants have infringed the 653 Patent. The plaintiffs are also entitled to an order directing the quantification of their damages or the defendants' profits by a reference. In light of the declaration of infringement of the 994 Patent in my Section 8 Decision, the reference shall consider infringement of the 653 Patent and the 994 Patent. It shall also consider the following:

1. any experimental and regulatory use exemptions,

2. whether the plaintiffs will be allowed to elect an accounting of the defendants' profits instead of their own damages, and
3. whether the plaintiffs will be awarded pre-judgment and post-judgment interest, and if so, the rates and terms thereof.

[38] For greater certainty, and subject to any further order in this matter, discovery shall encompass both the plaintiffs' damages and the defendants' profits.

ORDER in T-1668-10

THIS COURT ORDERS that:

1. The plaintiffs' motion is granted in part.

2. The defendants' motion is dismissed.

3. Each of the defendants has infringed Canadian Patent No. 2,139,653 (the 653 Patent).

4. The quantification of the plaintiffs' damages from infringement of the 653 Patent and of Canadian Patent no. 2,193,994 (the 994 Patent) or the defendants' profits arising from their infringement of the 653 and 994 Patents will be determined at a trial preceded by discovery, which trial shall also consider:
    a. The pleaded experimental and regulatory use defence;
    b. Whether the plaintiffs are entitled to elect an accounting of the defendants' profits; and
    c. Whether the plaintiffs are entitled to pre-judgment and post-judgment interest, and if so, the rates and terms thereof.

5. The defendants shall pay the plaintiffs' costs of both motions in any event of the cause.

"George R. Locke"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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