

Federal Court



Cour fédérale

Date: 20140425

Docket: T-1156-12

Citation: 2014 FC 391

Ottawa, Ontario, April 25, 2014

PRESENT: The Honourable Madam Justice Mactavish**BETWEEN:****GILEAD SCIENCES, INC., AND
GILEAD SCIENCES CANADA, INC.****Plaintiffs****And****IDENIX PHARMACEUTICALS INC.,
UNIVERSITA DEGLI STUDI DI CAGLIARI,
L'UNIVERSITE MONTPELLIER II AND
CENTRE NATIONAL DE LA RECHERCHE
SCIENTIFIQUE****Defendants****AND BETWEEN:****IDENIX PHARMACEUTICALS INC.****Plaintiff By Counterclaim****And****GILEAD PHARMASSET LLC
GILEAD SCIENCES, INC., AND
GILEAD SCIENCES CANADA, INC.****Defendants By Counterclaim****REASONS FOR ORDER AND ORDER**

[1] The appellant, Idenix Pharmaceuticals Inc., characterize the questions raised by this appeal as being whether, as a matter of policy, the Canadian patent system should countenance

outright fraud, and whether this important policy question should be decided by a pleadings motion.

[2] For the reasons that follow, I have concluded that the appellants should be permitted to amend their pleadings to add a further claim of invalidity, based upon an alleged wilful misrepresentation as to the inventorship of the patent in issue. Consequently, the appeal from the order of a Prothonotary refusing leave to make such an amendment will be allowed.

I. Background

[3] Through its counterclaim in this patent action, Idenix Pharmaceuticals Limited (Idenix) seeks to invalidate Canadian Patent 2,527,657 (the '657 Patent) owned by Gilead Pharmasset LLC (Pharmasset). The '657 Patent issued from a PCT application, which in turn claimed priority to a United States Patent Application 60/474,368 (the '368 Application).

[4] Two Pharmasset employees, Jeremy Clark and Lieven Stuyver, are listed as the inventors on the '368 Application. In contrast, only Jeremy Clark is listed as an inventor on the PCT application that resulted in the '657 Patent.

[5] Idenix appeals from a February 26, 2014 Order of a Prothonotary denying it leave to further amend its Amended Statement of Defence and Counterclaim to add an additional ground of invalidity in relation to the '657 Patent, based upon subsection 53(1) of the *Patent Act*, R.S.C., 1985, c. P-4.

[6] Section 53(1) of the *Patent Act* provides that:

53. (1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading. [my emphasis]

53. (1) Le brevet est nul si la pétition du demandeur, relative à ce brevet, contient quelque allégation importante qui n'est pas conforme à la vérité, ou si le mémoire descriptif et les dessins contiennent plus ou moins qu'il n'est nécessaire pour démontrer ce qu'ils sont censés démontrer, et si l'omission ou l'addition est volontairement faite pour induire en erreur. [je souligne]

[7] With its proposed amendment, Idenix sought to add the following additional allegations of fact, as summarized by the Prothonotary:

- That Lieven Stuyver was one of the inventors of the invention claimed in the '368 Provisional Application and the '657 Patent;
- That Pharmasset and individually named members of its management team were aware that Lieven Stuyver was one of the inventors;
- That Pharmasset's manager was aware of the "materiality" of naming the correct inventors on patent applications;
- That Pharmasset and certain identified managers knowingly, and for purposes unrelated to Dr. Stuyver's substantial contribution to the invention (such as spite or vengefulness) omitted Dr. Stuyver's name as an inventor in the PCT Application which led to the '657 Patent; and

- That Pharmasset and its management threatened Dr. Stuyver to get him to sign a false declaration as to his inventorship in order to correct the inventorship originally declared on the '368 Provisional Application.

II. The Prothonotary's Decision

[8] The Prothonotary denied Idenix leave to make the amendments sought. While she was satisfied that Idenix's proposed pleadings adequately pleaded an untrue allegation that had been wilfully made, the Prothonotary nevertheless found that they failed to disclose a reasonable cause of action as "they fail to plead any material fact upon which the Court could reasonably make a finding that the untrue allegation was material" within the meaning of section 53(1) of the *Patent Act*.

[9] The Prothonotary concluded by observing that, assuming that all of Idenix's allegations and proposed allegations were true, identifying Dr. Stuyver as a co-inventor of the invention claimed by the '657 Patent would not have made any difference to Pharmasset's entitlement to the patent, given that both inventors' rights to the invention were held by their employer at the material time.

III. Standard of Review

[10] As the Federal Court of Appeal observed in *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, at paras. 18-19, 30 C.P.R. (4th) 40, discretionary orders of Prothonotaries ought not to be disturbed on appeal unless the question raised by the motion is vital to the final issue in the case, or the order is clearly wrong, in the sense that the exercise of discretion was based upon a wrong principle or a misapprehension of the facts.

[11] The parties agree that the question of whether Idenix's proposed amendment to its pleading raises a reasonable cause of action is a question of law that is reviewable on the standard of correctness and may be considered on a *de novo* basis.

IV. Analysis

[12] The *Federal Courts Rules*, SOR/98-106 govern amendments to pleadings and provide for a liberal approach to amendments: *Sanofi-Aventis Canada Inc. v. Teva Canada Ltd.*, 2014 FCA 65, at para. 13. [2014] F.C.J. No. 254. Nevertheless, the party seeking to amend its pleadings bears the burden of proving that the cause of action that it seeks to plead discloses a triable issue.

[13] In *Canderel Ltd. v. Canada*, [1994] 1 F.C. 3, at para. 9, [1993] F.C.J. No. 777, the Federal Court of Appeal held that "while it is impossible to enumerate all the factors that a judge must take into consideration in determining whether it is just, in a given case, to authorize an amendment, the general rule is that an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice".

[14] An amendment may, however, be disallowed if it is "plain and obvious" that the proposed pleading discloses no reasonable cause of action. However, a plaintiff should not be precluded from advancing a plea if there is a chance that the plaintiff might succeed. As the Federal Court of Appeal has noted "[n]either the length and complexity of the issues, the novelty of the cause of action, nor the potential for the defendant to present a strong defence should prevent the plaintiff from proceeding with his or her case". Indeed, it is only if the claim "is certain to fail because it contains a radical defect" that an amendment should be disallowed:

Laboratoires Servier v. Apotex Inc., 2007 FCA 350, at para. 25, , 61 C.P.R. (4th) 408, citing *Hunt v. Carey Inc.*, [1990] 2 S.C.R. 959 at p. 980, [1990] S.C.J. No. 93.

[15] Pharmasset asserts that Idenix's proposed amendment was properly refused in this case, as it was "doomed to fail". According to Pharmasset, it did not allege sufficient material facts addressing all of the required elements under subsection 53(1) of the *Patent Act*.

[16] Pharmasset contends that the jurisprudence has definitively established that in order for an untrue allegation in a patent application to void a patent under subsection 53(1) of the *Patent Act*, the allegation must be "material".

[17] Pharmasset further asserts that Idenix has failed to plead or identify any facts that could establish the materiality of the alleged mis-statement as to the identity of the inventors of the invention claimed by the '657 Patent. In particular, Idenix has failed to demonstrate how the alleged misrepresentation could have any bearing on the validity, scope or ownership of the patent, or the public's ability to access or use the patent.

[18] For the purposes of this appeal, Idenix does not dispute that, in accordance with the terms of their employment with Pharmasset, both Mr. Clark and Dr. Stuyver were obliged to assign ownership of any inventions made by them in the course of their employment to their employer. In light of this, Pharmasset says that even if Dr. Stuyver had been named as a co-inventor of the invention claimed by the '657 Patent, it would have had no effect on patent ownership and would not have affected the public's access to the invention. Consequently, Idenix's proposed amendment does not raise a triable issue, and was properly disallowed by the Prothonotary.

[19] I have carefully reviewed the jurisprudence cited by the parties and have concluded that the law in this area is not quite as settled as Pharmasset contends.

[20] First of all, it has been held that the question of “materiality” requires “a fact-specific determination”, and that “the materiality of inventorship will depend on the circumstances of any particular case”: *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, at paras. 126 and 128, [2011] F.C.J. No. 1090.

[21] To the extent that the question of materiality is dependent on the facts of the individual case, this suggests that the issue of materiality may not be something that should be determined in the context of a pleadings motion.

[22] I recognize that in *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.* (1978), 39 C.P.R. (2d) 145, [1978] F.C.J. No. 812, this Court held that “it is really immaterial to the public whether the applicant is the inventor or one of two joint inventors as this does not go to the term or to the substance of the invention nor even to the entitlement”: at p. 157, (aff'd (1979), 42 C.P.R. (2d) 33 (F.C.A.), [1979] F.C.J. No. 405).

[23] Moreover, in *671905 Alberta Inc. v. Q'Max Solutions Inc.*, 2003 FCA 241, [2003] 4 F.C. 713 (*Q'Max*), the Federal Court of Appeal held that “an untrue ‘material allegation’ that consists of a failure to name co-inventors in a petition for a patent will not render the patent void if the allegation was not ‘wilfully made for the purpose of misleading’”: at para. 31.

[24] That said, the Federal Court of Appeal’s statement in *Q'Max* suggests that it is at least arguable that an untrue ‘material allegation’ that consists of a failure to name co-inventors in a

petition for a patent could render the patent void if the allegation was ‘wilfully made for the purpose of misleading’.

[25] The Supreme Court of Canada found that it did not have to address this question in *Apotex v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153, because of its finding that the individuals allegedly omitted from the patent application in that case were not in fact co-inventors of the invention in question, and because there was “no evidence whatsoever that the omission to name them was ‘wilfully made for the purpose of misleading’”: at para. 109.

[26] In contrast, in this case, it is alleged that the misstatement was indeed wilfully made for the purpose of misleading, an allegation which must be presumed to be true for the purposes of this motion.

[27] Most recently, in *Weatherford Canada Ltd.*, above, it was argued by the appellants that an intentional misstatement as to inventorship is always material for purposes of subsection 53(1) of the *Patent Act*. The Federal Court of Appeal rejected this contention on the basis that the premise underlying the appellant’s argument was faulty, as there had been no express finding of intentional misleading by the trial judge: at para. 120.

[28] The Court considered “public policy” arguments such as those advanced by Idenix in this case, namely “the identification of inventors, the need to promote integrity of the Commissioner’s office and the Canadian patent system, Canada’s international obligations, and the personal benefits to which inventors are entitled in respect of their inventions”: at para. 123. While noting that these arguments were “not to be minimized”, the Court concluded that it was

“highly doubtful” that such arguments would be “determinative for purposes of interpreting materiality in the context of subsection 53(1)”: at para. 123.

[29] The Court further noted that the voiding of a patent on the basis of misstated inventorship is a “draconian remedy”, and that the appellants’ policy arguments had to be balanced against this potential result: at para. 123.

[30] Two comments have to be made in this regard.

[31] Firstly, the Federal Court of Appeal held that it was “highly doubtful” that public policy arguments would be determinative of the question of materiality. It did not, however, rule it out altogether as a possibility in the appropriate case.

[32] More importantly, however, the Court’s comments as to the balancing that had to be carried out between the “draconian remedy” of voiding a patent and the “public policy” arguments relating to the integrity of the patent system were made in the context of a case where *no* intentionally misleading statements had been found to have been made. It remains to be seen where the balance would be struck, in the event that Idenix is ultimately able to establish that there had been an intentional misstatement by Pharmasset as to the true identity of the inventors in this case.

[33] The Federal Court of Appeal went on in *Weatherford Canada Ltd.* to consider arguments as to the materiality of inventorship, based upon the facts of that case, noting that “misstating inventors has previously been considered sufficient to invalidate a patent”: at para. 126, citing *Comstock Canada v. Electec Ltd.* (1991), 38 C.P.R. (3d) 29, 45 F.T.R. 241 (F.C.T.D.).

[34] The Court further observed at paragraph 126 of *Weatherford Canada Ltd.* that in *Merck & Co. v. Canada (Minister of Health)*, 2010 FC 1042, 88 C.P.R. (4th) 98, at paragraph 56, the Federal Court had held that a subsection 53(1) argument “would have had considerable force”, but for the finding that no untrue allegation had been made as to inventorship.

[35] At the same time, the Federal Court of Appeal noted that inventorship has been found to be immaterial in other cases, citing the comment in *Procter & Gamble Co.* cited above, where the finding as to the lack of materiality was made “on the facts of that case”: *Weatherford Canada Ltd.*, above at para. 127.

[36] The Federal Court of Appeal concluded its analysis in *Weatherford Canada Ltd.* by stating that “[t]he appellants have not demonstrated, as a matter of law, that inventorship is material *in all circumstances*. Nor have they established that any particular combination of facts will *necessarily* render the identity of an inventor material for the purpose of subsection 53(1)” [my emphasis].

[37] In none of the cases cited by Pharmasset had it been proven that an intentionally misleading statement as to inventorship had been made in the context of a patent application. As a consequence, there is no clear judicial pronouncement as to how such a finding would factor into the subsection 53(1) analysis, particularly in relation to the question of materiality.

[38] Moreover, as noted above, the Federal Court of Appeal has taught that the question of “materiality” requires “a fact-specific determination”, and that “the materiality of inventorship will depend on the circumstances of any particular case”.

[39] In these circumstances, I am satisfied that the law in this area is not so settled that Idenix should be precluded at this stage from advancing its plea. It is not “plain and obvious” that Idenix cannot succeed on the issue raised by its proposed amendment. The legal arguments advanced by Pharmasset should be considered by the trial judge in the context of the proven facts of the case, and should not be determined in a factual vacuum in the context of a pleadings motion.

[40] For these reasons, the appeal is allowed. Leave is granted to Idenix to amend its Amended Statement of Defence and Counterclaim to add the allegations set out in paragraphs 58A to 58F of its original Notice of Motion. Costs of this appeal shall be in the cause.

ORDER**THIS COURT ORDERS that:**

1. The appeal is allowed. Leave is granted to Idenix to amend its Amended Statement of Defence and Counterclaim as set out in paragraphs 58A to 58F of its original notice of motion; and

2. Costs of the appeal shall be in the cause

"Anne L. Mactavish"

Judge

FEDERAL COURT**SOLICITORS OF RECORD**

DOCKET: T-1156-12

STYLE OF CAUSE: GILEAD SCIENCES, INC., AND GILEAD SCIENCES CANADA, INC. v IDENIX PHARMACEUTICALS INC., UNIVERSITA DEGLI STUDI CAGLIARI, L'UNIVERSITE MONTPELLIER II AND CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE

AND BETWEEN:

STYLE OF CAUSE: IDENIX PHARMACEUTICALS INC. v GILEAD PHARMASSET LLC GILEAD SCIENCES, INC., AND GILEAD SCIENCES CANADA, INC.

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: MARCH 18, 2014

REASONS FOR ORDER AND ORDER: MACTAVISH J.

DATED: APRIL 25, 2014

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