Federal Court Cour fédérale

Date: 20191217

Docket: T-226-18

Citation: 2019 FC 1579

Toronto, Ontario, December 17, 2019

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

**VIIV HEALTHCARE COMPANY,
SHIONOGI & CO., LTD. AND
VIIV HEALTHCARE ULC**

**Plaintiffs/
Defendants by Counterclaim**

and

GILEAD SCIENCES CANADA, INC.

**Defendant/
Plaintiff by Counterclaim**

JUDGMENT AND REASONS

I. Introduction

[1] This is an appeal of an Order of Prothonotary Milczynski [the Prothonotary] dated October 9, 2019. The plaintiffs, and appellants in this motion, are ViiV Healthcare Company, Shionogi & Co Ltd, and ViiV Healthcare ULC [collectively ViiV], and the defendant is Gilead

Sciences Canada Inc [Gilead]. The Prothonotary dismissed ViiV's motion for production of documents containing underlying data for a study referred to in BICGILEADCA0003351. The relevant information disclosed in this document is also disclosed in a publicly available presentation submitted as part of ViiV's motion record. All references in this decision will refer to the publicly available document [the ASM Microbe Presentation].

II. Background

[2] This appeal arises in the context of a patent infringement action commenced by ViiV on February 7, 2018. ViiV alleges that Gilead has infringed Canadian Patent No. 2,606,282 [the 282 Patent] by making, using, selling, or offering to sell bictegravir as a component in its BIKTARVY product. Gilead denies all allegations of infringement, and counterclaims alleging that the 282 Patent is invalid.

[3] Pleadings closed on August 27, 2018, and documentary productions are ongoing. Initial productions took place on April 25, 2019. On July 31, 2019, ViiV requested additional documents from Gilead.

[4] On August 6, 2019, Gilead filed a notice of motion for summary trial, seeking a finding of non-infringement of claims 1, 11, and 16 of the 282 Patent. The sole issue for the summary trial is whether "Ring A" in claims 1, 11, and 16, properly construed, covers a bridged ring structure. If not, Gilead's position is that it does not infringe the asserted claims of the 282 Patent.

[5] The ASM Microbe Presentation is a PowerPoint presentation dated June 2016, produced by Gilead on April 25, 2019. In this presentation, Gilead reports having conducted a Structure-Activity-Relationship Study [SAR Study] comparing the structure of the Ring A component of ViiV's HIV drug dolutegravir and its anti-viral activity against variations of Ring A.

[6] The underlying SAR Study documents were not included in the initial productions. On September 10, 2019, ViiV requested:

> "documents and underlying data relating to the bridged Ring A experiments and studies reported on those pages, and any and all other studies and experiments done by or for Gilead that relate to Ring A or Gilead's variations of it."

[7] On October 2, 2019, ViiV filed an amended notice of motion to compel production of the raw data underlying the SAR Study with respect to the experiments and studies reported in Tables 1, 2, and 5 of the ASM Microbe Presentation.

[8] Gilead produced the underlying SAR Study data that relate to bictegravir prior to the hearing, but did not agree to produce background data relating to other compounds in Tables 1 and 2 of the ASM Microbe Presentation. Gilead refused because in its view, the "bridged Ring A experiments and studies" referenced in the ASM Microbe Presentation are irrelevant because they relate to compounds other than bictegravir, and because the experiments and studies are not relevant to claim construction.

III. The Prothonotary's Decision

[9] The motion took place on October 8, 2019. The Prothonotary dismissed the motion for production of the additional documents and background data by decision dated October 9, 2019.

[10] The Prothonotary identified the principles of claim construction from *Free World Trust v Électro Santé Inc,* 2000 SCC 66 [*Free World Trust*] and found that the information sought is irrelevant and inadmissible for the purpose of claim construction. At page 6 of her reasons, she found that post-publication evidence, such as the SAR Study data, cannot be used to construe the claims of the 282 Patent, on the basis that the relevant considerations for claim construction are the common general knowledge of a person ordinarily skilled in the art at the time of publication of the patent. Specific to the question of whether a variant of an element included in each of claims 1, 11, and 16 can nevertheless result in a finding of infringement, the Prothonotary found that the relevant consideration is "what such person at that time would have seen as a variant."

[11] The Prothonotary further found that "extrinsic evidence (such as other patents and contemporary documents) is not admissible for claim construction, including in determining whether an element is essential or not."

[12] ViiV appeals the Prothonotary's decision.

IV. Issues

[13] The issues are:

(1) Did the Prothonotary err in finding that post-publication date documents are not relevant for the purpose of claim construction?

(2) Did the Prothonotary err in finding that post-publication date documents are extrinsic evidence inadmissible for claim construction?

(3) Did the Prothonotary otherwise err in not ordering production of non-bictegravir documents?

V. Standard of Review

[14] On appeal, this Court will only interfere with discretionary decisions made by prothonotaries if they are incorrect in law or based on a palpable and overriding error with respect to the facts (*Hospira Healthcare Corporation v Kennedy Institute of Rheumatology*, 2016 FCA 215 at para 64).

[15] Palpable means an error that is obvious, and overriding means an error that effects the outcome of the case (*Mahjoub v Canada (Citizenship and Immigration)*, 2017 FCA 157 at paras 62-64).

[16] The power to compel documentary production is discretionary, and is therefore reviewable on the palpable and overriding error standard unless an extricable error of law is established (*Canada (Attorney General) v Fink*, 2017 FCA 87 at para 7).

VI. Analysis

A. *Did the Prothonotary err in finding that post-publication date documents are not relevant for the purpose of claim construction and that extrinsic evidence is inadmissible for that construction?*

[17] The parties agree that the analytical framework for determining whether claim elements are essential or non-essential was set out by the Supreme Court in *Free World Trust*. However, the parties disagree on how the relevant passages of the decision should be interpreted.

[18] ViiV's line of argument is based on the "variant question" of essentiality, articulated by Justice Binnie at paragraph 31(e)(iii) of *Free World Trust*:

> (e) The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. The identification of elements as essential or non-essential is made:
>
> […]
>
> (iii) having regard to whether or not it was obvious to the skilled reader at the time the patent was published that a variant of a particular element would not make a difference to the way in which the invention works; or
>
> (iv) according to the intent of the inventor, expressed or inferred from the claims, that a particular element is essential irrespective of its practical effect;

[19] Justice Binnie expands on the variant question at paragraph 55:

> It would be unfair to allow a patent monopoly to be breached with impunity by a copycat device that simply switched bells and whistles, to escape the literal claims of the patent. Thus the elements of the invention are identified as either essential elements (where substitution of another element or omission takes the device outside the monopoly), or non-essential elements (where substitution or omission is not necessarily fatal to an allegation of infringement). **For an element to be considered non-essential and thus substitutable, it must be shown** either (i) that on a purposive construction of the words of the claim it was clearly not intended to be essential, or (ii) **that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention, i.e., had the skilled worker at that time been told of both the element specified in the claim and**

> **the variant and "asked whether the variant would obviously work in the same way", the answer would be yes**: *Improver Corp. v. Remington, supra,* at p. 192.
>
> [emphasis added]

[20] ViiV relies on Justice Binnie's recitation of the "*Improver* questions" at paragraph 55 for the legal test for the "variant question":

> In *Improver Corp. v. Remington*, Hoffmann J. attempted to reduce the essence of the *Catnic* analysis to a series of concise questions, at p. 182:
>
> (i) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no: –
>
> (ii) Would this (i.e.: that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes: –
>
> (iii) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

[21] In ViiV's submission, the first *Improver* question—Does the variant have a material effect upon the way the invention works—is directed at a present day factual question, not a theoretical one. Therefore, post-publication evidence that a variant has a material effect on the way the invention works is relevant. Only at the second *Improver* question does the focus revert to the publication date.

[22] Conversely, Gilead argues that *Free World Trust* explicitly states that the essentiality assessment is limited to "known and obvious substitutability at the date of publication of the patent" (*Free World Trust*, above at para 57).

[23] I invited counsel for the parties to comment on the decisions of this Court and the Federal Court of Appeal in *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2009 FC 1141 [*Eurocopter FC*] and *Bell Helicopter Textron Canada Limitée v Eurocopter*, 2010 FCA 142 [*Eurocopter FCA*].

[24] Not surprisingly, counsel for ViiV takes the position that these decisions support the view that: (1) post-publication date extrinsic testing and correspondence as to whether a variant of a claim element performs "substantially the same function, in substantially the same way to obtain substantially the same result" as the invention is relevant in answering the *Free World Trust* question "does the variant have a material effect upon the way the invention works" and that (2) extrinsic evidence may be relevant to claim construction.

[25] Conversely, counsel for Gilead argues that bictegravir is the only Gilead compound in issue and if the Court finds that "Ring A" is a non-essential claim element, bictegravir is the only "variant" relevant to the infringement analysis that will follow.

[26] Gilead's position is that *Eurocopter FC* and *Eurocopter FCA* stand for the proposition that to the extent any of Gilead's post-publication information may be relevant to identify

essential elements in a claim, it is limited to information about the accused product(s), not every other potential product of the defendant.

[27] Moreover, the non-bictegravir compounds at issue on this motion are not allegedly infringing products – documents and underlying data related to bictegravir have been produced.

[28] Finally, in the later Eurocopter decisions of this Court in *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2012 FC 113 and the Federal Court of Appeal in *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2013 FCA 219, (1) the trial judge rejected a results-oriented approach to claims construction, and (2) the Court of Appeal found that comparing the invention and the defendant's infringing product to determine functional equivalence between a claim element and a "variant" for the purpose of infringement was inconsistent with the teachings of *Free World Trust* because "it fails to recognize the primacy of the language of the claims on determining the essential elements" (para 96).

[29] While these two sets of decisions in the Eurocopter cases appear to be at odds, at least in part, on the applicability of *Free World Trust* on claims construction and essentiality of claims elements, I find that the "variant question" branch of non-essentiality must be focused on the knowledge of the skilled addressee at the publication date. While Justice Binnie did recite the *Improver* questions, he specifically stated that these questions were an attempt to "reduce the essence of the *Catnic* analysis to a series of concise questions," and "the three questions are not exhaustive but they encapsulate the heart of Lord Diplock's analysis [in *Catnic*]" (*Free World Trust* at paras 55-56).

[30] ViiV's approach to the "variant question" parses the *Free World Trust* decision and treats the *Improver* questions as a strict legal test that is divorced from the remainder of the decision. Reading the decision in its entirety, I find that the focus of the analysis when determining the essentiality of a claim element must be on the skilled addressee at the publication date of the patent.

[31] The Prothonotary's statement that the relevant inquiry is "what [the skilled addressee] at that time would have seen as a variant" may appear to be slightly at odds with *Free World Trust*. The skilled addressee would not have necessarily needed to independently identify the variant in question. Rather, the inquiry should be framed as "had the skilled addressee been told of the element in question and the variant at the publication date, would they have appreciated that the element could be substituted for the variant without affecting the working of the invention?" That said, this slight nuance does not change the outcome of her analysis on this issue, which was focused on post-publication date documents.

[32] Applying the variant question as articulated at paragraph 55 of *Free World Trust* directly to the element in issue in this matter, the inquiry would be as follows:

> For **Ring A** to be considered non-essential and thus substitutable, it must be shown that <u>at the date of publication of the patent</u>, the skilled addressee would have appreciated that **Ring A** could be substituted without affecting the working of the invention. In other words, had the skilled worker at that time been told of **Ring A** and **bictegravir's "bridged ring"** and asked whether **the bridged ring** would obviously work in the same way, the answer would be yes.

[33] When framed in this way, I have difficulty seeing the relevance of the SAR Study data—published a decade after publication of the patent—to the essentiality of Ring A. In my view, the

Prothonotary did not err in finding that post-publication date documents are not relevant for the purpose of claim construction.

B. *Did the Prothonotary err in finding that post-publication date documents are extrinsic evidence inadmissible for claim construction?*

[34] ViiV also submits that the Prothonotary erred in law by holding that "extrinsic evidence (such as other patents and/or contemporary documents) is not admissible for claim construction, including in determining whether an element is essential or not." ViiV argues that this approach is inconsistent with principles of claim construction, as claim construction requires consideration of the common general knowledge, which includes extrinsic evidence such as patents, journal articles, and technical information (*Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219 at paras 64-65).

[35] ViiV argues that the decisions the Prothonotary relied on to support her position only exclude extrinsic evidence *regarding the inventor's intention* (*Free World Trust* at para 31(e)(iv); *Bombardier Recreational Products Inc v Arctic Cat Inc*, 2018 FCA 172 at para 22 [*Bombardier*]).

[36] The principle that the Court cannot consider extrinsic evidence when construing the claims of a patent is well established (*Bombardier*, above at paras 22-24, 51; *Merck Frosst Canada & Co v Canada (Minister of Health)*, 2001 FCA 136 at para 9 [*Merck Frosst*]; *Novartis Pharmaceuticals Canada Inc v Canada (Minister of Health)*, 2003 FCA 299 at para 22). Rather, the claims are read through the eyes of the skilled person using his or her common general

knowledge at the date of publication (*Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 53-56; *Free World Trust* at paras 52-54; *Canamould Extrusions Ltd v Driangle Inc*, 2004 FCA 63 at para 28).

[37] Moreover, this Court has refused to consider expert evidence comparing the plaintiff and defendant's products for the purpose of claim construction (*MK Plastics Corp v Plasticair Inc*, 2007 FC 574 at para 46-47). The Federal Court of Appeal has stated that in "construing the claims of a patent, a court is not entitled to consider such extraneous matters as the content of a new drug submission" (*Merck Frosst*, above at para 9).

[38] ViiV's arguments about admissibility of extrinsic evidence of the inventor's intention pursuant to section 53.1 of the *Patent Act*, RSC 1985, c P-4 are not at play in this appeal; section 53.1 is a limited statutory exception to the exclusion of extrinsic evidence to construe claims and not a factor here.

[39] I find that ViiV mischaracterizes the Prothonotary's reasons by pointing to the Court's use of extrinsic evidence to establish the common general knowledge at the relevant time.

[40] The documents ViiV seeks did not exist when the patent was published and therefore cannot inform the common general knowledge as of the publication date. The Prothonotary did not err in law when she stated that extrinsic evidence is not admissible for the purpose of claim construction.

C. *Did the Prothonotary otherwise err in not ordering production of non-bictegravir documents?*

[41] Even if the Court could find that post-publication extrinsic information could be relevant for claim construction or the question of infringement, which I do not find, the non-bictegravir documents are not relevant in this case.

[42] For the purposes of discovery, a document is relevant if the party intends to rely on it or if the document tends to adversely affect the party's case or to support another party's case (*Federal Courts Rules*, SOR/98-106, Rule 222(2)).

[43] Relevance is based on the issues and facts as framed in the pleadings. The disclosure of documents is a matter of relevance, and not of discretion (*Novopharm Ltd v Eli Lilly Canada Inc*, 2008 FCA 287 at para 56).

[44] ViiV argues that the data it seeks related to compounds other than bictegravir in the SAR Study could lead a train of inquiry that might directly or indirectly advance the case of one party or damage that of the opposing party (*Apotex Inc v Canada*, 2005 FCA 217 at paras 15-16). ViiV then goes on to restate its position that the data it seeks is relevant to answering the variant question on claim construction, described above. For the reasons already discussed, the data it seeks is not relevant as it did not exist at the publication date.

[45] A further line of argument pursued by ViiV is that the Prothonotary erred by holding that "documents relating to non-bictegravir compounds…described in [the ASM Microbe

Presentation] are not relevant for claims construction and need not be produced." ViiV submits that this approach conflicts with the general rule that if a portion of a document is relevant, it must be produced in its entirety (*Horn v Canada*, 2006 FCA 234 at para 22).

[46] According to ViiV, by producing the ASM Microbe Presentation, Gilead effectively admitted the relevance of the entire SAR Study underlying the presentation. However, the ASM Microbe Presentation was produced as part of general productions, and Gilead expressly stated that it produced the underlying documents related to bictegravir in an effort to avoid an unnecessary motion, not because the data was necessarily relevant.

[47] Further, the proposition in *Horn v Canada* is not applicable in the present situation. In that case, the Court was dealing with one party's refusal to produce an unredacted version of documents the Court had ordered them to produce.

[48] ViiV also repeatedly refers to its "narrow" request for "a single document, not documents, namely an extensive SAR Study." ViiV does not explain how a SAR Study could be contained in a single document. In fact, Gilead submits that the SAR Study is not a single document, rather an extensive innovative research program. However, there is no actual evidence to support either party's view on this issue. Nevertheless, simply because Gilead produced the ASM Microbe Presentation and the relevant data underlying the SAR Study related to bictegravir, it does not follow that it must now produce further underlying data related to other compounds not in issue for the summary trial, on the basis that a relevant document must be produced in its entirety.

[49] Finally, ViiV argues that the raw data that underpins the SAR Study referred to in Tables 1, 2, and 5 of the ASM Microbe Presentation is relevant to the issues of claim construction, infringement, and validity of the 282 Patent. Therefore, even if the Court finds the Prothonotary did not err in refusing to compel production based on relevance to claim construction and infringement, the Prothonotary erred by not considering the relevance of the documents to the pleaded validity issues.

[50] Gilead argues that ViiV cannot raise new issues on appeal that it did not argue before the Prothonotary. I agree. Insofar as ViiV argues that the Prothonotary erred by not addressing relevance arguments not advanced at the initial motion, ViiV mistakes this appeal for a *de novo* hearing where it can argue new theories of relevance. While ViiV did state in its written submissions before the Prothonotary that the issues between the parties are defined by the pleadings, it did not go on to make any arguments on the relevance of the documents sought to issues of validity. Issues of validity are therefore not before the Court in this appeal.

[51] None of ViiV's other arguments advanced under this heading establish that the Prothonotary erred in law or otherwise committed a palpable and overriding error.

VII. Conclusion

[52] For the reasons above, the appeal is dismissed. ViiV's scientific verity argument based on the *Improver* questions is inconsistent with the accepted principles of claim construction established in *Free World Trust* and relied on in decisions of this Court, the Federal Court of Appeal and the Supreme Court of Canada.

JUDGMENT in T-226-18

THIS COURT'S JUDGMENT is that

1. The appeal is dismissed.

2. Costs to Gilead assessed at the middle of Column III of Tariff B.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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