

Federal Court



Cour fédérale

Date: 20121108

Docket: T-772-09

Citation: 2012 FC 1301

Toronto, Ontario, November 8, 2012

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

APOTEX INC.

Plaintiff

and

PFIZER IRELAND PHARMACEUTICALS

Defendant

REASONS FOR ORDER AND ORDER

[1] The defendant (Pfizer) moves, pursuant to Rule 220 of the *Federal Courts Rules*, to have this Court determine a question of law before, or at the outset of the trial of this action. The question it wishes determined is the following:

Is Apotex an “interested person” pursuant to section 60(1) of the Patent Act in respect of claims 1-8, 12, 20, 22, 24-26 of Canadian Patent No. 2,163,446?

[2] Only a brief background is necessary. Prior to the litigation, Pfizer disclaimed claims 9, 11, 13-17, 19, 21, and 27 of its Canadian Patent No. 2,163,446 (the '446 Patent). As a result, it says that only claims 1-8, 10, 12, 18, 20, 22-26 of the '446 Patent remain in force. During the course of the litigation Pfizer, on its own initiative, provided a unilateral covenant not to sue the plaintiff (Apotex) for infringement or induced infringement of any of the claims of the '446 Patent, other than claims 10, 18, and 23 (the Covenant Not to Sue).

[3] This action was commenced by Apotex on May 13, 2009, seeking declarations that "each of the claims of [the '446 Patent] is invalid, void and of no force or effect" and that "Apotex's sildenafil citrate ("sildenafil") tablets will not infringe any valid claim of the '446 Patent."

[4] In its initial Statement of Defence, Pfizer denied that Apotex had standing to sue with respect to all claims of the '446 Patent. In a letter dated September 13, 2011, Pfizer set out its position that only claims 7, 8, 10, 18, 22, and 23 were in issue in this action but offered no explanation for its position. At examinations for discovery in November 2011, Pfizer refused to answer questions on the claims of the patent, except claims 7, 8, 10, 18, 22, and 23. Subsequently, when Pfizer provided its positions on questions refused or taken under advisement, it delivered to Apotex the Covenant Not to Sue.

[5] Pfizer submits that because of the Covenant Not to Sue, Apotex can have no reasonable basis to believe that its activities will be impugned by Pfizer as an infringement of any claims other than claims 10, 18, and 23 of the '446 Patent and, accordingly it does not have standing as an "interested person" within the meaning of subsection 60(1) of the *Patent Act*, RSC 1985, c P-

4, to impeach any of the other claims of the '446 Patent. The parties agree that the issue of Apotex's standing as an "interested person" in respect of those claims is an issue in the litigation. Their respective positions are disclosed in the pleadings.

[6] Pfizer pleads at paragraph 10 of its Fourth Amended Statement of Defence, as follows:

In a written Covenant Not to Sue, dated December 8, 2011, Pfizer formally covenanted to Apotex that Pfizer will not assert or impugn against Apotex any claims of the '446 Patent except claims 10, 18, and 23, as they incorporate the formula of claim 7 [sildenafil] (the "Three Claims Asserted"). Apotex cannot have any reasonable cause to believe that the manufacture, use, and sale by Apotex of sildenafil tablets could constitute an infringement of any claim other than the Three Claims Asserted ...

[7] Apotex responds in its Fourth Amended Reply as follows:

4. With respect to paragraph 10 and the last sentence of paragraph 45 of the Defence, Apotex states that it is an interested person for the purposes of seeking a declaration of invalidity under the *Patent Act*. The Defendants listed the '446 Patent on the patent register pursuant to section 4 of the *Patented Medicines (Notice of Compliance) Regulations*. By virtue of so doing, it and Pfizer Canada Inc. were able to commence the application in Court File No. T-1312-5 and obtain a prohibition order preventing Apotex from selling its sildenafil citrate tablets ("sildenafil") on the Canadian market. Apotex's manufacture, use and sale of sildenafil is thus presently impugned as a result of the '446 Patent.

5. Apotex does not accept the characterization of the "Three Claims Asserted" by Pfizer. None of these claims are limited to "[sildenafil]" as pleaded by Pfizer in paragraph 10 of the Defence. To the contrary, they encompass each of claims 1 to 7 of the '446 patent.

6. Likewise, with respect to paragraphs 70 and 71 of the Defence, Pfizer plea that sildenafil is the only compound covered by the Three Claims Asserted is not correct. Each of the compounds of claims 1 to 7 of the '446 Patent is covered by claims 10, 18 and 23 of the '446 Patent.

7. Apotex further denies that the “*Covenant Not to Sue*” dated December 8, 2011, asserted in paragraph 10 of the Defence, in any way alters the standing of Apotex to bring the within suit. Indeed, the covenant provides no assurance or agreement to permit the Minister of Health to issue Apotex a Notice of Compliance for its sildenafil product in the event that it prevails in establishing the invalidity of only claims 10, 18 and 23 of the ’446 Patent.

8. With respect to paragraphs 8, 18, 22 to 28, 30, 33, 35 to 40, 45, 58, 65, 67 to 70, 74 and 75 of the Defence, Apotex denies that Pfizer is able, as Defendant, to unilaterally narrow the scope of the within litigation. The “*Covenant Not to Sue*” does not have the effect of narrowing the issues in this case. Indeed, Pfizer has not asserted that any of the other claims raised in Apotex’s Claim, save as to claim 6, do not encompass within their scope the compound sildenafil. As such, all claims of the ’446 Patent are at issue in the within proceeding. Further, the “*Covenant Not to Sue*” does not render the propriety of the first or second disclaimer irrelevant.

[8] The test when requested to determine a question of law prior to trial is set out in *Perera v Canada*, [1998] 3 FC 981 (CA) [*Perera*]. There, the Court of Appeal stated that prior to ordering that the proposed question be determined before trial, the Court must be satisfied that:

- (i) The “proposed questions are pure questions of law, that is to say questions that may be answered without having to make any findings of fact;” and
- (ii) The “questions to be answered are not academic and will be ‘conclusive of a matter in dispute’.”

Perera also teaches that even if these two requirements are met, “the Court is under no obligation to grant the Rule [220] motion” because it is “exceptional and should be resorted to only when the Court is of the view that the adoption of that exceptional course will save time and expense [emphasis added].”

[9] When deciding whether to determine a question of law prior to trial, it is no doubt preferable to first consider whether those two requirements are met before considering whether the Court is satisfied that determining the proposed question will save time and expense. However, because providing detailed reasons on the first two requirements would cause considerable, and likely prejudicial delay (the trial is set to commence in less than three weeks), and because I am not satisfied that determining the proposed question will save time and expense, I will provide brief reasons only as to the latter to explain why I have concluded that the exceptional course sought by Pfizer will not be granted.

[10] When considering whether stating a question for determination will save time and expense, the Court of Appeal in *Perera* indicated that the “Court must take into consideration all of the circumstances of the case” including (i) any agreement of the parties, (ii) “the probability that the question will be answered in a manner that will dispose of the litigation,” (iii) the complexity of the facts that will have to be proved at the trial and the desirability, for that reason, of avoiding such a trial,” (iv) the difficulty and importance of the proposed question of law,” (v) “the desirability that they not be answered in a ‘vacuum’,” and (vi) “the possibility that the determination of the questions before trial might, in the end, save neither time nor expense.”

[11] I now turn to consider these six factors which, in my analysis, strongly favour refusing this motion.

[12] First, there is no agreement on stating a question for determination. In fact, this motion was vigorously opposed by Apotex.

[13] Second, regardless of the answer to the proposed question, the litigation will continue. Even if it is found that Apotex is not an interested party to any of the claims of the '446 Patent, other than claims 10, 18, and 23, there is no dispute that the trial must proceed on those claims – Apotex is an interested party to those claims.

[14] Third, it is not evident, and I am not satisfied, that an answer to the proposed question that restricts Apotex to the three claims that remain will result in there being a corresponding reduction of any significance in the complexity of the facts at trial. The allegations of invalidity are made by Apotex with respect to all of the 27 claims of the '446 Patent. Pfizer submits the following:

Apotex's allegations of invalidity must be considered on a claim by claim basis. By eliminating a number of claims from the matters in dispute, the litigation will be significantly simplified and shortened."

While that statement has a superficial attractiveness, Pfizer has offered no evidence to support it. The burden is on Pfizer to show that by reducing the claims, there will be a corresponding reduction not only in the amount of the evidence tendered but in the complexity of the evidence that will be tendered. The Court is simply not in a position, knowing nothing of the action except what is disclosed in the pleadings to make any reasoned assessment as to whether reducing the claims at issue will result in a shortened trial. I note that Apotex in its memorandum submits that no savings of the sort suggested by Pfizer will result. Absent any evidence from Pfizer as the party that bears the burden on this motion, the Court is unable to

accept its bald proposition that a reduction of necessary evidence or a lessening of complexity will occur.

[15] Fourth, the proposed question is both difficult and important. As was observed by Case Management Judge Aalto, it is “a fascinating issue ... and there has been much written on the topic.” Given its difficulty, it is uncertain that a considered opinion can be provided by the Court in the few days remaining before trial, even if the parties were in a position to make their submissions on the question immediately.

[16] Fifth, it appears that the only material facts are the ‘446 Patent, the Covenant Not to Sue, and the disclaimers, and thus the question does not appear to be one that would be determined in a vacuum. This is the only factor that favours Pfizer, assuming the question is a pure question of law and not, as Prothonotary Aalto stated, a question of mixed fact and law.

[17] Sixth, it is quite likely that no time or expense will be saved if the question is determined before trial. The trial is set to commence in less than three weeks, therefore there is no saving to be had in time and expense related to pre-trial pleading, discovery, or proceedings – they have concluded. Further, because the hearing of the requested motion will likely take at least a day, and a decision reached only days before trial, if not at the commencement of the trial, there will be little saving in time and expense with respect to the parties’ and the Court’s pre-trial preparation. On the contrary, there is quite likely to be an increase for both. Moreover, a trial must be held in any event, as at least three of the claims of the ‘446 Patent would remain at issue.

[18] Furthermore, I accept the submission of Apotex that “a further delay of the disposition of this action is strongly to the prejudice of Apotex in light of its desire to market its own sildenafil containing drug product [and given that] the ‘446 Patent is to expire on May 14, 2014.”

Although prejudice is not mentioned in *Perera*, the list offered by the Court of Appeal is not a closed list of considerations. In my view, prejudice is a relevant consideration in determining whether or not to state a question for determination prior to trial, especially when, as here, it is brought so close to the scheduled trial date.

[19] Because Pfizer has been unsuccessful and waited until the last moment before bringing its motion for the determination of a question of law, Apotex is entitled to its costs of this motion, in any event of the cause.

ORDER

THIS COURT ORDERS that the motion is dismissed, the Court will not determine the question proposed before trial or at the outset of trial, and Apotex is awarded its costs of this motion, in any event of the cause.

"Russel W. Zinn"

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-772-09

STYLE OF CAUSE: APOTEX INC. v. PFIZER IRELAND
PHARMACEUTICALS

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**REASONS FOR ORDER
AND ORDER:** ZINN J.

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