Federal Court Cour fédérale

Date: 20161003

Dockets: T-1056-16
T-998-16

Citation: 2016 FC 1099

Ottawa, Ontario, October 3, 2016

PRESENT: Madam Prothonotary Mireille Tabib

Docket: T-1056-16

BETWEEN:

APOTEX INC.

Plaintiff

and

SHIRE LLC AND
SHIRE PHARMA CANADA ULC

Defendants

Docket: T-998-16

AND BETWEEN:

SHIRE PHARMA CANADA ULC

Applicant

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

and

SHIRE LLC

Respondent Patentee

ORDER AND REASONS

I. Background and overview

[1] Shire LLC is the owner of Canadian Patent 2,547,646 (the '646 Patent) entitled "Abuse Resistant Amphetamine Compounds", said to cover Shire Pharma Canada ULC's lisdexamfetamine dimesylate capsules sold under the name Vyvanse. (Both Shire entities will collectively be referred to below as "Shire").

[2] Apotex wishes to obtain a Notice of Compliance to market and sell in Canada a generic version of Vyvanse. It therefore served on Shire, in May 2016, a Notice of Allegation pursuant to the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 (the "*PM (NOC) Regulations")* alleging, *inter alia*, that the '646 Patent is invalid and that, in any event, its proposed product would not infringe any claim of the Patent found to be valid. In response to Apotex's NOA, Shire filed an application for a prohibition order pursuant to section 6 of the *PM (NOC) Regulations* in Court file T-998-16 on June 24, 2016. Ten days later, Apotex commenced, in Court file T-1056-16, an action against Shire seeking a declaration that the '646 Patent is

invalid and that its proposed lisdexamfetamine dimesylate tablets would not infringe any valid claim of the Patent.

[3] Citing the need for the just, most expeditious and least expensive determination of both proceedings on their merits, Shire asks the Court to partially consolidate the proceedings, so that they are heard at a common hearing, on common *viva voce* evidence, but subject to the parties' ability to argue the admissibility or relevance of evidence to one or the other proceeding. Apotex opposes Shire's motion.

[4] Apotex has proposed another solution to Shire. It proposes that Shire discontinue the prohibition application and that the action continue to its conclusion, on the mutual understanding that, should Apotex's product become approvable, Apotex would remain out of the market until a decision is rendered and Shire would give it an undertaking for damages Apotex might thereby suffer. I will not further discuss Apotex's proposal as Shire has rejected it and as Apotex concedes that the Court does not have jurisdiction to impose it without Shire's consent. Apotex's fallback position is that both proceedings should continue to be litigated in parallel, to separate hearings.

II. Discussion

[5] The grounds for invalidity and non-infringement cited by Apotex in its NOA and in its action are the same and in that regard, there is a substantial commonality between the facts at issue in both proceedings. At the same time, it is common ground between the parties that there

are significant differences between the two proceedings in terms of the causes of action, their effect, the burden of proof and the applicable procedural rules.

[6] In the normal course, the prohibition application brought by Shire would proceed in a summary fashion, as an application governed by Rules 300 and following of the *Federal Court Rules* and by the particular regime of the *PM (NOC) Regulations*.

[7] Under these rules, the commencement of the prohibition proceedings operates as an interim injunction, preventing the issuance of an NOC to Apotex for a period of up to 24 months; evidence is constituted out of court by way of affidavits and cross examinations; typically, but not always, Shire's evidence would be constituted and served first; other than the possibility of obtaining Apotex's relevant ANDS filings, there are no discoveries; there can be no amendments made by Apotex to the grounds for invalidity or non-infringement cited in its NOA; unless an extension of time is granted by the Court, either by consent or by reason of Apotex's conduct, the Court has 24 months in which to hear and determine the application; the burden of proof rests on Shire, and requires it to establish that the allegations made by Apotex in the NOA are not justified; the sufficiency of the NOA may be contested, as can the validity of Shire's listing of the'646 Patent in respect of Vyvanse; the Court's decision is not finally determinative of the validity of the Patent or of whether it is infringed; either party may pursue a different result in a subsequent action; finally, the dismissal or discontinuance of the prohibition proceeding, for whatever reason, triggers a right by Apotex pursuant to section 8 of the *PM (NOC) Regulations* to seek damages for losses it has suffered as a result of the delay in obtaining its NOC.

[8] By contrast, in Apotex's action for impeachment or a declaration of non-infringement, Apotex bears the burden of proving that the '646 Patent is invalid or would not be infringed; both parties have extensive rights of discovery and Apotex may move to amend its statement of claim to adapt its allegations to what it might learn on discovery; at trial, each party can lead extensive *viva voce* evidence; Apotex as plaintiff would typically lead its evidence first; the Court's jurisdiction to determine the action is not time-limited; while the Court endeavors to bring such actions to trial within 24 months, a determination is rarely made before approximately three years from the date of filing; subject to appeal, the results of the action are final and binding on both parties; a finding that the Patent is valid and infringed, if made subsequent to an unsuccessful prohibition application, is not a complete defence to a claim for section 8 damages but may substantially or completely reduce the damages awarded.

[9] Even though they are summary proceedings, prohibition proceedings conducted under the *PM(NOC) Regulations* require significant time and expense. Substantial evidence from the inventors and from numerous experts from both sides is typically marshaled, set out in lengthy and voluminous affidavits and tested by cross-examination. Application Records, often consisting of thousands of pages, are presented to the Court. The oral argument alone routinely requires three to five hearing days, or almost as long as the closing arguments in a full-fledged trial.

[10] Conducting such proceedings in parallel with an action involving the same patent and the same product represents a significant challenge for both parties. Where the same parties, facts and science are involved, using the same experts and counsel seems a logical and cost-saving

measure, but the task of coordinating the demands of two proceedings on the time of counsel and experts can be onerous and lead to delays. Using different counsel or experts facilitates coordination, but is duplicative of efforts and costs. Whether the parties choose to use the same or different counsel and experts, the evidence before me is to the effect that there are nine inventors listed on the ‘646 Patent, none of whom are currently employed by Shire. Coordinating their attendance and availabilities across two separate but parallel proceedings is not a matter of choice.

[11] Duplications and coordination issues arising from the parallel proceedings affect the Court as well: it is the Court’s practice to attempt to assign the same Judge to hear all proceedings involving the same patent, as the Judge’s familiarity with the scientific background greatly reduces the time needed for the Judge to learn and become familiar with the basic, yet often extremely complex, scientific principles involved. Having a three to five day prohibition application proceed in close proximity to a two week trial on the same patent and the same drug either requires the Court to block a single Judge’s time for several months or to assign two different Judges to the hearings, with the attendant loss of efficiency.

[12] Apotex does not disagree that running the two proceedings in parallel is costly, onerous and duplicative for the parties and the Court. It does not, however, agree that Shire’s proposal strikes an appropriate balance between preserving all of the parties’ procedural and strategic rights and avoiding duplication and waste.

[13] The solution proposed by Shire through this motion is one that was adopted in the case of *Novartis Pharmaceuticals Canada Inc. v Apotex Inc.*, 2013 FC 142 ("*Gleevec*"). In that case, two actions and two prohibition applications involving two separate generics but in relation to the same drug were commenced in close temporal proximity. Pursuant to a case management order made on consent of the parties, the four proceedings were partially consolidated so that instead of the applications proceeding on the basis of affidavit evidence, they would be determined by the same judge and on the basis of the evidence adduced at a joint trial of the actions. Use of the *viva voce* evidence for determining the applications was however subject to the parties' arguments as to the evidence's admissibility and relevance for the purposes of each application, as defined and delineated in the respective Notices of Allegations. All four proceedings were determined after a single hearing consisting of only 14 days of evidence and five days of argument.

[14] It is very clear that proceeding in the same manner here would equally significantly reduce duplications between the two proceedings. The evidence would be adduced only once, *viva voce*, before the Court. This would eliminate entirely the need for the parties to prepare separate affidavits and to conduct cross-examinations for the purpose of the application. It would also eliminate a significant source of potential delay, in that the attendance of the inventors would need to be secured only twice: once for discovery and once for an eventual trial.

[15] This manner of proceeding does add an additional layer of complexity. It can give rise to much debate as to whether parts of the evidence adduced at trial falls outside the four corners of the Notice of Allegation and must accordingly be ignored in determining the application. The

elimination of some portions of the evidence may result in different evidentiary records being constituted, to which a different burden of proof must be applied, resulting in potentially very complex arguments. The difficulty and the time required of the parties and the Court to address this added complexity however pales in comparison with the efficiencies and savings gained from eliminating the parallel, written record.

[16] Determining an application on the basis of evidence adduced in open court also addresses a perennial source of frustration on the part of the Court, who is being asked to consider, in so-called “summary” proceedings, massive amounts of detailed and intricate technical evidence in writing. In her judgment on the *Gleevec* applications, Justice Snider had this to say about the process:

> [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.

[17] Apotex, who was one of the parties involved in *Gleevec*, was less satisfied with its experience. It argues that the procedure was and would be, if adopted again here, prejudicial to it as the generic party, for the following reasons:

- Hearing prohibition proceedings and impeachment actions together has the effect of erasing the difference in the burden of proof applicable to each proceeding, effectively robbing Apotex of the advantage it enjoys in the prohibition proceeding, that it is Shire who has the onus of showing that Apotex's allegations are not justified. Apotex's written submissions argue that "the Court will devote less attention to the differing burdens operative in the two proceedings and, instead, rely upon the standard that governs actions for impeachment and infringement".

- Hearing the application and action together deprives Apotex of the procedural advantages derived from the typical order of presenting evidence in applications, whereby Shire would be required to serve its evidence first and Apotex would be permitted to respond. The joint hearing would have the effect of a reversal of the order of evidence (insofar as the issues in the application are concerned), to Apotex's prejudice.

- Determining the prohibition application on the basis of *viva voce* evidence rather than on a paper record and cross examination out of court removes the tactical and strategic elements inherent to the usual way of proceeding.

- To the extent the prohibition application is determined without due regard for the difference in the burden of proof, Apotex loses the benefit of potential s. 8 damages that come from being successful on an application, even when a subsequent action is determined in the innovator's favour.

[18] I will consider each of these alleged causes of prejudice in turn.

[19] I do not accept Apotex's argument that where the Court is tasked with determining, on a common evidentiary record, the respective rights of each party pursuant to two distinct legal processes subject to different evidentiary burdens, it might be unable or unwilling to properly apply the burden of proof, or that it might be unwilling or unable, where the application of the evidentiary burden requires it, to reach a result which is not uniform but is nevertheless appropriate to each process. Apotex cited no evidence or authority to support its argument. It illustrated its fear by referring to the case of *Biovail Corporation v Canada (Minister of Health) and Apotex Inc.*, 2010 FC 46, where Apotex succeeded in a prohibition application specifically because of the application of the burden of proof, the Court having expressly found the evidence to be evenly balanced. That illustration does not assist Apotex. It seems to me that, were the Court to find, on joint evidence adduced for the purposes of an impeachment action and a prohibition application, that the evidence was equally balanced, it would be particularly clear and easy for the Court to reach the correct result: the generic would succeed on the application, but fail on the action.

[20] The second form of prejudice cited by Apotex is that the order sought by Shire would result in a *de facto* reversal of the order of evidence. The Court, in the context of motions to reverse the order of presenting evidence in PM(NOC) proceedings, has specifically considered whether such orders cause prejudice or result in an injustice to the generics. While the Court has recognized that the party who files its evidence first enjoys a legitimate tactical advantage, it has also concluded that this advantage is neither substantive nor procedural. Accordingly, the Court

has found that the loss of this tactical advantage is neither prejudicial nor "unjust", and that it is not a sufficient reason to defeat an order of reversal where the Court was otherwise satisfied that reversal would be most likely to achieve the most expeditious and least expensive determination of the issues. (see *Purdue Pharma v Pharmascience Inc.*, 2007 FC 1196, at para 19, *Eli Lilly Canada Inc. v Novopharm Ltd.*, 2002 FC 875 at para 13, *Lundbeck Canada Inc. v Ratiopharm Inc.*, 2008 FC 579 at para 20). I further note that the tactical advantage of leading evidence first would be far less important in the situation proposed by Shire, because evidence would be introduced *viva voce* and the Court would be able to seek clarifications on any uncertain points.

[21] I concede that the strategies and tactics are different when dealing with a paper record or evidence adduced orally at trial. However, I fail to see, and Apotex has not explained, how the "loss" of these elements represents a prejudice to Apotex and not to Shire. Apotex has explained how it has found it challenging in *Gleevec* to keep in mind the different strategies and tactics that might apply to the different uses and burdens to which the evidence might be put, depending on the proceeding to which it applies. However those challenges apply equally to both parties and it has not been shown, through evidence or cogent argument, that Apotex would stand to be disadvantaged in any way.

[22] Finally, as I am not persuaded that a joint evidentiary hearing would lead the Court to disregard the applicable burden of proof, I cannot conclude that Shire's proposal would deprive Apotex of any potential section 8 rights.

[23] Apotex's argument, to the effect that Shire's proposal would cause it procedural or tactical prejudice, is unsubstantiated.

[24] Apotex does not otherwise argue that proceeding as suggested by Shire would prejudicially affect any of its substantive rights, and I am satisfied that all of Apotex's rights would be protected. In particular, Shire acknowledges that if, for any reason, the joint proceedings could not be heard and determined within 24 months, Shire would have no automatic right to the extension of the 24 month period mandated by the *PM (NOC) Regulations*. The Court could only grant an extension of time if the conditions set out in the *PM (NOC) Regulations* were met.

[25] I am satisfied that taking all circumstances into account, Shire's proposal would lead to very significant savings of time and expense for both parties, represents the most efficient and judicious use of the Court's resources, eliminates wasteful duplication and generally leads to the just, most expeditious and least expensive determination of both proceedings on their merits.

[26] The following three additional observations should be made.

[27] Apotex does have full control over the timing of the two proceedings. It chose when to serve its NOA, and when to file its action. It could still choose to withdraw its NOA and serve the same or a different one at a later time. It could also, subject to a potential argument of abuse of process, choose to discontinue its action and refile the same statement of claim later on. It was

Apotex's decision to trigger both proceedings at the same time that makes the litigations particularly taxing, but it is also that decision which makes the partial joinder possible and necessary to alleviate the burden. Apotex cannot impose its own schedule on Shire and on the Court while at the same time resist reasonable and just means to make the most efficient use of scarce judicial resources, all for the sake of preserving its own perceived tactical advantage.

[28] I noted earlier that the Court will likely derive assistance in determining the application from hearing the *viva voce* evidence of the experts. This, however, is only an interesting additional benefit to the joinder; I have not given this factor any weight in coming to my decision.

[29] Finally, just as I was not persuaded by Apotex's argument of procedural or tactical prejudice, I found no merit to Shire's argument that allowing both proceedings to continue in parallel would be unfair because Apotex would be able to use discovery information for the purpose of the application, because Apotex would have multiple chances to cross-examine the same witnesses, or because the application would be determined first and an unsuccessful innovator in a prohibition proceeding faces "an uphill battle" in a subsequent trial.

ORDER

THIS COURT ORDERS that:

1. The Application in T-998-16 shall be heard simultaneously to and by the same judge as the action in T-1056-16;

2. The issue of whether the allegations made in Apotex's May 12, 2016 Notice of Allegation are justified shall be decided on the basis of the evidence led at the trial of the action, subject to the evidence's relevance for the purpose of the application;

3. Evidence regarding Shire's assertion, in the Application, that the NOA is not a valid NOA shall be adduced at the trial of the action;

4. The judicial administrator shall advise the parties of available dates for a four week trial of this matter, in English and in French, in the period between February 1 and April 30, 2018;

5. The parties shall, no later than 10 days from the date of this order, file submissions as to a schedule for the next steps to be taken in this matter;

6. Costs of this motion, in the amount of $3000 plus reasonable disbursements, are awarded to Shire in the cause.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1056-16
STYLE OF CAUSE:	APOTEX INC. v SHIRE LLC AND SHIRE PHARMA CANADA ULC
AND DOCKET:	T-998-16
STYLE OF CAUSE:	SHIRE PHARMA CANADA ULC v APOTEX INC. AND THE MINISTER OF HEALTH AND SHIRE LLC
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	SEPTEMBER 8 AND 14, 2016
REASONS FOR ORDER AND ORDER:	TABIB P.
DATED:	OCTOBER 3, 2016

APPEARANCES: (File T-1056-16)

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Mr. Jay Zakaib Mr. Alex Gloor	FOR THE DEFENDANTS

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