Federal Court Cour fédérale

Date: 20160819

Docket: T-1693-14

Citation: 2016 FC 856

Ottawa, Ontario, August 19, 2016

PRESENT: The Honourable Mr. Justice Brown

BETWEEN:

GILEAD SCIENCES, INC. AND GILEAD SCIENCES CANADA, INC.

Applicants

and

THE MINISTER OF HEALTH AND APOTEX INC.

Respondents

PUBLIC JUDGMENT AND REASONS

(Confidential Judgment and Reasons released July 21, 2016)

I. Nature of the Matter

[1] This was originally an application for an order pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/1993-133 as amended, SOR/1998-166, SOR/1999-379, SOR/2006-242 (*PM(NOC) Regulations*) prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) in respect of a Notice of Allegation (NOA) sent by Apotex Inc. (Apotex or the Respondent) to Gilead Sciences Canada, Inc. (Gilead or the

Applicant) dated June 19, 2014 in respect of three (3) Canadian Patents: N^{os} 2,261,619 (619 Patent), 2,298,059 (059 Patent) and 2,512,475 (475 Patent) and tablets for oral administration containing the active pharmaceutical ingredient for the prodrug tenofovir disoproxil fumarate (TDF, marketed as VIREAD®), and the active pharmaceutical ingredient FTC (marketed as EMTRIVA® and earlier as Coviracil, or as the generic emtricitabine).

[2] The combination drug TRUVADA® is comprised of (300 mg) of TDF (VIREAD®), which is the medicine patented by the 619 Patent, and (200 mg) FTC (EMTRIVA®). TDF and FTC separately, and in the 475 Patent combination drug, are nucleoside reverse transcriptase inhibitors (NRTIs), which are useful in the treatment of human immunodeficiency virus (HIV). The combination drug covered by the 475 Patent has achieved a considerable degree of success and has become widely prescribed for the treatment of HIV.

[3] For the following reasons, only the 475 Patent is now in issue.

[4] Justice Barnes struck out Gilead's Notice of Application regarding the validity of the 059 Patent by Order dated May 8, 2015 (*Gilead Sciences, Inc v Canada (Health)*, 2015 FC 610), pursuant to s. 6(5)(*a*) of the *PM(NOC) Regulations*, on the basis that this patent for the particular fumarate salt used with TD had already been found invalid for obviousness in another proceeding, *Gilead Sciences, Inc v Teva Canada Limited*, 2013 FC 1272, and the litigation in this proceeding consisted in an abuse of process by Gilead. I will not refer further to the 059 Patent.

[5] Justice Heneghan found the 619 Patent ineligible for listing on the Patent Registry, and therefore ineligible for NOC proceedings in *Gilead Sciences, Inc v Canada (Health)*, 2016 FC 231. As a result the 619 Patent was also struck from this proceeding. The Federal Court of Appeal dismissed an appeal from that decision: *Gilead Sciences, Inc v Apotex Inc*, 2016 FCA 140. The parties subsequently advised the Court that this decision of the Federal Court of Appeal means that only Apotex's allegations regarding the 475 patent need to be adjudicated in this proceeding. Further they agreed that the Federal Court of Appeal decision has no impact on the decision I am to make in the companion Court file T-1694-14 concerning the 619 Patent, referred to in the following paragraph.

[6] Also by way of background, there is a companion case to the one at bar, namely T-1694-14, which concerns the validity of the 619 Patent for the drug TDF, i.e., VIREAD®, which I heard at the same sittings and which is decided contemporaneously with the case at bar. The companion case concerns a different but related application for prohibition brought by Gilead in respect of a Notice of Allegation sent by Apotex to Gilead (also dated June 19, 2014) in respect of the 619 Patent, the 059 Patent (in respect of which claims were struck by Barnes J: *Gilead Sciences, Inc v Canada (Health)*, 2015 FC 610), and tablets for oral administration containing TDF (300 mg).

[7] The parties agree my decision in T-1694-14 regarding the 619 Patent will apply in relevant parts to this decision concerning the 475 Patent. The allegations and evidence regarding the 619 Patent are identical in both court files. The 619 Patent issues concern validity, and are examined on the merits in the companion case.

[8] I am granting Gilead's application for prohibition in the companion NOC case T-1694-14 concerning the 619 Patent, having concluded that Gilead successfully established on a balance of probabilities that Apotex's allegations of invalidity are not justified. However, Gilead's application for prohibition in the present case concerning the 475 Patent is dismissed for the reasons that follow.

[9] Because of a Protective Order dated January 22, 2016, I am issuing these confidential reasons which will become public after necessary redactions as discussed later.

II. Facts

A. 475 Patent Claims

[10] The 475 Patent relates to the use of combinations of TDF and FTC, in a pharmaceutical composition or formulation, for the treatment of HIV infections.

[11] In the 475 Patent, the five asserted claims state:

> 15. A pharmaceutical formulation comprising [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate, hereafter called tenofovir disoproxil fumarate, and (2R, 5S, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)pyrimidin-2-one, hereinafter called emtricitabine.
>
> 16. The pharmaceutical formulation according to claim 15, further comprising one or more pharmaceutically acceptable carriers or excipients.
>
> (…)

> 24. The pharmaceutical formulation according to claim 15, wherein tenofovir disoproxil fumarate and emtricitabine are present in a ratio of about 300:200 by weight.
>
> 25. The pharmaceutical formulation according to claim 24, comprising about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.
>
> (…)
>
> 28. The pharmaceutical formulation according to claim 15, suitable for administration once per day to an infected human.

[12] The Summary of the Invention at page 3 of the 475 Patent states:

> The present invention provides combinations of antiviral compounds, in particular compositions and methods for inhibition of HIV. In an exemplary aspect, the invention includes a composition including tenofovir disoproxil fumarate and emtricitabine which has anti-HIV activity. The composition of tenofovir DF and emtricitabine is both chemically stable and either synergistic and/or reduces the side effects of one or both of tenofovir DF and emtricitabine. Increased patient compliance is likely in view of the lower pill burden and simplified dosing schedule.
>
> The present invention relates to therapeutic combinations of [2-(6-amino-purin-9-yl)-l-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate, tenofovir DF, TDF, Viread®) and (2R, 5S, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(lH)-pyrimidin-2-one (emtricitabine, Emtriva™, (-)-cis FTC) and their use in the treatment of HIV infections including infections with HIV mutants bearing resistance to nucleoside and/or nonnucleoside inhibitors. The present invention is also concerned with pharmaceutical compositions and formulations of said combinations of tenofovir disoproxil fumarate and emtricitabine. Another aspect of the invention is a pharmaceutical formulation comprising a physiologically functional derivative of tenofovir disoproxil fumarate or a physiologically functional derivative of emtricitabine.

B. Witnesses

(1) Experts

(a) Gilead

(i) Dr. Angela D.M. Kashuba

[13] Dr. Kashuba is a Clinical Pharmacologist and Diplomate of the American Board of Clinical Pharmacology. Dr. Kashuba is also a Professor and Vice-Chair for Research and Graduate Education in the Eshelman School of Pharmacy at the University of North Carolina at Chapel Hill. Dr. Kashuba further is an adjunct professor of medicine at the UNC School of Medicine. Dr. Kashuba has developed an internationally recognized HIV clinical pharmacology program at UNC since joining in 1997, and has published extensively on HIV pharmacology.

[14] Apotex has challenged part of the evidence provided by Dr. Kashuba, including her opinion on chemical stability, pharmaceutical formulations, or in treatment of diseases, because of her lack of expertise in pharmaceutics and the stated fields. I agree with Apotex and accept Dr. Kashuba's evidence only insofar as she is qualified to provide it and it lies within her field of expertise, clinical pharmacology.

(b) Apotex

(i) Dr. Charles William Flexner

[15] Dr. Flexner is and has been a medical doctor since 1982, specializing in clinical pharmacology and virology. Dr. Flexner is currently a Professor of Medicine (Clinical

Pharmacology and Infectious Diseases) and Professor of Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. In addition to his teaching task, Dr. Flexner serves in various administrative roles at The Johns Hopkins University. Dr. Flexner has experience in the clinical development of new drugs for treating HIV, among other diseases, and has been an investigator for clinical trials employing many of the antiretroviral drugs currently on the market, including emtricitabine (EMTRIVA®) and tenofovir disoproxil fumarate (VIREAD®).

(ii) Professor Arthur H. Kibbe

[16] Prof. Kibbe is a Professor of Pharmaceutical Sciences at the Wilkes University School of Pharmacy, Wilkes University, as well as the past Chair of the Department of Pharmaceutical Sciences in the School of Pharmacy. Prof. Kibbe has an extensive career in pharmaceutics, including in academia, industry and government. For example, Prof. Kibbe taught courses on formulation design and development, pharmacokinetics, and continuing education for pharmacists. Prof. Kibbe also chaired a special panel appointed by the Commissioner of the FDA to investigate the generic drug approval process. Prof. Kibbe's career has focussed on pharmaceutical formulation development, pharmacokinetics, and the pharmaceutical testing, regulatory and approval processes.

(2) Fact Witnesses

[17] Gilead presented affidavits from fact witnesses to provide context for the invention of TRUVADA®. The witnesses include: Dr. Michael Miller, current Senior Director of Clinical

Virology, and from 2000 to 2003 the Director of Clinical Virology at Gilead; and Dr. Reza Oliyai, currently Vice-President of Product Development and Clinical Supplies, and Research Scientist from 1994 to 2004 at Gilead.

[18] Gilead acquired Triangle Pharmaceuticals (Triangle) in 2003. The evidence shows that the acquisition was entered into in large part with a view to allow the combined entity to market a combination drug that would consist of TDF, in respect of which Gilead had rights, and FTC, in respect of which Triangle had rights. Specifically, Triangle had the rights to FTC, through patent protection at one time. Gilead for its part had rights to TDF or bis(POC)PMPA, a prodrug protected by the 619 Patent.

[19] Both Triangle's FTC and Gilead's TDF were known to a lesser and greater extent respectively to have potential for, or to be effective as treatments for, HIV; TDF was specifically marketed for that purpose, while FTC was known to be in clinical trials for the same purpose. Both drugs are nucleoside reverse transcriptase inhibitors (NRTIs), which are compounds known to be useful in the treatment of HIV.

[20] Triangle scientists, in the months leading up to its acquisition by Gilead, prepared an internal document ["Triangle Report"] **[……..Redacted……..]**. Triangle provided the Triangle Report to Gilead prior to the acquisition. The Triangle Report was not made public.

[21] At the relevant time, the treatment of HIV was known to lead to resistance in mono-therapies, namely treatment regimens requiring patients to take one or, in the case of those suffering from HIV, multiple drug pills throughout the day. There was motivation for the creation of a less onerous pill-count combination therapy, such as the proposed once-daily therapy in the 475 Patent, to improve long-term viability of treatment.

III. Issues

[22] By not alleging non-infringement of claims 5, 16, 24, 25 and 28, Apotex concedes that the Apotex Product infringes these claims. The parties agree that infringement is not in play, as I understand them.

[23] In my view, the issues are:

A. Whether Apotex has discharged its relatively low burden in connection with its allegations of invalidity concerning the 475 Patent relating to claims 15, 16, 24, 25 and 28 on the grounds of:

i. Anticipation, if the combination drug was disclosed in a press release or at a press conference before the relevant date;

ii. Obviousness, if the combination drug of TDF and FTC was obvious, or obvious to try, as discussed in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61.

iii. Lack of sound prediction of or demonstrated utility as measured against the promise of the 475 Patent.

B. If any of the grounds raised by Apotex are given an air of reality, then the issue is whether Gilead has discharged its burden to establish on a balance of probabilities that such allegations are not justified.

[24] In my view, Gilead has not established on a balance of probabilities that Apotex's allegations of anticipation and obviousness are not justified, but met its burden re demonstrated utility and sound prediction. Therefore this application must be and is dismissed.

IV. Statutory Provisions

[25] The *Patent Act*, R.S.C., 1985, c. P-4 [*Patent Act*], provides at section 2 that to be patented an invention must be new and useful:

invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (*invention*)	***invention*** Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité. (*invention*)
[emphasis added]	[non souligné dans l'original]

[26] The *Patent Act*, provides at section 28.2 that the subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed:

28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed	**28.2 (1)** L'objet que définit la revendication d'une demande de brevet ne doit pas :
(a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;	**a)** plus d'un an avant la date de dépôt de celle-ci, avoir fait, de la part du demandeur ou d'un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
(b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;	**b)** avant la date de la revendication, avoir fait, de la part d'une autre personne, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
(c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or	**c)** avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt est antérieure à la date

	de la revendication de la demande visée à l'alinéa (1)a);
[emphasis added]	[non souligné dans l'original]

[27] The *Patent Act* provides at section 28.3 that the subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious:

28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to	**28.3** L'objet que définit la revendication d'une demande de brevet ne doit pas, à la date de la revendication, être évident pour une personne versée dans l'art ou la science dont relève l'objet, eu égard à toute communication :
(a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and	**a)** qui a été faite, plus d'un an avant la date de dépôt de la demande, par le demandeur ou un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs;
(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the	**b)** qui a été faite par toute autre personne avant la date de la revendication de manière telle qu'elle est devenue

information became available to the public in Canada or elsewhere.	accessible au public au Canada ou ailleurs.
[emphasis added]	[non souligné dans l'original]

V. Analysis

A. Preliminary Issues

(1) Relevant Dates

[28] Throughout these reasons, I note the relevant dates for the assessment of the justifiability of the various allegations of invalidity are:

i. Patent Construction – Publication Date: August 5, 2004

ii. Anticipation/Novelty: One year before Canadian Filing Date (January 13, 2004) – January 13, 2003

iii. Obviousness (State of the Art): Claim Date (Priority Date) – January 14, 2003

iv. Utility: Canadian Filing Date – January 13, 2004

[29] These relevant dates are agreed to by the parties.

(2) Expert Blinding

[30] I make the same comments in this case as I make in the companion case T-1694-14, but for convenience repeat my analysis here.

[31] The parties chose different methods of gathering information from their experts for their respective opinion affidavits. While counsel for Gilead provided the legal framework to its experts early, including legal tests for anticipation, obviousness, and utility, Apotex states it did not do so before the experts had drawn their own conclusions on issues such as the promise of the patent, claim construction and the prior art.

[32] Apotex submits expert blinding has been recognized by this Court as a preferred method of gathering expert evidence and refers to: *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638, per Rennie J, at para 321; *Teva Canada Innovation v Apotex Inc*, 2014 FC 1070, per Gleason J (as she then was), at paras 94-96; *Takeda Canada Inc. v Canada (Health)*, 2015 FC 570, per O'Reilly J, at paras 27, 29; *Allergan Inc v Apotex Inc*, 2016 FC 344, per Zinn J, at para 13. For this reason, it asks the Court to assess greater weight to the opinions of its experts when addressing these issues and conclusions by the expert witnesses. In my view the blinding of a witness may be a factor, one of perhaps several, that goes to credibility and weight, but it is not a matter that goes to admissibility.

[33] Gilead, as a counter to Apotex's allegations that Gilead's expert evidence should be given less weight because experts were not blinded, argues that Apotex's experts for the most part did

not conduct their own research to determine the prior art, which I find was substantially the case. Instead, the Apotex experts were provided with all or virtually all of the material relevant to their opinions on prior art and skilled person in the art by counsel for Apotex. Gilead submits this diminishes the weight I should give to Apotex's expert evidence, essentially because Apotex witnesses are not stating what the state of the prior art or skilled person was, but were in effect simply opining on what Apotex's counsel told them was the state of the prior art and knowledge of the skilled person.

[34] The Court has to weigh the evidence before it. On the blinding issue, I agree with Justice Gleason (as she then was) in *Eli Lilly Canada Inc v Apotex Inc*, 2015 FC 875 at para 166:

> [166] Insofar as concerns the allegation regarding lack of "blinding", Apotex has tried to apply the decisions in *Teva* and *AstraZeneca* out of context. There, the experts whose credibility was found to be wanting based their construction of the patents in suit with a view to infringement and were able to come to their opinions based on the information in the generic company's NOA. In *Teva*, this led to an especially tortured construction. In *Teva* and *AstraZeneca*, the approach taken was found to undercut the experts' credibility as it led to an improper results-oriented opinion. Neither case can be read for the position that Apotex sought to advance here, namely, that in any case where one party blinds its experts but the other does not, the former's evidence is to be preferred. Rather, these two decisions must be limited to the facts that arose in these cases.

And see to the same effect the approach taken by Justice Locke in *Shire Canada Inc v Apotex Inc*, 2016 FC 382 at paras 42-48.

[35] More generally the weighing of expert evidence is a question of fact. Having reviewed the law, and as counsel for Apotex candidly noted at the hearing, I have concluded that the blinding issue is a question of relevance, reliability and weight, and is not a doctrinal matter.

[36] For reasons set out, I prefer some experts' evidence on certain issues, and other experts' evidence on other matters, taking into account the arguments raised by both parties and assessing the appropriate weight to be given to the expert testimony.

(3) Claim Construction

(a) Person Skilled in the Art

[37] Claim construction is a question of law to be determined by the Court. Where the meaning of terms or elements of claims are not apparent from a reading of the claim itself or from reference to the specification, the experts may provide guidance on this matter. The claims are to be construed, as they would be read by a Person of Ordinary Skill in the Art ("Skilled Person"), at the relevant date, looking to the patent with a view to understand.

[38] A patent is addressed to this notional Skilled Person, who is "unimaginative and uninventive, but at the same time is understood to have an ordinary level of competence and knowledge incidental to the field to which the patent relates and to be reasonably diligent in keeping up with advances": *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 at para 51 (citing *Merck & Co v Pharmascience Inc*, 2010 FC 510 at paras 34-40), aff'd 2015 FCA 158. The "unimaginative and uninventive" language is found in *Beloit Canada Ltd v Valmet OY*

(1986), 8 C.P.R. (3d) 289 (F.C.A.) [*Beloit*], where the Federal Court of Appeal refers to the "unimaginative skilled technician", and *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 81, where the Supreme Court refers to inventiveness as foreign to the Skilled Person in the obviousness analysis. In my view, the Federal Court retained these concepts in its interpretation of the skilled technician in patent law: *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 at para 51 (Rennie, J as he then was) (citing *Merck & Co v Pharmascience Inc*, 2010 FC 510 at paras 34-40 (Hughes, J)), aff'd 2015 FCA 158 (Dawson, J.A.).

[39] The parties disagree on the abilities of the Skilled Person in relation to the 475 Patent. The 475 Patent relates to the use of combinations of TDF and FTC, in a pharmaceutical composition or formulation, for the treatment of HIV infections.

[40] In my view, the Skilled Person has education, knowledge and training in the areas of pharmaceutical formulations, treatment and prevention of HIV infection and its symptoms, and the pharmacology of antiretroviral drug therapies. The Skilled Person does not need to have clinical experience to understand the 475 Patent, though this experience would be helpful. I make this finding because the 475 Patent is for a chemically stable combination therapy useful in the treatment of HIV. These properties could only be fully assessed and understood by a person skilled in both pharmaceutical formulations (stability) and pharmacology (useful in the treatment of HIV).

(b) Claim Construction

[41] Justice Kane in *Alcon Canada Inc v Apotex Inc*, 2014 FC 699 cited Justice Hughes on principles of claim construction:

> [121] Justice Hughes provided a useful summary of the relevant principles following a review of all the jurisprudence in *Pfizer Canada Inc v Pharmascience Inc*, 2013 FC 120, [2013] FCJ No 111:
>
> > [64] There have been many judicial instructions as to the construction of a claim. To summarize:
> >
> > - construction must be done before considering the issues of validity and infringement;
> > - construction is done by the Court alone, as a matter of law;
> > - the Court is to construe the claim through the eyes of the person skilled in the art to which the patent pertains;
> > - the Court may obtain the assistance of experts to explain the meaning of particular words and phrases, and as to the state of the art as of the date the claim was published;
> > - the Court should read the claim in the context of the patent as a whole, including the description and other claims;
> > - The Court should avoid importing this or that gloss from the description;
> > - the Court should not restrict the claim to specific examples in the patent;
> > - the Court should endeavour to interpret the claim in a way that gives effect to the intention of the inventor;
> > - the Court should endeavour to support a meritorious invention.

[42] Given I am only to consider the five asserted claims, and considering the whole of the 475 Patent, I construe the claims as comprising of a pharmaceutical formulation of FTC and TDF (Claim 15), with appropriate excipients and carriers (Claim 16), in a ratio of 200:300 by weight (Claim 24), or more specifically in formulations of 200 mg and 300 mg by weight (Claim 25), to be administered once daily to a human infected with HIV (Claim 28).

(4) Admission of Press Release and Conference Call Transcript

[43] The parties disagreed on the admissibility of certain documents put forward by Apotex in its argument of invalidity on the ground of anticipation. In summary, the documents are what are alleged to be public reports relating to the merger between Gilead and Triangle, including a purported press release by Gilead dated December 4, 2002 (Press Release), and a purported transcript of a Conference Call taking the form of a Press Conference held by Gilead on December 4, 2002 (Conference Call Transcript or CCT).

[44] Also disputed were various newspaper articles and news reports covering these events dated between December 4, 2002 and January 2003. Apotex does not ask the Court to admit the newspaper articles and other news reports appended to its NOA. It asks the Court to look to those as support for the fact that the Conference Call was held on December 4, 2002. I accept the newspaper articles on this basis.

[45] The documents most relevant to this proceeding are the purported Press Release and the purported Conference Call Transcript. The alleged Press Release mentions a Conference Call to be held on December 4, 2002, and that a recording of it would be available for the public until

December 7, 2002. The Press Release purports to be issued by Gilead and available on its website. It names as contact the Gilead Public Affairs Department and lists Susan Hubbard as a contact person for investors or Amy Flood for media. There is also a quote included by John C. Martin, President and CEO of Gilead then, and who remains on the Gilead executive.

[46] The Press Release was submitted as an attachment to Apotex's NOA; it was also presented to Gilead's witness, Dr. Miller, in his cross-examination. Apotex did not introduce the Press Release by affidavit, and was frustrated by Gilead's counsel in its efforts to introduce it through oral testimony of Gilead's Dr. Miller for reasons I shall come to shortly. The Press Release was not authenticated or introduced into evidence by anyone associated with its preparation, albeit for reasons outlined later, through no fault of Apotex whatsoever. Nor was there any oral or affidavit evidence that its contents were true.

[47] The Conference Call Transcript purports to have been prepared by CCBN, Inc., and to be found on a website of LexisNexis. On its face the Conference Call Transcript contains the following dates, which the parties flagged: "Copyright 2002 FDCHeMedia, Inc.", "Copyright 2002 CCBN, Inc.", and "LOAD DATE: January 18, 2003". The Conference Call Transcript purports to have been transcribed from the Conference Call itself; the Conference Call allegedly took place on December 4, 2002. Arguably, if the contents of the Conference Call Transcript are admitted for the truth of what was said in such a proceeding, these dates are only relevant in my assessment of the test for anticipation, where the invention must be disclosed in a single disclosure earlier than one year before the Canadian Filing date.

[48] The Conference Call Transcript names the following as present for the Conference Call: John C. Martin (President and CEO, Gilead Sciences); John F. Milligan (Senior Vice-President and Chief Financial Officer, Gilead Sciences); Norbert Bischofberger (Executive Vice President, Research and Development, Gilead Sciences); Susan Hubbard (Associate Director of Investor Relations); Mark Perry (Executive Vice President of Operations); Margaret H. Malloy (Analyst); Elise Wang (Analyst, Salomon Smith Barney); Craig Parker (Analyst, Lehman Brothers); Michael King (Analyst, Banc of America Securities); Caroline Copithorne (Analyst, Morgan Stanley); Eric J. Ende (Analyst, Merrill Lynch); John S. Sonnier (Analyst, Prudential); Ben Pat (Analyst, RBC Capital); Jason D. Kantor (Analyst, WR Hambrecht and Co).

[49] Apotex also attached the Conference Call Transcript to its NOA. The Conference Call Transcript was not authenticated or introduced by affidavit or oral testimony of anyone associated with its preparation, nor was the truth of its contents deposed to by anyone associated with its preparation. No one from CCBN, Inc. or LexisNexis was asked to give evidence to support the veracity of the Conference Call Transcript, i.e., that it accurately sets out what was said in the Conference Call by its various alleged participants.

[50] Gilead objects to the reliance on both the Press Release and on the Conference Call Transcript on the ground they both constitute hearsay. There is no doubt both are hearsay. Both are documents introduced not to show that they were made but to establish that what is contained in them is true. The only issue is whether they are admissible into evidence. I will examine each separately.

(a) The Press Release

[51] Apotex argues the Press Release is admissible on several grounds. First, the Press Release was written and released by Gilead itself, who could have but did not contest the contents or origins of the Press Release in any way, which should preclude Gilead from now arguing inadmissibility. Second, Dr. Michael Miller, Senior Director of Clinical Virology at Gilead, was served with a Direction to Attend by Apotex instructing him to produce the Press Release. Dr. Miller asked Gilead's counsel for instructions on required steps to comply with the Direction to Attend. In his cross-examination, Dr. Miller said that Gilead's counsel instructed him to leave this matter for counsel to address. Neither Dr. Miller nor counsel produced the Press Release as requested in the Direction to Attend. Third, Apotex argues the Press Release is both reliable and necessary, as is required by the jurisprudence setting out exceptions to the hearsay rules: *R v Finta*, [1994] 1 SCR 701 at 854-855 [*Finta*]. Fourth, Apotex submits that for anticipation, the Press Release's contents must not be proven as true, merely that the Press Release was issued and that its contents disclosed the subject-matter of the patented claim.

[52] On the admissibility of the Press Release, of importance is the fact that Gilead's witness, Dr. Michael Miller, was provided with a Direction to Attend that specifically identified the Press Release as a document he was required to bring to his cross-examination. Contrary to our *Rules*, neither Dr. Miller nor Gilead provided the Press Release. The rules of this Court governing Directions to Attend (Rules 94 and 97 of the *Federal Courts Rules*, (SOR/98-106)) state:

94 (1) Subject to subsection (2), a person who is to be examined on an oral examination or the party on whose behalf that person is being examined shall produce for inspection	**94 (1)** Sous réserve du paragraphe (2), la personne soumise à un interrogatoire oral ou la partie pour le compte de laquelle la personne est interrogée produisent

at the examination all documents and other material requested in the direction to attend that are within that person's or party's possession and control, other than any documents for which privilege has been claimed or for which relief from production has been granted under rule 230.	pour examen à l'interrogatoire les documents et les éléments matériels demandés dans l'assignation à comparaître qui sont en leur possession, sous leur autorité ou sous leur garde, sauf ceux pour lesquels un privilège de non-divulgation a été revendiqué ou pour lesquels une dispense de production a été accordée par la Cour en vertu de la règle 230.
(2) On motion, the Court may order that a person to be examined or the party on whose behalf that person is being examined be relieved from the requirement to produce for inspection any document or other material requested in a direction to attend, if the Court is of the opinion that the document or other material requested is irrelevant or, by reason of its nature or the number of documents or amount of material requested, it would be unduly onerous to require the person or party to produce it.	**(2)** La Cour peut, sur requête, ordonner que la personne ou la partie pour le compte de laquelle la personne est interrogée soient dispensées de l'obligation de produire pour examen certains des documents ou éléments matériels demandés dans l'assignation à comparaître, si elle estime que ces documents ou éléments ne sont pas pertinents ou qu'il serait trop onéreux de les produire du fait de leur nombre ou de leur nature.
97 Where a person fails	**97** Si une personne

to attend an oral examination or refuses to take an oath, answer a proper question, produce a document or other material required to be produced or comply with an order made under rule 96, the Court may	ne se présente pas à un interrogatoire oral ou si elle refuse de prêter serment, de répondre à une question légitime, de produire un document ou un élément matériel demandés ou de se conformer à une ordonnance rendue en application de la règle 96, la Cour peut :
(a) order the person to attend or re-attend, as the case may be, at his or her own expense;	**a)** ordonner à cette personne de subir l'interrogatoire ou un nouvel interrogatoire oral, selon le cas, à ses frais;
(b) order the person to answer a question that was improperly objected to and any proper question arising from the answer;	**b)** ordonner à cette personne de répondre à toute question à l'égard de laquelle une objection a été jugée injustifiée ainsi qu'à toute question légitime découlant de sa réponse;
(c) strike all or part of the person's evidence, including an affidavit made by the person;	**c)** ordonner la radiation de tout ou partie de la preuve de cette personne, y compris ses affidavits;
(d) dismiss the	**d)** ordonner que

proceeding or give judgment by default, as the case may be; or	l'instance soit rejetée ou rendre jugement par défaut, selon le cas;
(e) order the person or the party on whose behalf the person is being examined to pay the costs of the examination.	**e)** ordonner que la personne ou la partie au nom de laquelle la personne est interrogée paie les frais de l'interrogatoire oral.
[emphasis added]	[non souligné dans l'original]

[53] Here, Gilead did not argue that the Press Release was not under its control, nor that Dr. Miller was not in a senior position at Gilead and involved in Gilead's acquisition of Triangle. Gilead and Dr. Miller deliberately did not seek relief from production under Rule 94(2), instead, they unilaterally refused to make the required production under Rule 94(1).

[54] Gilead's evidence was that it was instructed by its counsel not to look for the Press Release or related documents.

[55] In my view, Gilead's non-compliance with Rule 94(1) results in the Press Release meeting the test of necessity. Necessity together with reliability are the tests to admit hearsay evidence established by the Supreme Court in *Finta, R. v Khan,* [1990] 2 SCR 531, *R v Smith,* [1992] 2 SCR 915 [*Smith*] , *R v Blackman*, 2008 SCC 37, and recently discussed by the Federal Court of Appeal in *Pfizer Canada Inc v Teva Canada Limited*, 2016 FCA 161. In *Smith*, Chief

Justice Lamer confirmed that the necessity principle is engaged where the direct evidence is not available. That is the situation here: the direct evidence is not available:

> The criterion of necessity, however, does not have the sense of "necessary to the prosecution's case". If this were the case, uncorroborated hearsay evidence which satisfied the criterion of reliability would be admissible if uncorroborated, but might no longer be "necessary" to the prosecution's case if corroborated by other independent evidence. Such an interpretation of the criterion of "necessity" would thus produce the illogical result that uncorroborated hearsay evidence would be admissible, but could become inadmissible if corroborated. This is not what was intended by this Court's decision in *Khan*.
>
> As indicated above, the criterion of necessity must be given a flexible definition, capable of encompassing diverse situations. What these situations will have in common is that the relevant direct evidence is not, for a variety of reasons, available. Necessity of this nature may arise in a number of situations. Wigmore, while not attempting an exhaustive enumeration, suggested at §1421 the following categories:
>
> > (1) The person whose assertion is offered may now be dead, or out of the jurisdiction, or insane, or otherwise unavailable for the purpose of testing [by cross-examination]. This is the commoner and more palpable reason. . . .
> >
> > (2) The assertion may be such that we cannot expect, again or at this time, to get evidence of the same value from the same or other sources . . . . The necessity is not so great; perhaps hardly a necessity, only an expediency or convenience, can be predicated. But the principle is the same.
>
> Clearly the categories of necessity are not closed. In *Khan*, for instance, this Court recognized the necessity of receiving hearsay evidence of a child's statements when the child was not herself a competent witness. We also suggested that such hearsay evidence might become necessary when the emotional trauma that would result to the child if forced to give *viva voce* testimony would be great. Whether a necessity of this kind arises, however, is a question of law for determination by the trial judge.
>
> [emphasis added]

[56] In my view, the Press Release is necessary as set out above. Apotex did all it could to have the Press Release produced. It called on Gilead as its alleged author. However, Gilead did not respond to the Direction to Attend or seek relief as provided by the Rules. Gilead's counsel blocked its production; this frustrated both the authentication of the Press Release and the giving of evidence to show its contents were true. Those present still at Gilead were silent about the Press Release (and the Conference Call Transcript) – nothing prevented their giving evidence to this Court. This conduct made it necessary for Apotex to produce the Press Release.

[57] I also find the Press Release to be reliable: it purports to have been taken from Gilead's website and published before the start of litigation. Gilead's silence on the veracity and reliability of the document constituted non-compliance with the Rules, and again leads me to draw an inference in support of the reliability of the Press Release: *Eli Lilly & Co v Nu-Pharm Inc* (1996), 69 C.P.R. (3d) 1 at 18-19 (FCA). Gilead had ample opportunity to challenge the reliability of the document or to bring a witness forward if the document contained inaccuracies. Gilead failed to do so.

[58] Given it is both necessary and reliable, I therefore admit the Press Release. I find it is a copy of an actual Press Release issued by Gilead dated December 4, 2002. That said, as noted below, the Press Release does not advance the position taken by Apotex except to lend credence to the fact of the public access to the Conference Call at the relevant time for anticipation.

(b) The Conference Call Transcript

[59] I agree with Gilead that the Conference Call Transcript would ordinarily constitute inadmissible hearsay. I note the importance of the Conference Call Transcript to establish the breadth of the public disclosure during the Conference Call on December 4, 2002. I also note the document itself says that before relying on the transcript, the transcript from the company itself should be reviewed: "THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. (…). USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS." (Emphasis added.) In this case, the company in whose possession a transcript could arguably be found is Gilead.

[60] However, I agree with Apotex that the Conference Call Transcript should be admitted as an exception to the hearsay rule, and do so for the same reasons that led me to admit the Press Release: the exception based on necessity and reliability. Again, Apotex did all it could to prove the Conference Call Transcript including serving a Direction to Attend on Dr. Miller, the only witness in this proceeding who presumably had access to it. Despite being obliged to produce the Conference Call Transcript in full under Rule 94(1) of the *Federal Courts Rules* or to seek relief under Rule 94(2), Gilead complied with neither component of Rule 94. Gilead's evidence was that it was instructed by counsel not to look for this or related documents. Perhaps Gilead's witnesses or employees kept notes, or their own copies of the Conference Call; perhaps they

could recall what words were spoken; perhaps they had their own recording. The Court does not know. This state of affairs is brought about because of Gilead's unilateral conduct. Gilead made it unavailable; the Conference Call Transcript meets the test of necessity.

[61] I also agree the Conference Call Transcript is reliable; the Conference Call was contemporaneously transcribed in 2002. In this connection I note copyright on the transcript is dated 2002. The transcript was published by LexisNexis, a well-known legal publisher and content provider, and was published well before the present litigation arose. I also Note that the Conference Call Transcript's content was not contested by Gilead, whose principals participated in it. I note also that Gilead is the only party with actual knowledge and possession of these relevant facts. Moreover, two persons identified on the Conference Call Transcript, Dr. Norbert Bischofberger and Dr. John Martin, remain in leadership positions at Gilead, and would have been able to produce evidence supporting any inaccuracy in the Conference Call Transcript had there been any such inaccuracies. However, Gilead chose not to provide any evidence from these witnesses under its control. Its counsel instructed the Gilead witness not to search for either the Press Release or the Conference Call Transcript.

B. Anticipation or Novelty

[62] The *Patent Act* provides that a patent may not be granted for an invention which was previously disclosed or which was not novel, where the content of the disclosure would be available to the public in Canada. The relevant time to determine whether the 475 Patent was anticipated was January 13, 2003, or one year before the 475 Patent's Canadian Filing Date of January 13, 2004. The *Patent Act* states in relevant part:

28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed	28.2 (1) L'objet que définit la revendication d'une demande de brevet ne doit pas :
(a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;	a) plus d'un an avant la date de dépôt de celle-ci, avoir fait, de la part du demandeur ou d'un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
(b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;	b) avant la date de la revendication, avoir fait, de la part d'une autre personne, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
(…).	(…).
[emphasis added]	[non souligné dans l'original]

[63] The Supreme Court of Canada in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at paras 18-37 [*Sanofi*] prescribes that anticipation consists in one publicly available document disclosing the content of the patent at issue, such that the patent would infringe the prior disclosure when made, and that this prior disclosure enable the "skilled person" to make the invention as claimed. Justice Rothstein (for the Court) stated:

[20] In his reasons after referring to s. 27(1) of the Act, the applications judge defined anticipation as meaning "that the exact invention had already been made and publicly disclosed" (para. 55). Shore J. cited this Court's decision in *Free World Trust v. Electro Santé Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66, at para. 26, which approved of the test for anticipation described in *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 (F.C.A.), at p. 297:

> One must, in effect, be able to look at a prior, single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. *The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention.* [Emphasis added by the applications judge.]

[21] The applications judge noted that the English Court of Appeal stated in *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.*, [1972] R.P.C. 457, at p. 486:

> *If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness*. To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented . . . . [Emphasis added by the applications judge.]

He then noted that in *Free World*, at para. 26, this Court approved the following statement from *General Tire*:

> A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee. [p. 486]

[22] The law of anticipation as explained in *Beloit* and *General Tire* has been accepted in Canada without reservation: see *Free*

World, at para. 26. In his application of the law to the facts, there is no doubt that Shore J. was using the test as set out in *Beloit* when he stated, at para. 57:

> Based on the law, the question before the Court is whether a person skilled in the art was given such a clear direction that, by reading and following the ’875 patent (or its U.S. or French equivalents) would in every case and without possibility of error make a compound or pharmaceutical composition within the claims of the ’777 patent (e.g. the bisulfate salt of clopidogrel).

(c) Recent United Kingdom Jurisprudence

[23] For the reasons that follow, and in light of recent jurisprudence, I am of the respectful opinion that the applications judge overstated the stringency of the test for anticipation that the “exact invention” has already been made and publicly disclosed.

[24] In the 2005 decision of the House of Lords in *Synthon*, Lord Hoffmann has brought some further clarity to the law of anticipation as understood since *General Tire*. His reference at para. 20 to the “unquestionable authority” of Lord Westbury in *Hills v. Evans* (1862), 31 L.J. Ch. (N.S.) 457, at p. 463, makes it plain that his analysis does not depend on any change on English law flowing from the enactment of the *Patents Act 1977* (U.K.), 1977, c. 37, or the U.K.’s adoption of the *Convention on the Grant of European Patents*, 1065 U.N.T.S. 199 (entered into force October 7, 1977). He distinguishes between two requirements for anticipation that were not theretofore expressly considered separately, prior disclosure and enablement.

[25] He explains that the requirement of prior disclosure means that the prior patent must disclose subject matter which, if performed, would necessarily result in infringement of that patent, and states, at para. 22:

> If I may summarise the effect of these two well-known statements [from *General Tire* and *Hills v. Evans*], the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent. . . . It follows that, whether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such that, if performed, it

> must result in the patent being infringed, the disclosure condition is satisfied.
>
> When considering the role of the person skilled in the art in respect of disclosure, the skilled person is "taken to be trying to understand what the author of the description [in the prior patent] meant" (para. 32). At this stage, there is no room for trial and error or experimentation by the skilled person. He is simply reading the prior patent for the purposes of understanding it.
>
> [26] If the disclosure requirement is satisfied, the second requirement to prove anticipation is "enablement" which means that the person skilled in the art would have been able to perform the invention (para. 26).

[64] In this connection I note the test laid out in *Sanofi* was based on different statutory language from that in effect in this application. At the time *Sanofi* was decided, the law specifically stated that disclosure had to be in a patent or in a publication form:

> 27. (1) Subject to this section, any inventor or legal representative of an inventor of an invention that was
>
> (a) not known or used by any other person before he invented it,
>
> (b) not described in any patent or in any publication printed in Canada or in any other country more than two years before presentation of the petition hereunder mentioned, and
>
> (c) not in public use or on sale in Canada for more than two years prior to his application in Canada,
>
> may, on presentation to the Commissioner of a petition setting out the facts, in this Act termed the filing in the application, and on compliance with all other requirements of this Act, obtain a patent granting to him an exclusive property in the invention.

[65] The current provision does not specify the form of disclosure, which now may be written or oral. Both parties relied on the current provision:

> 28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> > (a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
> >
> > (b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
> >
> > (c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or
> >
> > (d) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if (…).

[66] In *Stratton: Annotated Patent Act*, s. 28.2 Commentary, the form of disclosure is explained:

> Regarding availability to the public, in contrast to previous definitions of novelty, and to definitions in other jurisdictions, the current Act does not define separate categories for different means of disclosure to the public. For example, there is no special category for anticipation by publication, nor for anticipation by offering for sale or selling products embodying the subject-matter of a claim.

[67] Apotex noted the public nature of the Conference Call, which I accept. The Press Release stated there would be a conference call. The Conference Call Transcript itself confirms the Conference Call took place. The key date for anticipation is January 13, 2003. While the call took place December 4, 2002, it appears the Conference Call Transcript was loaded or published

on January 18, 2003. The Conference Call was open to the public; it could be heard live and for three days after it was held. The Conference Call Transcript is the transcript of the public call. If the Patent was anticipated by the Conference Call, in my view such anticipation took place on December 4, 2002, before the relevant date for anticipation .

[68] In *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638, Justice Rennie (as he then was) summarized anticipation as follows:

> [223] Apotex asserts that the '653 patent is invalid because what the patent claims was not new, or rephrased in positive terms, because it was "anticipated." Novelty is a requirement for a valid patent under sections 2 and 28.2 of the *Patent Act*. In essence, an alleged patent is anticipated if the skilled person, before the patent claim date (May 28, 1993), and with reference to a single prior art reference, could have performed the patent without "undue burden."
>
> [224] The Supreme Court of Canada established a refined two-part test for anticipation in *Sanofi-Synthelabo Plavix*, at paras 30-33. For a patent to be anticipated there must be, from the perspective of the skilled person: (1) prior disclosure and (2) enablement from that prior disclosure.

[69] I will now analyze the two parts of the anticipation doctrine: prior disclosure and enablement.

(1) Disclosure

[70] As discussed above, for there to be disclosure of the 475 Patent by either the Press Release or Conference Call or the Conference Call Transcript, I am required to find that the Press Release and/or the Conference Call Transcript, being a record of the Conference Call itself, disclose all the information needed for the Skilled Person, who is unimaginative and without

inventive skill, to make subject matter that would necessarily result in infringement of the 475 Patent.

[71] I agree with Gilead that the *Beloit* test set out in *J.M. Voith v Beloit* (1991), 36 CPR (3d) 322 (FCA) [*Beloit*] continues to be the law after *Sanofi*. *Beloit* is a decision of the Federal Court of Appeal. *Beloit* explains disclosure as one disclosure, which contains so clear a direction that the Skilled Person reading and following it would in every case and without possibility of error be led to the claimed invention:

> One must, in effect, be able to look at a prior, single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention. Where, as here, the invention consists of a combination of several known elements, any publication which does not teach the combination of all the elements claimed cannot possibly be anticipatory.
>
> [emphasis added]

[72] Gilead argues and I agree that the *Beloit* test was reaffirmed when it was quoted by the Federal Court of Appeal post-*Sanofi* in *Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, 2013 FCA 219 [*Eurocopter*]:

> [109] Anticipation may occur by prior publication, oral communication, or use. In this case, Bell Helicopter only raises anticipation by prior publication. Anticipation by prior publication requires that the invention be in fact disclosed in written documentation made available to the public, such as patents, journal articles, and trade literature, including instruction and repair manuals and brochures. The objective test for disclosure by prior publication is set out as follows in *Beloit Canada Ltée/Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289, 64 N.R. 287, at para. 30 of the N.R. ed.:

> One must, in effect, be able to look at a prior, single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention. Where, as here, the invention consists of a combination of several known elements, any publication which does not teach the combination of all the elements claimed cannot possibly be anticipatory.
>
> [110] This test for anticipation was cited with approval in Free World Trust at para. 26, where it was further noted that it was a difficult test to meet. Subject to the distinction between disclosure and enablement, this test for anticipation by publication still applies: Sanofi at para. 28.
>
> [emphasis added]

[73] In construing the asserted claims of the 475 Patent, I may be guided by the experts. On the one hand, Gilead's expert Dr. Kashuba, without any experience in pharmaceutics, considers the alleged claimed invention to be the combination of at least TDF and FTC in a pharmaceutical formulation that has antiviral activity, and that is chemically stable or synergistic, or both chemically stable and synergistic.

[74] On the other hand, Apotex's witness Dr. Kibbe stated that the invention is the co-formulation of TDF and FTC for use in the treatment of HIV.

[75] Dr. Flexner for Apotex explains in his opinion the invention is the single dose co-formulation of FTC and TDF for the treatment of HIV infection.

[76] In this case, I am not satisfied that the Press Release, on its own, discloses the claimed invention, that is, the combination of TDF and FTC in a once-daily co-formulation pill, which necessarily must exhibit a certain chemical stability and effectiveness in order to be of any use in the treatment of HIV infection. In my respectful opinion, the overall purpose and tone of the Press Release is to address the commercial and business synergies between Gilead and Triangle. The only relevant evidence for drug or pharmaceutical disclosure in the Press Release is the following:

> In addition to pursuing the commercialization of Coviracil [FTC] as a single agent, Gilead plans to immediately initiate development of a co-formulation of Viread and Coviracil as a potential fixed-dose combination treatment for patients with HIV.

[77] As Gilead explains, at the time, FTC (or Coviracil) was not fully developed and available for distribution as a single formulation; it was only in the clinical trial phase. Moreover, there is no indication in the Press Release that any testing was done showing the co-formulation was a sound option for development, or that the co-formulation would prove chemically stable. While TDF and FTC and their respective dosage forms would have been known to the Skilled Person, in my view the Press Release does not contain so clear a direction that the Skilled Person reading and following it would in every case and without possibility of error be led to the claimed invention. The Press Release does not demonstrate to me that a Skilled Person would be lead to the 300 mg and 200 mg co-formulation immediately and without possibility of error.

[78] Therefore, I am not prepared to find the Press Release taken alone discloses the invention of TRUVADA®, which comprises a once-daily chemically stable co-formulation of TDF and FTC in a 300 mg and 200 mg combination to treat HIV.

[79] On the other hand, the Conference Call itself, reflected in the Conference Call Transcript, discloses far more than the Press Release. In my view, the Conference Call discloses information on which a Skilled Person would be lead to the claimed once-daily 300 mg and 200 mg co-formulation of TDF and FTC to treat HIV immediately and without possibility of error. The Conference Call Transcript (which I find accurately reports the Conference Call itself) quotes Gilead's Dr. Bischofberger as stating:

> The co-formulation work is currently ongoing, but based on the physical chemical properties of both components we don't anticipate that there will any big challenges in doing that. With regards to regulatory pathway it's pretty clear all we would really need is a CMC package. So, you need the chemistry manufacturing information plus bio-equivalent study, so to show that the co-formulated tablet gives you the same exposure to the individual components as the individual components do. But in addition to that, we are initiating and we actually have ongoing studies already to look at the combination of FTC of our Coviracil and Viread in HIV infected patients.

[80] In my view, this statement discloses to the Skilled Person with a view to understand that the co-formulation only requires a CMC package, which to a Skilled Person would mean that the doses in the co-formulation are the same as the doses in the individual tablets. This statement also discloses the use of the co-formulation for HIV infected patients.

[81] Later in the Conference Call, Gilead's John F. Milligan states:

> The pathway for co-formulated products is very straight forward. It is limited by stability studies. So, it's limited not by clinical data, but by stability to have a shelf life, (…).

This statement further explains that the co-formulation must be chemically stable for purposes of its shelf-life.

[82] Given the invention claims a once-daily chemically stable co-formulation of TDF and FTC in doses of 300 mg and 200 mg, which I note are identical to the doses in their individual tablets, for the treatment of HIV, the claim was in fact disclosed during the Conference Call. Therefore, I find the Conference Call discloses subject matter which, if performed, would necessarily result in infringement of the patent, which comprises a once-daily chemically stable co-formulation of TDF and FTC in a 300 mg and 200 mg combination to treat HIV. Taken together and read as a whole, I find there was sufficient disclosure in the Conference Call and/or the Conference Call Transcript to establish anticipation.

(2) Enablement

[83] Because the invention was disclosed in the Conference Call as reported in the Conference Call Transcript, I must now consider enablement. At the enablement phase routine trial and error is permitted by the Skilled Person, who however could not take any inventive steps or undergo undue burden to arrive at the claimed invention:

> [27] Once the subject matter of the invention is disclosed by the prior patent, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. While trial and error experimentation is permitted at the enablement stage, it is not at the disclosure stage. For purposes of enablement, the question is no longer what the skilled person would think the disclosure of the prior patent meant, but whether he or she would be able to work the invention.
>
> *Sanofi* at para 27.

[84] *Sanofi* discussed the following factors to be considered when determining whether the disclosure also enabled the claimed invention:

> [37] Drawing from this jurisprudence, I am of the opinion that the following factors should normally be considered. The list is not exhaustive. The factors will apply in accordance with the evidence in each case.
>
> 1. Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to discover how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art.
>
> 2. The skilled person may use his or her common general knowledge to supplement information contained in the prior patent. Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time.
>
> 3. The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.
>
> 4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.

[85] In *Eurocopter*, the Federal Court of Appeal wrote, citing *Sanofi*:

> [108] The second requirement, enablement, is assessed once it has been determined, on an objective basis, that the subject matter of the invention has indeed been disclosed. For the purposes of enablement, the question is no longer what the skilled person understands from the disclosure, but whether that person would be able to work the invention without undue burden: *Sanofi* at paras.

> 26 and 37. When considering whether there is undue burden, the nature of the invention must be taken into account. Some trials and experiments are allowed at this stage. But these are not to be prolonged, even in the fields of technology in which trials and experiments are generally carried out: *Sanofi* at paras. 27 and 33 to 37.

[86] In summary, *Sanofi* says the following are to be considered when determining whether there was enablement:

1. The entire disclosure;

2. Common general knowledge of the Skilled Person;

3. Whether the trials are routine or long and arduous; and

4. Whether reasonable skill and knowledge in the art could readily correct obvious errors or find what was omitted in the disclosure.

[87] These factors have been followed in later judgments. I will now consider each.

1. The Disclosure

[88] In the present application, the disclosure in the Press Release falls short of meeting the requirements for enablement. However the disclosure in the Conference Call is another matter. It contains the following elements:

i. Coviracil (FTC or EMTRIVA®) was "highly complementary" to VIREAD®, i.e., TDF, for HIV (page 2);

ii. FTC is a once-daily pill that has a safety profile similar to a placebo (page 2);

iii. FTC and TDF have "no overlapping resistance mutations. This would suggest that they would be highly compatible when used in combination" (page 2);

iv. Gilead's John Milligan: "there is an obvious need for new once daily therapies…Viread and Coviracil have a very strong complementarity to them. They are both once daily. They are both potent. There are no overlapping [irritations]. They are both very well tolerated products and so there is an obvious synergy there." (page 4);

v. Gilead's Norbert Bischofberger: "The co-formulation work is currently ongoing, but based on the physical chemical properties of both components we don't anticipate that there will be any big challenges in doing that." (page 5);

vi. TDF (sold as VIREAD®) was already being combined with 3TC (lamivudine) (another NRTI drug useful in the treatment of HIV) in 50% of the patients taking VIREAD®;

vii. The drug to be made by the merged company would be a co-formulation;

viii. The co-formulation would comprise VIREAD® and Coviracil (FTC);

ix. Gilead was to initiate development of the co-formulation of VIREAD® and Coviracil as a potential fixed combination treatment for patients with HIV. This could result in the first combination product dose that is one pill once daily; and

x. Gilead did not "anticipate that there will be any big challenges in [co-formulating VIREAD® and Coviracil]". (page 5)

2. Common General Knowledge of the Skilled Person

[89] Dr. Kibbe for Apotex provided helpful expert evidence on the common general knowledge of the Skilled Person. Here I note that while Gilead's Dr. Kashuba is a pharmacology expert, she has admitted to having no expertise in pharmaceutical chemistry or formulation, which is the determined field for this disclosure. Because Gilead did not provide the Court with expert evidence on this topic, and because of Dr. Kibbe's excellent credentials in this field, I

prefer Dr. Kibbe's evidence on the common general knowledge of the pharmaceutical formulator.

[90] In the prior art, Coviracil and VIREAD® would have active pharmaceutical ingredients with known dosage and whose preparation methods were known, though perhaps covered by patents.

[91] I therefore find that the Skilled Person who is a chemical formulator would know that Coviracil's dosage was 200 mg, and that VIREAD®'s dosage was 300 mg.

3. Type of Testing

[92] For the reasons explained above, here again I prefer Dr. Kibbe's opinion. Dr. Kibbe provides evidence describing the nature of the work of a Skilled Person who is a pharmaceutical formulator. In his affidavit, Dr. Kibbe states a formulator would readily perform routine tests for chemical stability to ensure the two active pharmaceutical ingredients are compatible for co-formulation. Once these routine tests are completed, the skilled pharmaceutical formulator would readily prepare appropriate excipients and manufacture the co-formulation into a one-dose pill form medicament, as is claimed by the invention.

4. Obvious Errors or Omissions

[93] The disclosure obviously does not disclose the method of preparation for Coviracil, VIREAD®, or its co-formulation. However, the Skilled Person may look to the prior art or elsewhere to supply this omission at the enablement stage.

[94] Here, I note Coviracil and VIREAD®'s active pharmaceutical ingredient preparation was known and disclosed in prior patents, thus readily available to the Skilled Person.

[95] With this additional knowledge, in my respectful view, the routine tests described earlier become even more straightforward.

[96] The invention was to combine two drugs with known dosage for once-daily oral administration to create a once-daily, one-pill co-formulation. I find the invention was enabled by the Conference Call such that looking at its disclosure, and looking to the prior art and common general knowledge as would a skilled pharmaceutical formulator, the Skilled Person would only have to conduct routine tests to arrive at the claimed invention in the 475 Patent.

[97] In this manner, the Conference Call disclosed and enabled the invention claimed in the 475 Patent. Therefore I must conclude Gilead has failed to establish on a balance of probabilities that Apotex's allegations of anticipation were not justified. On this ground I would dismiss Gilead's application for prohibition.

C. Obviousness

(1) Obvious and obvious to try

[98] Apotex alleges the combination of TDF and FTC was obvious in light of the state of the art and the treatments offered at the relevant time. Gilead disagrees. Given my finding on anticipation I need not address this issue, but will do so because it was fully argued.

[99] The Supreme Court of Canada in *Sanofi* established the following framework for the obviousness inquiry:

> [67] It will be useful in an obviousness inquiry to follow the four-step approach first outlined by Oliver L.J. in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd*., [1985] R.P.C. 59 (C.A.). This approach should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis. The Windsurfing approach was recently updated by Jacob L.J. in *Pozzoli SPA v. BDMO SA*, [2007] F.S.R. 37 (p. 872), [2007] EWCA Civ 588, at para. 23:
>
> > In the result I would restate the Windsurfing questions thus:
> >
> > (1) (a) Identify the notional "person skilled in the art";
> >
> > (b) Identify the relevant common general knowledge of that person;
> >
> > (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
> >
> > (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
> >
> > (4)Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention? [Emphasis added.]

> It will be at the fourth step of the *Windsurfing/Pozzoli* approach to obviousness that the issue of "obvious to try" will arise.

[100] According to the Supreme Court of Canada in *Sanofi*, the "obvious to try" test may also be applied to assess obviousness, although it is not the sole factor in the obviousness inquiry:

> [66] For a finding that an invention was "obvious to try", there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.
>
> (…)
>
> i. <u>When Is the "Obvious to Try" Test Appropriate?</u>
>
> [68] In areas of endeavour where advances are often won by experimentation, an "obvious to try" test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an "obvious to try" test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.
>
> ii. <u>"Obvious to Try" Considerations</u>
>
> [69] If an "obvious to try" test is warranted, the following factors should be taken into consideration at the fourth step of the obviousness inquiry. As with anticipation, this list is not exhaustive. The factors will apply in accordance with the evidence in each case.
>
> 1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
>
> 2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
>
> 3. Is there a motive provided in the prior art to find the solution the patent addresses?

> [70] Another important factor may arise from considering the actual course of conduct which culminated in the making of the invention. It is true that obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art. But this is no reason to exclude evidence of the history of the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person.

[101] I will now review these factors.

1. (a) "Person skilled in the art"

[102] I previously described the Skilled Person as a person or a team of persons with an advanced degree in pharmaceutical formulation, and with education, knowledge and training in the areas of pharmaceutical formulations, treatment and prevention of HIV infection and its symptoms, and the pharmacology of antiretroviral drug therapies. The Skilled Person does not need to have clinical experience to understand the 475 Patent, though this experience would be helpful.

(b) Relevant common general knowledge of the Skilled Person

[103] I previously described the common general knowledge of the Skilled Person in the anticipation analysis: the Skilled Person would know of VIREAD® and Coviracil and their active pharmaceutical formulations and individual dosage as disclosed in publications and in the testing conducted. The Skilled Person would have known both were administered once-daily. The experts agree that the standard of care for the treatment of HIV infection by January 2003 was the chronic use of a combination of drugs. The Skilled Person would also have known from

the Conference Call and or the Conference Call Transcript that the co-formulation of VIREAD® and Coviracil was not expected by Gilead to present any particular challenges.

[104] The skilled chemical formulator would also know how to conduct chemical stability tests and otherwise choose appropriate filler and excipients in the formulation of a drug.

(2) Inventive concept of the claim

[105] The claims before me are claims 15, 16, 24, 25 and 28 of the 475 Patent. These claims provide that the co-formulation is of TDF and FTC (Claim 15), with carriers and excipients (Claim 16), in 300 mg and 200 mg dosage (Claims 24 and 25), and in a pharmaceutical formulation which can be administered once daily to a human infected with HIV (Claim 28).

[106] The inventive concept is the chemically stable co-formulation of FTC and TDF for a once-daily oral pill with anti-HIV activity.

[107] Although Gilead argues the synergy of FTC and TDF is part of the inventive concept, I am not satisfied that this is an essential element of the claimed invention. First I note the co-formulation has the exact same dosage of APIs for both FTC and TDF, which indicates their co-formulation was not necessarily invented as a synergistic co-formulation. Where a property is inherent in a product, this cannot be an invention in the sense which would be protected under Canadian patent law: *Calgon Carbon Corporation v North Bay, City*, 2005 FCA 410 at para 16. Second I note the testing in the Triangle Report was not public, or complete, and otherwise does

not demonstrate to a Skilled Person that **[.. Redacted..]** was part of the inventive concept. It appears to me that the co-formulation was made as a quick-to-market product, and that some initial tests incidentally showed there may be *in vitro* **[……. Redacted……..... ……..]**. I also note the 475 Patent itself does not state the synergy is an essential part of the claim, but rather that it may be a result of the co-formulation: "In an exemplary aspect, the invention includes a composition including tenofovir disoproxil fumarate and emtricitabine which has anti-HIV activity. The composition of tenofovir DF and emtricitabine is both chemically stable and either synergistic and/or reduces the side effects of one or both of tenofovir DF and emtricitabine" (emphasis added) at page 3 of the 475 Patent; and also generally, "In some embodiments, a synergistic antiviral effect is achieved. In other embodiments, a chemically stable combination is obtained" (emphasis added) at page 9 of the 475 Patent. Importantly, the asserted claims make no mention of the inherent properties of the co-formulation, such as the chemical stability, or the synergistic properties, although the 475 Patent does claim chemical stability, and does mention synergistic properties. No claim in the 475 Patent mentions synergistic properties of the co-formulation.

[108] These factors are insufficient for me to conclude the purported synergy found to exist *in vitro* in the co-formulation was part of the inventive concept of the asserted claims.

(3) Differences between the matter cited as forming part of the "state of the art" and the inventive concept of the claim

[109] When measuring the invention against the yardstick of the state of the art, I find the main differences between the state of the art and the inventive concept are that the invention is a (1) once-daily; (2) co-formulation; (3) of FTC and TDF. In this connection, combination therapies

were sought after as desirable in HIV treatment; for example, at the relevant time, VIREAD® was prescribed with 3TC (another NRTI) 50% of the time.

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention? Is it obvious to try?

[110] In order to determine whether the alleged invention as claimed required an inventive step, *Sanofi* allows application of the "obvious to try" test and its factors, to which I now turn.

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

[111] At the outset, I note the "obvious to try" doctrine is to be used cautiously; it is not a panacea: *Sanofi* at para 64. Generally, I would not consider a combination drug "obvious to try" simply because its components were or might be used to treat similar medical conditions but held by different entities which became one through acquisition, merger or otherwise. This could make the doctrine far too easy to apply.

[112] However, in this case, Gilead itself disclosed the co-formulation in the Conference Call. Once the idea of the co-formulation was disclosed in the Conference Call, I agree with Dr. Kibbe that a skilled pharmaceutical formulator would only have a finite number of identified predictable solutions for the development of a chemically stable co-formulation of TDF and FTC.

[113] Specifically in this connection, doses for TDF and FTC were already determined. TDF was approved as a monotherapy in tablet form at 300 mg; FTC was not yet approved but was in clinical trials as a 200 mg tablet. The 475 Patent does not alter this dosage. Although it is possible the Skilled Person may have been tempted to try another dose amount for the co-formulation, I see no reason why this possibility should be considered in the analysis for the number of predictable solutions; in my view, it was more or less self-evident that the current doses ought to work.

[114] Moreover, the chemical stability of the co-formulation would be required to ensure adequate shelf-life and usefulness as an anti-HIV treatment. I find that chemical stability is readily determined through routine tests for a skilled pharmaceutical formulator, as expressed by Dr. Kibbe. Although Dr. Kashuba may have expressed otherwise, her lack of expertise in chemical stability weighs against the evidence she provides on this issue.

[115] I agree Gilead could have looked at other anti-HIV drugs and NRTIs with FDA approval as Gilead states. But the number is finite and relatively small, and still smaller when looking at NRTIs suitable for administration once daily.

2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

[116] In my view the tests for chemical stability of the co-formulation were routine. Gilead had no arduous invention story for this co-formulation; it was a quick-to-market approach. Once the co-formulation idea was put forward, it appears the anti-HIV products of Gilead and Triangle,

TDF and FTC, were found to be chemically stable **[……Redacted……..**

……..……..]. That report does not disclose any strenuous effort to arrive at a co-formulation of TDF and FTC for anti-HIV activity. Nor were any arduous or prolonged trials anticipated or argued by Gilead before getting the product to market. Only routine trials were done; that was all that was required.

3. Is there a motive provided in the prior art to find the solution the patent addresses?

[117] The 475 Patent and the prior art establish that there was motivation to find the solution the 475 Patent addresses. The 475 Patent states there was a need for a once-daily co-formulation for anti-HIV therapy. This need stemmed from possible problems for treatment where mutant drug resistance was common in monotherapies (such as using VIREAD® alone), thereby reducing long-term efficacy of certain drugs. At the time of the merger between Gilead and Triangle, doctors were already prescribing VIREAD® in combination with other anti-virals such as NRTIs for HIV treatment. In my view, combination therapies represented the state of the art in HIV treatment at the relevant time, namely the Claim date, or here the claimed Priority date, January 14, 2003. Moreover, patient compliance was an issue with higher pill count; it was anticipated a once-daily oral co-formulation therapy could increase effectiveness of treatment and patient compliance.

[118] I find there was motivation to produce co-formulations of the anti-HIV drugs TDF and the known NRTI, FTC, to address these issues in HIV treatment.

[119] Gilead asks the Court to consider whether there was specific motivation to co-formulate Coviracil and VIREAD®, and suggests that where these drugs were not yet widely used or prescribed together, there would not have been a motive for the co-formulation of the claimed invention. I disagree that this level of specificity was required in the motivation analysis. I find that the Conference Call establishes general motivation to develop a single-dose, once-daily co-formulation of VIREAD® and FTC. This was enough for the skilled formulator to turn his or her attention to the co-formulation of TDF and FTC. Moreover, the Conference Call Transcript reports that Gilead's Dr. John Martin specifically stated: "This transaction brings to Gilead a life-stage HIV product candidate and an antiviral pipeline of HIV (…) therapeutics (…). Triangles' most advanced product candidate is the antiviral Coviracil, a nucleotide analogue in Phase III studies, for the treatment of HIV. The team at Triangle has successfully brought this product from pre-clinical through all stages of development. They recently announced the acceptance of their new drug applications with the U.S. Food and Drug Administration with a [inaudible] date of September 4, 2003"; "[Gilead believes] great long-term opportunities lies in co-formulation". John Milligan, Senior Vice-President and Chief Financial Officer of Gilead also stated "The message of once-daily therapy is very powerful right now"; and, "the two products are highly complementary as John said in the former part of this. (…) [T]here is an obvious need for new once daily therapies, and as John pointed out Viread and Coviracil have a very strong complementarity to them. They are both once daily. There are both potent. There are no overlapping [irritations]. They are both very well tolerated products and so there is an obvious synergy there" (emphasis added).

[120] In my respectful view, these statements demonstrate what I find is an obvious motivation for the resulting once-daily co-formulation of the two drugs.

[121] In conclusion, and notwithstanding the need to be cautious, I find the co-formulation of TDF and FTC was obvious to try, because Gilead's Conference Call disclosed an intention to develop this very co-formulation, at a time where there was a strong need to develop a once-daily co-formulation product for a more effective anti-HIV therapy. Only routine testing was required by the Skilled Person to arrive at the invention claimed by the 475 Patent.

[122] In light of my conclusion that the co-formulation of TDF and FTC was obvious to try because of the Conference Call, the distance between the state of the art and the alleged invention did not require an inventive step. I find the alleged invention was obvious to the Skilled Person at the relevant time. Therefore Gilead has failed to establish on a balance of probabilities that Apotex's allegations of obviousness and obvious to try are not justified. For this reason also, Gilead's application must be dismissed.

D. Utility or Sound Prediction

[123] Given my findings above in terms of anticipation and obviousness, it is not necessary to consider Apotex's allegations of invalidity based on utility. Notwithstanding, because it was argued before me, I will do so.

[124] Utility is required for an invention to be patentable: *Patent Act* at s. 2. Section 2 requires that an invention must be "useful":

invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (*invention*)	***invention*** Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité. (*invention*)
[emphasis added]	[original non souligné]

[125] Justice Rennie (as he then was) explains in *AstraZeneca Canada Inc v Apotex inc*, 2014 FC 638 the difference between goals and promises when construing the utility of the patent:

> [115] There is a difference between the goals that a patent hopes to address, and the outcomes that a patent promises will occur. In *AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 [*Mylan Arimidex*], I observed that "not all statements of advantage in a patent rise to the level of a promise. A goal is not necessarily a promise" (at para 139). This distinction between goals and promises has been affirmed by the Federal Court of Appeal (see e.g. *Apotex Inc v Sanofi-Aventis*, 2013 FCA 186 at para 67 [*Sanofi-Aventis Plavix*]).
>
> [116] Differentiating goals and promises is a question of characterization. Thus, before interpreting whether or not the '653 patent's reference to an improved therapeutic profile is a goal or a promise, goals must be distinguished from promises in the abstract.
>
> [117] Goals merely describe "a hoped-for advantage of the invention" (*Mylan Arimidex*, at para 139). For example, in *Mylan Arimidex*, I found that an object clause, beginning with "it is a particular object of the present invention to," merely described a goal that the patent strived to achieve rather than a promised outcome. Similarly, in *Sanofi-Aventis Plavix*, at paras 55-67, Justice Pelletier found the inference of a promise of therapeutic utility based on indirect references to the use of the drug in humans (e.g. references to human diseases and dosages that potentially correspond to use in humans) was insufficient to substantiate a promise and merely alluded to potential uses. In sum, promises are explicit and define *guaranteed or anticipated results* from the patent (depending on whether the promise is demonstrated or soundly predicted), whereas goals merely relate to *potential uses* for the patent.

[126] It is settled law that inutility must be assessed on a claim by claim basis, and that promises can be construed to impose utility requirements across each of a patent's claims or for only a subset of the claims: *Astrazeneca Canada Inc v Apotex Inc*, 2015 FCA 158 at paras 4-5.

[127] Utility is assessed against the promise of the patent. In *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197, Justice Layden-Stevenson explains that utility may be either demonstrated or soundly predicted as of the date of filing. Where the specification sets out an explicit promise, utility will be measured against that promise:

> [74] Section 2 of the Act requires that the subject matter of a patent be new and useful. The general principle is that, as of the relevant date (the date of filing), there must have been either demonstration of utility of the invention or a sound prediction of the utility. Evidence beyond that set out in the specification can, and normally will, be necessary.
>
> [75] To establish lack of utility, the alleged infringer must demonstrate "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do": *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 (*Consolboard*).
>
> [76] Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise: *Consolboard*; *Pfizer Canada Inc. v. Canada* (*Minister of Health*), [2009] 1 F.C.R. 253, 2008 FCA 108 (*Ranbaxy*). The question is whether the invention does what the patent promises it will do.

[128] This reasoning was also discussed in *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, following the Supreme Court's decision in *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 (*AZT*):

> [38] As the courts below noted, all that is required to meet the utility requirement in s. 2 is that the invention described in the patent do what the patent says it will do, that is, that the promise of the invention be fulfilled: see also S. J. Perry and T. A. Currier, *Canadian Patent Law* (2012), at §7.11. Patent '446 states that the claimed compounds, including sildenafil, will be useful in treating ED. At the time the application was filed, sildenafil could assist in treating ED. This is all that is required. The fact that Pfizer did not disclose that the tested compound was sildenafil goes to the issue of disclosure of the *invention*, not to that of disclosure of the invention's *utility*.
>
> [39] That the invention must be useful as of the date of the claim or as of the time of filing is consistent with this Court's comments in *AZT*, at para. 56:
>
> > Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if . . . the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, "[t]here is evidence of lack of utility in respect of some of the area covered". [Italics in original; underlining added.]

(1) Promise of the 475 Patent

[129] The parties agree the 475 Patent provides for promises against which the utility or sound prediction is to be measured. However, the parties disagree on defining the promise of the 475 Patent. Gilead submits that Apotex's allegations are far broader than the actual promise of the 475 Patent.

[130] Gilead's expert Dr. Kashuba in her affidavit (at para 101) said that the promise of the 475 Patent is limited to a co-formulation that contains a combination of TDF and FTC that is

chemically stable and has synergistic anti-viral activity (Promised Utility). However, on page 3 of the 475 Patent, the inventors provide a "Summary of the Invention" disclosed and claimed, which states that the invention includes a composition of TDF and FTC which has anti-HIV activity, that "is both chemically stable and either synergistic and/or reduces the side effects of one or both of" (emphasis added) TDF and FTC. According to Gilead's factum at para 99, reading the 475 Patent in combination with the disclosed studies and their results, the Skilled Person would understand chemical stability and synergistic anti-HIV activity to be the promised utility of the co-formulation of TDF and FTC, and not reduce side effects.

[131] On the other hand, Apotex submits Gilead promised a much greater utility for the 475 Patent. According to Apotex, the 475 patent explicitly promises that the combinations of TDF and FTC will: (1) treat and prevent HIV infection in humans; (2) be chemically stable; (3) be either synergistic and/or will reduce the side effects of one or both TDF and FTC; and (4) treat infections with HIV mutants bearing resistance to nucleosides and/or non-nucleoside inhibitors.

[132] Gilead denies the 475 Patent promises to treat infections with HIV mutants bearing resistance to nucleosides and/or non-nucleoside inhibitors. Apotex argues this is part of the promise of the patent, because the Summary of the Invention states, "The present invention relates to therapeutic combinations of [TDF] and [FTC] and their use in the treatment of HIV infections including infections with HIV mutants bearing resistance to nucleoside and/or non-nucleoside inhibitors."

[133] In my view, the areas of disagreement are:

1. Whether the 475 Patent promises synergy and/or side effect reduction of one or both of FTC and TDF or only synergistic effect; and

2. Whether the 475 Patent promises to treat infections with HIV mutants bearing resistance to nucleosides and/or non-nucleoside inhibitors.

[134] In *Astrazeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023, Justice Rennie (as he then was) stated that construction of the promise of the patent is a question of law within the exclusive purview of the Court:

> [90] Construction of the promise of the patent is a question of law within the exclusive province of the Court: *GlaxoSmithKline rosiglitazone*, above at para 86. Courts should be careful in relying on expert evidence to construe the promise of the patent. In *Pfizer donepezil*, above at para 224, Justice Roger Hughes reinforces the need for a clear demarcation of roles:
>
> > These illustrations, which are by no means exhaustive, demonstrate the perils in asking experts to stray from their expertise and to enter into the realm of advocacy in construing a patent. It is very tempting for lawyers to seek to put words into the mouths of experts and then seek to urge upon the Court that these words be accepted as being assistance from the expert in interpretation of a patent.

[135] Reading the Patent, I am unable to accept that synergistic anti-HIV activity is part of the promise of the 475 Patent. While it is so claimed by Gilead's expert Dr. Kashuba, and pressed by Gilead, the Patent itself puts this as only one of two possible alternative attributes (the other being reduced side effects). Given this, and acknowledging guidance from Dr. Kashuba, in my

opinion while anti-HIV activity is part of the promise, synergistic activity is not. To construe the Patent otherwise would be inconsistent with the Patent which states:

> The composition of tenofovir DF and emtricitabine is both chemically stable and either synergistic and/or reduces the side effects of one or both of tenofovir DF and emtricitabine. (Emphasis added.)

For the same reason – synergistic activity being offered as but one of two possible alternative attributes – I do not accept that side effect reduction is part of the promise of this Patent. Dr. Kibbe correctly noted the inconsistency of finding synergy but not reduction of side effects as promises. But how may attributes described as alternatives to one another both be promises? With respect, my reading of the Patent leads me to conclude that neither side-effect reduction nor synergistic effect are guaranteed or promised: each is but a hoped-for result. Apotex may no more have me construe this Patent as promising both synergistic effect and reduced side effects, than Gilead may have me construe it as promising synergistic effects alone.

[136] Justice Rennie, as he then was, explains in *AstraZeneca Canada Inc v Apotex inc*, 2014 FC 638, that there is a difference between goals and promises when construing the promised utility for the patent:

> [117] Goals merely describe "a hoped-for advantage of the invention" (*Mylan Arimidex*, at para 139). For example, in *Mylan Arimidex*, I found that an object clause, beginning with "it is a particular object of the present invention to," merely described a goal that the patent strived to achieve rather than a promised outcome. Similarly, in *Sanofi-Aventis Plavix*, at paras 55-67, Justice Pelletier found the inference of a promise of therapeutic utility based on indirect references to the use of the drug in humans (e.g. references to human diseases and dosages that potentially correspond to use in humans) was insufficient to substantiate a promise and merely alluded to potential uses. In sum, promises are explicit and define *guaranteed or anticipated results* from the

> patent (depending on whether the promise is demonstrated or soundly predicted), whereas goals merely relate to *potential uses* for the patent.

[137] Finally, in reading the 475 Patent with the guidance of the experts, I am unable to conclude that treatment for HIV mutants is promised in this Patent. This is because the Patent promises anti-HIV activity of the drug in those infected with HIV. Gilead's Dr. Kashuba in her affidavit at para 102 said that the Patent does not promise activity against mutant HIV strains. Apotex's experts Dr. Flexner and Dr. Kibbe disagree. None of the experts provide convincing arguments or explanations for their conclusions. Having regard to those opinions and reading the Patent as a whole, I find that treatment of HIV mutants is not part of the promise of the Patent.

[138] In my view, this aspect of the invention's summary is simply another goal of the claimed invention; I see no guaranteed or anticipated result concerning treatment for HIV mutants.

[139] I therefore conclude the promise of the 475 Patent is the co-formulation of TDF and FTC which has anti-HIV activity, and is chemically stable. The promised utility to be demonstrated or soundly predicted need not include synergistic properties of the co-formulation, reduction of side effects, or activity against HIV mutants bearing resistance. Moreover, the person reading the 475 Patent with a mind to understand would understand the promised synergistic effect to occur in the treatment for HIV, or *in vivo*.

(2) Soundly Predicted or Demonstrated Utility

[140] Having defined the promise of the 475 Patent, I turn to whether utility was demonstrated or soundly predicted at the time of filing of the 475 Patent. The utility may be demonstrated or soundly predicted based on evidence found within or outside the patent. The parties argued utility as against the promise of the 475 Patent instead of claim by claim. As permitted by the Federal Court of Appeal in *Astrazeneca Canada Inc v Apotex Inc*, 2015 FCA 158 at paras 7-8, I will measure utility against the Patent's promise, because the issue was cast in this way by the parties.

[141] Gilead did not argue sound prediction, but Apotex did. I turn to analyse the evidence to determine whether these promises were demonstrated or soundly predicted.

(a) Chemical Stability

[142] The 475 Patent states testing in container closure systems for chemical stability was conducted by Gilead scientists. The results are included in the 475 Patent. Although these tests may not reflect all of the required tests before getting the co-formulation to market, this test demonstrates there was chemical stability, if only at the specific moisture/temperature parameters tested.

[143] The 475 Patent does not clearly indicate whether the promised chemical stability is for the shelf life of TRUVADA® or for its *in vivo* delivery of the active pharmaceutical ingredients. However, looking to the Patent as a whole, I find chemical stability for the product's shelf life is soundly predicted through the disclosed testing. In this connection a patent does not need to demonstrate every property of the claimed invention. A balance must be struck between filing

for a patent i.e., claiming a monopoly, and the need to firmly ground the promises of the patent through time-consuming testing. With this in mind, I find on a balance of probabilities, that the disclosure is sufficient to meet the chemical stability promise of the 475 Patent.

(b) Anti-HIV properties

[144] The parties did not dispute the anti-HIV activity for the co-formulation. I have found synergistic activity was not promised. Nonetheless, for completeness, I will discuss synergistic anti-HIV properties.

[145] In my view, if synergistic anti-HIV properties are part of the promised utility of this Patent (which they are not) then such synergistic effect is neither demonstrated nor soundly predicted in the 475 Patent itself. I must look to the disclosure and to external evidence. To ground this promised utility, Gilead submits the Triangle Report through Dr. Michael Miller's fact affidavit and Dr. Kashuba's expert opinion. **[…….. . ……Redacted…… ……....]**. The scientists who signed the report did not provide evidence in these proceedings. Apotex submits the Triangle Report is inadmissible, because Gilead seeks to admit it for the truth of its content without first establishing it meets the tests for necessity and reliability to be exempted from hearsay rules.

[146] Apotex's Dr. Flexner states that *in vivo* synergy has not been observed in humans when combining antiretroviral drugs, either at the relevant date or, indeed, to date. Dr. Flexner explains

synergy is a purely *in vitro* phenomenon, and that *in vivo* synergy could not be soundly predicted because it is scientifically unlikely. Apotex's Dr. Kibbe states evaluating synergy *in vivo* is the expertise of the pharmacologist, and therefore he did not opine on this matter.

[147] Gilead's Dr. Kashuba in her affidavit expresses the need to test combinations to determine whether there is an additive or synergistic effect. Dr. Kashuba states it is entirely unpredictable whether two drugs will exhibit synergistic activity; testing must be conducted. Dr. Kashuba explains synergy testing is usually drawn out and not routine to the Skilled Person. This confirms the unlikelihood that **[…….. Redacted……..]** , is a sound predictor of *in vivo* synergy.

[148] Looking to the Triangle Report, I note it was dated mere months before the merger between Gilead and Triangle. **[……... Redacted…….]**. **[.. Redacted..]** In my view, given the evidence of both parties, even if the **[….. Redacted..…] [……..Redacted……..]** it falls short of demonstrating synergy *in vivo* as promised.

[149] Given this, it is not necessary to decide the hearsay issue. The Triangle Report, even if truthful, does not base either sound prediction or demonstrated utility. If I had to decide this point, I would hold the Triangle Report is properly authenticated in that it comes to Court through Gilead's expert testimony and is in any event a document owned by Gilead itself as a result of its acquisition of Triangle. However, there is no evidence to support its truthfulness, i.e., the Court has not heard from those at Triangle who prepared it. It is hearsay in that Gilead's experts offer it for the truth of what it says not having conducted the tests themselves. Because

the Court knows nothing of the availability or unavailability of those who conducted the experiments and signed the Triangle Report, I am unable to find it necessary in the sense required to base an exception to the hearsay rule. For the same reason the Court is unable to make a finding that the Triangle Report is reliable. Therefore the Triangle Report is and remains inadmissible hearsay.

[150] In support of its position that it soundly predicted synergistic effect, Gilead also presented testing by Dr. Miller performed after the relevant date, which however does not assist on this point. For example, the poster presented at the 43rd Annual Inter-science Conference on Antimicrobial Agents and Chemotherapy, September 14-17, 2003 by M.R. Blum et al., "Lack of Pharmacokinetic Interaction between Emtricitabine and Tenofovir DF when Co-administered to Steady State in Healthy Volunteers", presented Poster A-1621, says there was no observed *in vivo* influence of either compound on the other's effectiveness. This does not assist Gilead, but rather Apotex. Other testing seems to have been conducted only *in vitro* and after the relevant Canadian filing date of the 475 Patent.

[151] For this reason, had I found it to be part of the Patent's promise, which I did not, I would conclude that the 475 Patent's alleged promise of synergy was neither demonstrated nor soundly predicted.

[152] I find the 475 Patent has utility. Therefore, Gilead has established on a balance of probabilities that Apotex's allegation of invalidity based on utility is not justified.

VI. Conclusions

[153] I find on a balance of probabilities that Gilead has not established that Apotex's allegations of invalidity on the basis of anticipation and obviousness are not justified. Therefore Gilead's application must be dismissed.

VII. Costs

[154] The parties have agreed on costs which agreement is set out in the Court's Judgment as Schedule "A" - Agreed Terms of Costs Order, which are reasonable and I accept and so order.

VIII. Confidential Reasons

[155] These Reasons contain information subject to a Protective Order and are therefore marked Confidential. The Parties shall have 20 days to consult with one another and advise the Court what if any portions they wish redacted, failing which these Reasons will become the Public Reasons and be placed on the public file. Note: the foregoing sentence was included in the Confidential Judgment and Reasons; these present reasons contain redactions requested by the Applicant and thus redacted are now public.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application is dismissed.

2. Gilead shall pay Apotex its costs of this application as per the Schedule "A" - Agreed Terms of Costs Order attached hereto.

3. The Parties shall have 20 days to consult with one another and advise the Court what if any portions of this Confidential Judgment and Reasons they wish redacted, failing which these Reasons will become the Public Reasons and placed on the public file accordingly. Note: this part of the Judgment was included in the Confidential Reasons but having heard from the parties is now spent; see para 155.

"Henry S. Brown"
Judge

Schedule "A" **– Agreed Terms of Costs Order**

1. The successful party will be awarded costs in accordance with the following directions, provided that the following directions in no way modify or supersede any existing Orders or Directions with respect to costs for particular motions or steps before the hearing of this Application:

    a) Costs are to be assessed at the middle of Column IV of Tariff B;

    b) No costs are recoverable for in-house counsel, law clerks, students and support staff;

    c) Costs are recoverable only for those experts who provided affidavits or reports that were filed in the proceeding (the "allowable experts");

    d) The hourly rate for allowable experts shall not exceed the hourly rate of senior counsel;

    e) Fees paid to allowable experts for time not spent preparing the expert's own affidavit/report or preparing for the expert's own cross-examination are recoverable only where it is demonstrated that it was reasonable and necessary to provide technical assistance to counsel;

    f) Counsel fees shall be assessed on the basis of:

        i. one senior and one junior counsel at the hearing;

ii. one senior and one junior counsel in conducting cross-examinations; and

iii. one senior counsel for defending cross-examinations;

g) Travel and accommodation expenses will be assessed on the basis of economy air fares and single rooms; and

h) Photocopying costs will be assessed at $0.25 per page, and the number of recoverable copies shall be limited to that which is reasonable and necessary.

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Patrick Kierans Brian Daley Louisa Pontrelli Brian J. Capogrosso Nisha Anand	FOR THE APPLICANTS GILEAD SCIENCES, INC. and GILEAD SCIENCES CANADA, INC
- Nil -	FOR THE RESPONDENT THE MINISTER OF HEALTH
Belle Van Andrew Brodkin Dino Clarizio	FOR THE RESPONDENT APOTEX INC

SOLICITORS OF RECORD:

Norton Rose Fulbright Canada LLP Barristers and Solicitors Montréal, Quebec	FOR THE APPLICANTS GILEAD SCIENCES, INC. and GILEAD SCIENCES CANADA, INC
William F. Pentney Deputy Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENT THE MINISTER OF HEALTH

Goodmans LLP
Barristers & Solicitors
Toronto, Ontario

FOR THE RESPONDENT
APOTEX INC