Federal Court Cour fédérale

Date: 20170725

Dockets: T-598-17
T-599-17
T-600-17
T-601-17
T-602-17
T-603-17
T-604-17
T-605-17

Citation: 2017 FC 676

Ottawa, Ontario, July 25, 2017

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

ABBVIE CORPORATION AND
ABBVIE BIOTECHNOLOGY LTD.

Applicants

and

SAMSUNG BIOEPIS CO., LTD. AND
THE MINISTER OF HEALTH

Respondents

AMENDED ORDER AND REASONS

I. Introduction

[1] There are three applications by the Applicants, AbbVie Corporation and AbbVie Biotechnology Ltd (together, "AbbVie"), for an Order pursuant to Rules 3, 55, 306, 307, and 385(1)(a) of the *Federal Court Rules* requiring the Respondents, Samsung Bioepis, Ltd. ("Bioepis"), to reverse the order of the Parties' evidence and serve its evidence on the issues of (1) claim relevancy, (2) priority date entitlement, and (3) material misrepresentation before AbbVie is required to deliver its evidence on those issues. The Applicants' also seek their costs of the motion.

II. Background

[2] On March 2,, 2017, Bioepis filed new drug submissions ("NDS") no. 203250 ("NDS 2032050"") and no. 203292 ("NDS 263292") for its adalimumab product named HADLIMA. The NDSs contain different but overlapping indications for HADLIMA. The indications for which NDS 203250 was filed include the treatment of Crohn's disease, ulcerative colitis, and hidradenitis suppurativa, whereas NDS 203292 does not include these indications.

[3] On March 13,20l7, Bioepis served eight Notices of Allegation ("NOAs") in relation to the HADLIMA product (the "Bioepis Letters"). For each NDS, Bioepis served a NOA for each of the following patents, which AbbVie had listed on the Patent Register: i) Canadian Patent No. 2,385,745 (the "'745 Patent"); ii) Canadian Patent No. 2,494,756 (the "'756 Patent"); iii)

Canadian Patent No. 2,847,142 (the "'142 Patent"); and iv) Canadian Patent No. 2,504,868 (the "'868 Patent").

[4] The Bioepis Letters each contain the following allegations of invalidity: anticipation, obviousness, double patenting, lack of utility, overbreadth, insufficiency, ambiguity, and unpatentable subject-matter (method of medical treatment). Bioepis also alleges that:

a) Bioepis is not required to address the claims of the '868 and '142 Patents;
b) AbbVie is not entitled to rely on any of the priority dates of the '868 and '142 Patents (April 9, 2004, April 12, 2004, or May 7, 2004) on the basis that the requirements of section 28.1(1) of the *Patent Act* were not met; and
c) the petitions for the '868 and '142 Patents contained a material allegation that was untrue and wilfully made for the purpose of misleading, pursuant to section 53 of the *Patent Act*.

[5] AbbVie denies each and every allegation made by Bioepis.

[6] On April 25, 2017, the AbbVie initiated eight applications, under the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*") in response to the NOAs, for orders prohibiting the Minister of Health from issuing notices of compliance to Bioepis for the Bioepis Products:

a) Court File No. T-598- l7 addressing the NOA for NDS 203250 and the '868 Patent;
b) Court File No. T-599-17 addressing the NOA for NDS 203250 and the '745 Patent;
c) Court File No. T-600-17 addressing the NOA for NDS 203292 and the '868 Patent;
d) Court File No. T-601-17 addressing the NOA for NDS 203292 and the '142 Patent;
e) Court File No. T-602-17 addressing the NOA for NDS 203292 and the '745 Patent;
f) Court File No. T-603-17 addressing the NOA for NDS 203292 and the '756 Patent;
g) Court File No. T-604-17 addressing the NOA for NDS 203250 and the '142 Patent; and
h) Court File No. T-605-17 addressing the NOA for NDS 203250 and the '756 Patent.

[7] In its motions for reversal of evidence, AbbVie asserts that Bioepis' allegations concerning claim relevancy, priority date entitlement, and material misrepresentation are

insufficient, unclear, and do not constitute a detailed statement pursuant to the *Regulations*. For this reason, AbbVie seeks a reversal of the ordinary order of evidence on these issues.

III. Analysis

[8] Rules 306 and 307 of the *Federal Court Rules* set out the order for evidence to be filed in an application, and generally provide that the applicant's evidence is to be filed before the respondent's evidence.

[9] However, the Court has the discretion to reverse the order of evidence where it would provide a just, most expeditious and least expensive determination of the proceeding on its merits (*Federal Court Rules* 3, 55, and 385(1)(a); *Eli Lilly Canada Inc v Novopharm Limited*, 2008 FC 875 at para 10; *Tekeda v Canada (Minister of Health)*, 2013 Carswell Nat 11553 at para 3).

[10] Moreover, reversal of evidence should only be granted where there are special circumstances and not where such a reversal will delay the proceedings and result in additional costs (*Pfizer Canada Inc v Apotex Inc*, 2013 FC 1036 at paras 1, 3; *Abbott Laboratories Limited et al v Novopharm et al*, 2007 FC 1291 at para 17).

[11] By Direction of this Court dated June 7, 2017, a timetable governing the proceedings was issued stating that, *inter alia*:

> 5. The Applicants' evidence on all issues shall be served by October 17, 2017.

6. The Respondent's evidence on all issues shall be served by February 9, 2018.

[12] Notwithstanding AbbVie's motion for a partial reversal of the filing of evidence relating to claim relevancy, priority date entitlement and material misrepresentation, AbbVie has otherwise agreed to serve its evidence first on issue of claim construction, non-infringement, anticipation, obviousness, lack of utility, insufficiency, and method of medical treatment.

[13] The three motions concerning these allegations are divided as follows:

i. T-598-17, T-600-17, T-601-17 and T-604-17, relating to the '868 Patent and '142 Patent;
ii. T-599-17 and T-602-17, relating to the '745 Patent; and
iii. T-603-17 and T-605-17, relating to the '756 Patent.

[14] I will deal with the motions by way of dealing with each of the three issues for all the patents.

A. *Claim Relevancy Allegations*

[15] At the hearing, counsel for Bioepis admitted that claim relevancy is no longer an issue with respect to the '898 Patent in T-598-17, T-600-17, T-601-17 and T-604-17. Counsel for AbbVie drew to the Court's attention the grounds for a Notice of Allegation under section 5(1) and 5(2) of the Patented Medicines (Notice of Compliance) Regulations:

5 (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the	5 (1) Dans le cas où la seconde personne dépose une présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une

submission, with respect to each patent on the register in respect of the other drug,	liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans sa présentation :
(a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or (b) allege that	a) soit une déclaration portant qu'elle accepte que l'avis de conformité ne sera pas délivré avant l'expiration du brevet; b) soit une allégation portant que, selon le cas :
(i) the statement made by the first person under paragraph 4(4)(d) is false, (ii) the patent has expired, (iii) the patent is not valid, or (iv) 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.	(i) la déclaration présentée par la première personne aux termes de l'alinéa 4(4)d) est fausse, (ii) le brevet est expiré, (iii) le brevet n'est pas valide, (iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle la présentation est déposée.
(2) If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the supplement, with respect to each patent on the register in respect of the other drug,	(2) Dans le cas où la seconde personne dépose un supplément à la présentation visée au paragraphe (1), en vue d'obtenir un avis de conformité à l'égard d'une modification de la formulation, d'une modification de la forme posologique ou d'une modification de l'utilisation de l'ingrédient médicinal, lequel supplément, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes de l'avis de conformité délivré à la première personne et à l'égard duquel une liste de brevets a été présentée — ou y fait renvoi — , cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans son supplément :
(a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or (b) allege that	a) soit une déclaration portant qu'elle accepte que l'avis de conformité ne sera pas délivré avant l'expiration du brevet; b) soit une allégation portant que, selon le cas :

(i) the statement made by the first person under paragraph 4(4)(d) is false, (ii) the patent has expired, (iii) the patent is not valid, or (iv) 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 supplement is filed.	(i) la déclaration présentée par la première personne aux termes de l'alinéa 4(4)d) est fausse, (ii) le brevet est expiré, (iii) le brevet n'est pas valide, (iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle le supplément est déposé.

[16] AbbVie argued that, for each of the patents in the three applications, the allegations relating to claim relevancy have no basis under either section 5(1) or 5(2), unless that allegation relates to subparagraph 5(1)(b)(iv), namely that :

> (iv) 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.

[17] Therefore, the allegations should have been clear and limited to the question of infringement in each of the applications.

[18] Counsel for Bioepis agreed that, pursuant to the decision of Justice Johanne Gauthier of the Federal Court (as she then was), in *Solvay Pharma Inc v Apotex Inc*, 2008 FC 308 at paragraphs 55 to 66, the allegation of claim relevancy is to be so limited, and the Parties agreed that as a result this issue as it relates to infringement is no longer part of the motions to be decided with respect to reversal of evidence.

B. *Priority Date Entitlement*

(1) T-598-17, T-600-17, T-601-17 and T-604-17: the ‘898 and ‘142 Patents

[19] AbbVie argues that the priority date allegations, in respect of the ‘898 Patent (section 5.1, page 40 of the NOA) and in respect of the ‘142 Patent (section 7.1, page 43 of the NOA), are deficient in not providing any basis for the priority date entitlement allegations. Specifically, Bioepis alleges that “AbbVie is not entitled to any of its priority dates of April 9, 2004, April 12, 2004, or May 7, 2004, because the requirements of section 28.1(1) of the *Patent Act* are not met”. Therefore, certain prior art to be relied on will be relevant to the issues of novelty and obviousness.

[20] Section 28.1(1) states:

Claim date 28.1 (1) The date of a claim in an application for a patent in Canada (the “pending application”) is the filing date of the application, unless (a) the pending application is filed by (i) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or (ii) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to	Date de la revendication 28.1 (1) La date de la revendication d’une demande de brevet est la date de dépôt de celle-ci, sauf si : a) la demande est déposée, selon le cas : (i) par une personne qui a antérieurement déposé de façon régulière, au Canada ou pour le Canada, ou dont l’agent, le représentant légal ou le prédécesseur en droit l’a fait, une demande de brevet divulguant l’objet que définit la revendication, (ii) par une personne qui a antérieurement déposé de façon régulière, dans un autre pays ou pour un autre pays, ou dont l’agent, le représentant légal ou le prédécesseur en droit l’a fait, une demande de brevet divulguant l’objet que définit la revendication, dans le cas où ce pays protège les droits de cette personne

citizens of Canada an application for a patent disclosing the subject-matter defined by the claim; (b) the filing date of the pending application is within twelve months after the filing date of the previously regularly filed application; and (c) the applicant has made a request for priority on the basis of the previously regularly filed application.	par traité ou convention, relatif aux brevets, auquel le Canada est partie, et accorde par traité, convention ou loi une protection similaire aux citoyens du Canada; b) elle est déposée dans les douze mois de la date de dépôt de la demande déposée antérieurement; c) le demandeur a présenté, à l'égard de sa demande, une demande de priorité fondée sur la demande déposée antérieurement.

[21] Bioepis' replies that it is readily apparent that only subparagraph 28.1(1)(a)(ii) applies, and therefore AbbVie is aware that the allegation is challenging whether Bioepis is entitled to claim priority on the basis that Bioepis did not acquire title through an agent, legal representative or predecessor in title, who previously regularly filed an application for a patent disclosing the subject-matter claimed in either the '898 or '142 Patent.

[22] AbbVie responds by arguing that the assignment and title issue is very complex, and will require substantial time, money, and expert testimony if a reversal of order for evidence on this issue is not granted by the Court.

(2) T-599-17 and T-602-17: the '745 Patent

[23] AbbVie argues that the priority allegation with respect to the '745 Patent (section 6.1, page 45 of the NOA), while it has some detail, nevertheless is insufficient, unjustified, and not a proper allegation under section 5 of the *Regulations*.

[24] Bioepis responds with the fact that the allegation at 6.1 specifies that:

> AbbVie is not entitled to the priority date of June 8, 2001 because the requirements of section 28.1(1) of the *Patent Act* have not been met. **At the time Canadian Patent Application 2,385,745 (the "745 Application") was filed, on May 10, 2002, this Application and the priority application (US60/296,961) were owned by two different entities. On May 10, 2002, the application of the 745 Application was Abbott Laboratories (Bermuda) Ltd., but the priority application was owned by another entity**. Abbott Laboratories (Bermuda) Ltd. was not the agent, the legal representative or the predecessor in title of the entity which owned the priority application, and Abbott Laboratories (Bermuda) Ltd. was therefore not entitled to take advantage of the priority date of US60/296,961. Therefore, the novelty and inventiveness of the 745 Patent must be analyzed as of the Canadian filing date of May 10, 2002.
>
> (Emphasis in original)

[25] Therefore, sufficient detail of the allegation is provided. Furthermore, Bioepis argues that AbbVie in its Notice of Application provides no detail as to how the priority application complies with the Patent Act.

(3) T-603-17 and T-605-17: the '756 Patent

[26] AbbVie concedes that the allegation concerning this priority claim is sufficient.

[27] Further, AbbVie agrees that there is no section 53 allegation in respect of this patent.

[28] I have considered the allegations concerning priority entitlement in detail. I am not convinced, on a balance of probabilities, that a reversal of evidence would be more just, and save

time or expenses in these proceedings, nor is there a basis to find that special circumstances exist that would benefit from such a reversal in dealing with the issue of priority entitlement.

[29] A partial reversal of evidence, particularly on one issue, in only some of the matters involved in these multiple proceedings, which are to be heard together, would probably result in more complex proceedings and necessitate reply evidence by Bioepis, if ordered.

[30] Moreover, I find that sufficient facts are provided on this issue for AbbVie to serve its evidence in the normal course (*AstraZeneca Canada Inc et al v Apotex Inc et al*, 2008 FC 537 at paras 8 to 10).

C. *Material Misrepresentation Allegation*

(1) T-598-17, T-600-17, T-601-17 and T-604-17: the ‘898 and ‘142 Patents

[31] AbbVie’s position is that the Bioepis allegation of material misrepresentation under section 53 of the *Patent Act* “baldy alleges that the failure to name the proper inventors was wilfully made for the purpose of misleading” (section 5.9, pp 85, 86 of the NOA). Given that the Court has held that section 53 allegations are essentially allegations of fraud, a consideration of the wrong doer’s state of mind is necessary, and no facts are provided in this regard.

[32] Bioepis replies by stating that the basis of the section 53 allegation is the failure to name the proper inventors, as fully set out in section 5.9:

> Claims 1-16 of the 142 Patent are invalid because a material allegation in the petition of the applicant in respect of the 142

> Patent is untrue and wilfully made for the purpose of misleading, contrary to section 53 of the *Patent Act*. **The petition fails to name the proper inventors of the 142 Patent. The failure to list the inventors was wilfully made for the purpose of misleading.**
>
> **The petition is the application for the 142 Patent stated that Rebecca Hoffman, Elliott Keith Chartash, Lori Taylor, George Richard Granneman and Philip Yan are the inventors of the 142 Patent.** The 142 Patent purportedly relates to the use of D2E7 to treat IBD and HS. Examples 1 and 2 in the 142 Patent related to the treatment of Crohn's disease and are the only examples in the 142 Patent related to IBD or HS.
>
> **Example 1 of the 142 Patent was disclosed in Hanaeur, "Human Anti-Tumor Necrosis Factor Monoclonal Antibody (Adalimumab) in Crohn's Disease: the CLASSIC-I Trial", *Gastroenterology*, 2006, 130:323-333 ("Hanauer 2006"). None of the authors of Hanauer 2006 are listed as inventors of the 142 Patent.** Hanauer 2006 states that "[t]his study was designed by Abbott Laboratories staff members and 2 of the investigators who are authors of this report (S.B.H. and W.J.S.)". S.B.H. is Stephen B. Hanauer and W.J.S. is William J. Sandborn.
>
> **Example 2 was disclosed is Sandborn 2004. None of the authors of Sandborn 2004 are listed as inventors of the 142 Patent.**
>
> **None of the proper inventors of the 142 Patent were named in the petition. The proper inventors included Stephen B. Hanauer, William J. Sandborn and possibly others who were not named as inventors in the petition of the 142 Patent. This failure to name the proper inventors was wilfully made for the purpose of misleading.**
>
> (Emphasis in original)

(2) T-599-17 and T-602-17: the '745 Patent

[33] AbbVie argues that, like in the motion related to the '898 and '142 Patents, the allegation of material misrepresentation in respect of the '745 Patent (section 6.7, page 74 of the NOA) is vague and insufficient, focussing on the lack of facts supporting any wilful intent in making the

alleged misrepresentation concerning named inventors – i.e., there is a lack of particularity (*Apotex Inc v Shire LLC*, 2016 FC 1267 at para 7; *Ratiopharm Inc v Pfizer Limited*, 2009 FC 711 at para 196).

[34] Once again, Bioepis responds by stating that the allegation of material misrepresentation is clear, in that the inclusion of Abbott Bermuda being listed as the applicant in the petition is a material misrepresentation, because Abbott Bermuda was not in fact the applicant when the petition was signed.

(3) T-603-17 and T-605-17: the ‘756 Patent

[35] As stated above, there is no section 53 allegation in respect of this application and therefore no issue with respect to the ‘756 Patent.

[36] For reasons similar to those given above, in respect of the issue of priority entitlement, I find that on the record before me there are sufficient facts in support of the alleged material misrepresentation for AbbVie to proceed in serving its evidence in the normal course, without a reversal order.

[37] If there is a deficiency in the allegation in that the wilfulness of the misrepresentation has not been set out, Bioepis will run the risk that it has failed to plead sufficient facts to support its allegation and, as admitted by Bioepis at the hearing, no reversal of evidence will remedy the defect – that is an issue for the applications judge.

[38] Further, I agree with Bioepis that a reversal order in this proposed piecemeal fashion will likely add to the complexity of the proceedings, and will not ensure the most expeditious and least expensive determination of this issue.

[39] One further note is worth making. Both Parties' counsel referred to extensive litigation in the United Kingdom involving the question of title and assignments involving the Parties under German and UK law, where a determination of ownership and title on related patents to those in issue here was reached. I encouraged counsel for the Parties to explore resolving this issue and questions of fact and law prior to the hearing on the merits, which could substantially reduce time and expense in the proceedings.

[40] The motion is dismissed with costs to Bioepis.

AMENDED ORDER in T-598-17, T-599-17, T-600-17, T-601-17,

T-602-17, T-603-17, T-604-17, T-605-17

THIS COURT ORDERS that:

1. The motion is dismissed with costs to Samsung Bioepis, Ltd., calculated at the midrange of Column 4 of Tariff B.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-598-17, T-599-17, T-600-17, T-601-17, T-602-17,T-603-17, T-604-17, T-605-17
STYLE OF CAUSE:	ABBVIE CORPORATION AND ABBVIE BIOTECHNOLOGY LTD. v SAMSUNG BIOEPIS CO., LTD. AND THE MINISTER OF HEALTH
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DATED:	JULY 25, 2017

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