# Federal Court of Appeal



# Cour d'appel fédérale

Date: 20170724

**Docket: A-483-15** 

**Citation: 2017 FCA 161** 

CORAM: PELLETIER J.A.

NEAR J.A. RENNIE J.A.

**BETWEEN:** 

IDENIX PHARMACEUTICALS, INC.

**Appellant** 

and

GILEAD PHARMASSET LLC, GILEAD SCIENCES, INC. and GILEAD SCIENCES CANADA, INC.

Respondents

Heard at Toronto, Ontario, on January 17, 2017.

Judgment delivered at Ottawa, Ontario, on July 24, 2017.

REASONS FOR JUDGMENT BY:

RENNIE J.A.

CONCURRED IN BY:

PELLETIER J.A. NEAR J.A.

# Federal Court of Appeal



# Cour d'appel fédérale

Date: 20170724

**Docket: A-483-15** 

**Citation: 2017 FCA 161** 

CORAM: PELLETIER J.A.

NEAR J.A. RENNIE J.A.

**BETWEEN:** 

IDENIX PHARMACEUTICALS, INC.

**Appellant** 

and

GILEAD PHARMASSET LLC, GILEAD SCIENCES, INC. and GILEAD SCIENCES CANADA, INC.

Respondents

# **REASONS FOR JUDGMENT**

# **RENNIE J.A.**

# I. Introduction

[1] This is an appeal from a judgment of the Federal Court *per* Justice Annis (the judge), reported as 2015 FC 1156. The respondents Gilead Sciences, Inc., Gilead Sciences Canada, Inc., and Gilead Pharmasset LLC (collectively, Gilead) challenged the appellant Idenix

Pharmaceuticals, Inc.'s (Idenix) Canadian Patent No. 2,490,191 (the 191 Patent). By way of counterclaim, Idenix challenged Gilead's subsequent Canadian Patent No. 2,527,657 (the 657 Patent) for infringement, lack of novelty and wilful misleading. Both impugned patents claimed compounds having activity against the family of Flaviviridae viruses, which includes, for example, Hepatitis C. The judge found the 191 Patent to be invalid on the grounds of insufficiency of disclosure and lack of sound prediction of utility. His conclusion on the invalidity of the 191 Patent led him to dismiss Idenix's counterclaim against Gilead.

- [2] On appeal, Idenix seeks an order declaring the 191 Patent valid and infringed by Gilead, that Gilead's 657 Patent is invalid, and costs and interest in this Court and the Federal Court. In the alternative, it seeks an order directing that this matter be sent back to the Federal Court for a new trial by a different judge.
- [3] As this case raises no new issues of principle or novel application of established principles to the facts, these reasons are intended to simply deal with allegations of error advanced by Idenix. As a result, the narrative portions of these reasons are fairly summary as they are addressed to the parties who are already familiar with the factual and legal context.

## II. Background and history of proceedings

[4] A nucleoside is a chemical compound that consists of a base attached to a 5-carbon sugar ring. Both patents at issue claim nucleosides analogues with various bases and a particular structure at the 2' (2 Prime) position on the sugar ring, specifically a methyl group in the "up" position and a fluorine atom in the "down" position. For the purposes of this appeal, the Claimed

Compound will be denoted as 2'-C-Me/F, which reflects the particular structure at the 2' position on the sugar ring as outlined above.

- [5] In the early 2000s, Idenix filed two patent applications in the United States for synthesized 2'-C-Me/OH nucleoside analogues that have activity against Flaviviridae viruses, a family of viruses that includes Hepatitis C. Idenix then set out to synthesize several similar compounds, including the Claimed Compound. A number of Idenix's scientists worked toward its synthesis, including Drs. Griffon and Stewart and Ms. Wang, to whose evidence I will later refer. Before they succeeded in synthesizing the compound, Idenix filed US patent applications in 2002 and 2003 that establish priority for the Canadian 191 Patent at issue.
- [6] In May 2003, a Pharmasset Inc. (now Gilead) chemist, Mr. Clark, succeeded in synthesizing 2'-C-Me/F. He submitted a provisional US patent application in 2004. This application is the foundation for Gilead's 657 Patent. It discloses the step-by-step synthesis of the 2'-C-Me/F compound and its antiviral activity against Hepatitis C virus infections (HCV) in some detail.
- [7] In 2012, Gilead brought a challenge to the validity of the 191 Patent in the Federal Court. The judge found in Gilead's favour that the 191 Patent was invalid on the basis that it did not sufficiently disclose the steps required to synthesize the Claimed Compound, and that there was no sound prediction of utility.
- [8] The judge recognized that there are three pathways by which the Claimed Compound can be synthesized: the nucleoside approach, the sugar approach and the Gemcitabine approach.

While all three approaches have since been found to result in the successful synthesis of the Claimed Compound, the judge found that, at the relevant time, the skilled person would not have been directed to any particular starting point for synthesis through the 191 Patent.

- [9] At trial and on appeal, Idenix argued that the 191 Patent taught the skilled person to select the nucleoside or sugar pathways or that it would have been apparent to the skilled person that those were the appropriate pathways to embark upon. According to Idenix, the references in the patent to the diastereomer of an intermediate or precursor compound (the Intermediate Compound) and the discussion of stereochemistry in the 191 Patent would have directed the skilled person to either of these pathways rather than the Gemcitabine pathway. This is because the Intermediate Compound is a necessary step in the nucleoside and sugar approaches, but not the Gemcitabine approach.
- [10] Even on the basis of the two pathways Idenix preferred, the judge found that multiple steps in the synthesis of the Claimed Compound were not disclosed. Of particular relevance on appeal, the judge found that the Intermediate Compound was not referenced, the methylation step required to make the Intermediate Compound was not disclosed, and it is common ground that the 191 Patent does not include instructions for how to install a fluorine group necessary to make the Claimed Compound. Despite Idenix's arguments to the contrary, the judge found that these gaps could not be filled by the common general knowledge and/or routine experimentation such that the person skilled in the art could have made the invention.
- [11] The judge found further that the inventors of the 191 Patent did not soundly predict the utility of the Claimed Compound. As noted, the 191 Patent claims antiviral activity of the

Claimed Compound against the family of viruses including HCV. Idenix filed the 191 Patent prior to having successfully synthesized the Claimed Compound. Although the judge found some evidence of a factual basis for sound prediction, he concluded that it was not sufficient.

[12] Although of no consequence given his findings with respect to the invalidity of the 191 Patent, the judge found that Gilead's activities fell within the scope of the claims asserted in the 191 Patent. As a result of the invalidity of the 191 Patent, the judge determined that Gilead's 657 Patent was not anticipated and dismissed Idenix's counterclaim.

#### III. Issues

- [13] Idenix alleges a substantial number of factual and legal errors in the decision below.

  Idenix argues that, once the errors are corrected, this Court will be in a position to make the decision that the judge should have made, which would involve upholding the validity of the 191 Patent and finding the 657 Patent to be anticipated and invalid.
- [14] With respect to the finding of invalidity of the 191 Patent, Idenix alleges that the judge made errors in his appreciation and application of the substantive law of sufficiency of disclosure and sound prediction including misappreciating the evidence of the expert witnesses, making unsupported findings of fact, unjustifiably preferring the evidence of certain expert witnesses, failing to read the disclosure through the eyes of a person skilled in the art with the benefit of common general knowledge and altering the test for sound prediction. With respect to Gilead's 657 Patent, Idenix alleges that the judge misinterpreted the requirements of inventorship and materiality and made numerous palpable and overriding errors in his factual findings.

- [15] The task of this Court on appeal remains determining whether the judge committed an error of law or a palpable and overriding error of fact or mixed law and fact to warrant intervention, regardless of the number of errors alleged or the manner in which those errors are plead (*Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 [*Housen*]).
- [16] Given that the judge found the 191 Patent invalid for both insufficiency of disclosure and lack of sound prediction of utility, Idenix must identify errors that justify intervention on both grounds of invalidity in order to be successful. For the reasons that follow, I am of the view that Idenix has not met this burden. I would dismiss the appeal.

# IV. Analysis

### A. Sufficiency of the disclosure of the 191 Patent

- [17] Subsection 27(3) of the *Patent Act* states:
  - (3) The specification of an invention must
    - (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
    - (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;

- (3) Le mémoire descriptif doit :
  - a) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur;
  - b) exposer clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner,

construire, composer ou utiliser l'invention;

c) s'il s'agit d'une machine, en

meilleure manière dont son

expliquer clairement le principe et la

- (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
  - ed the application of that inventeur en a conçu l'application; and inventeur en a conçu l'application; als of a process explain de s'il s'agit d'un procédé explique
- (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.
- d) s'il s'agit d'un procédé, expliquer la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention en cause d'autres inventions.
- [18] The Supreme Court of Canada in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 [*Teva*] confirmed the requirements for sufficient disclosure under subsection 27(3) of the *Patent Act*. At paragraph 70, the Court re-asserted its position in *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, 56 C.P.R. (2d) 145, and stated that the patent specification "must define the precise and exact extent of the privilege being claimed so as to ensure that the public can, having only the specification, make the same use of the invention as the inventor". The patent must disclose both the invention and how to make the invention.
- [19] At paragraph 79 of *Apotex Inc. v. Astrazeneca Canada Inc.*, 2017 FCA 9, [2017] F.C.J. No.22 (QL) [*Apotex*], this Court held that "[i]t is well established in patent law that when one claims a new and inventive product, an inventor is only required to enable the person skilled in the art to work the invention. He or she need only describe one method or process for making it". While a patent will not be found to be invalid for insufficient disclosure where routine experimentation is required of the skilled person, the Supreme Court of Canada in *Pioneer Hi-Bred v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at 1641, 1989 CanLII 64

[*Pioneer*], held that disclosure is insufficient if the specification "necessitates the working out of a problem".

# (1) Perspective of the skilled person

- [20] Idenix alleges that the judge did not read the 191 Patent's disclosure from the perspective of the person skilled in the art with the benefit of common general knowledge. Idenix argues that the judge's misunderstanding as to the appropriate perspective coloured his analysis; for example, causing him to find that the methylation step in the synthesis of the Claimed Compound was not disclosed.
- [21] At paragraph 455 of his Reasons, the judge states in reference to the 191 Patent's disclosure of the synthesis of the Claimed Compound that:

[t]he Court is here considering the <u>express written</u> disclosure contained in the '191 Patent without the added disclosure of synthesis from the common general knowledge [emphasis in original].

[22] Considered in isolation, the judge's use of the term "express written disclosure" may suggest that he applied a lawyer's or judge's perspective to the wording of the patent, as opposed to that of the person skilled in the art. I agree with Idenix that such an error would justify this Court's intervention (*Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at p. 1050 [*Free World Trust*]). However, a fair reading of the Reasons with "a mind willing to understand" (*Apotex Inc. v. Astrazeneca Canada Inc.*, 2017 FCA 9, at para. 100, [2017] F.C.J. No. 22 (QL)) demonstrates that although his description of his analytical approach does not withstand critical scrutiny, the analysis he actually undertook does.

- [23] Immediately preceding the paragraph of concern, at paragraphs 452-53, the judge set out his approach to the sufficiency analysis. First, he explained that he would consider, "whether and to what extent the synthesis of the 2'-C-Me/F nucleoside is expressly disclosed in the '191 Patent". He noted that he would then move on to "consider whether the common general knowledge and routine experimentation are sufficient to disclose the synthesis," based upon the testimony of the expert witnesses before him. I do not wish to have these reasons to be taken as endorsing such an approach, but, for the purposes of this appeal, I find that in the end the judge considered the words of the patent in light of the perspective of the person skilled in the art.
- The judge referenced the guidance set out in *Free World Trust*, noting that patents must be read as a person skilled in the art would have understood them at the date of issue (Reasons at para. 464). This section of the Reasons includes references to, and consideration of, expert witness testimony, as one would expect (see, for example paras. 482, 485, 489-90). For example, I note that the judge agreed with Idenix's expert, Dr. Damha, that the interpretation of the patent proposed by Gilead's expert, Dr. Wnuk, was "too literal" and not "what the skilled person would have eventually taken from it" (Reasons at para. 465).
- [25] The judge noted the jurisprudence concerning common general knowledge and routine experimentation (Reasons at paras. 421-25), and found that:

Idenix is relying on common general knowledge to advise the skilled reader, both that the 2'-C-OH/Me is the [I]ntermediate [Compound] required to make the 2'-C-Me/F nucleosides, as well as how to make that intermediate, with at best snipits of useful information well buried in the '191 Patent (Reasons at para. 491).

- [26] Further, the judge accepted Dr. Wnuk's evidence to the effect that, "the fact that, in hindsight, individual steps in a chemical synthesis have some precedent in the literature does not mean that the overall sequence of steps for making a new compound was easy to determine," and that undertaking such an endeavour "often requires significant creativity and/or an extensive amount of experimentation" (Reasons at paras. 547-548).
- [27] The judge concluded that Gilead had established that the 191 Patent, together with the common general knowledge, did not sufficiently disclose how to synthesize the Claimed Compound. While the judge's choice of the term "express written disclosure" is not appropriate, it is apparent on a fair reading of the Reasons that he was concerned with how the skilled person would have understood the patent. For these reasons, Idenix's allegations on this point fail.

# (2) Dr. Griffon and the notional skilled person

- [28] Idenix argues that the judge erred by using Dr. Griffon as a proxy for the skilled person and that this legal error justifies reversal of his decision. However, by the time the judge reached the parties' arguments regarding Dr. Griffon, he had already independently determined that the 191 Patent insufficiently disclosed how to make the Claimed Compound. As such, the error Idenix alleges is of no consequence. The judgment is able to stand on other grounds.
- [29] However, an observation must be made before leaving this point. Judges must be careful not to lose sight of the identity of the person of ordinary skill in the art. This person is a "mythical creature (the man in the Clapham omnibus of patent law)" (*Beloit Canada Ltée/Ltd. v. Valmet Oy*, 64 N.R. 287, 8 C.P.R (3d) 289 (F.C.A.)); *Healthcare at Home Limited v. Common Services Agency for the Scottish Health Service*, [2014] UKSC 49 at para. 3; [2014] W.L.R. (D)

351. In patent litigation the courts must be informed by the evidence as to what knowledge a person of ordinary skill in the art would have had and what that person would have been able to do with said knowledge.

# (3) Treatment of expert and fact witness evidence

[30] Idenix alleges that the judge made palpable and overriding errors in appreciating, weighing and preferring the evidence of certain experts. In particular, Idenix alleges that the judge erred in preferring the evidence of Gilead's expert, Dr. Wnuk, over that of Idenix's experts, Drs. Damha and Barrett. It alleges that the judge erred in making an adverse credibility finding against Dr. Damha, and misinterpreted a comment made by Dr. Damha at trial, in a manner that requires correction. Further, Idenix argues that the judge improperly admitted factual evidence of Dr. Stewart filed by Gilead, and erred in his treatment of the evidence relating to Idenix's fact witness, Ms. Wang.

#### (a) Dr. Damha

- [31] The alleged errors in relation to Dr. Damha's evidence may be readily disposed of.
- I disagree with Idenix that the judge made an unwarranted adverse credibility finding in respect of Dr. Damha. Idenix impugns the particular comment of the judge that it was "incomprehensible that [Dr. Damha] could testify that the '191 Patent provided the same level of specificity of synthesis" as the 657 Patent at paragraph 493 of his Reasons. It is my view that the judge did not, at this stage, make a finding on credibility. My view on this point is supported by the fact that the judge in fact relied on Dr. Damha's evidence at other points of his Reasons (see paras. 465, 503, 807, 828, 845, 872, 875).

[33] Idenix submits further that the judge made a palpable and overriding error by misinterpreting a comment made by Dr. Damha when he said that the steps to make the Claimed Compound were common general knowledge. I disagree that the judge misunderstood this statement when incorporating it at paragraph 432 of his Reasons, which I read as discussing inventiveness generally, not the inventiveness of the method of producing the Claimed Compound.

#### (b) Dr. Wnuk

- [34] Idenix argues that the judge's preference for Dr. Wnuk's evidence resulted from his mistaken view that Dr. Wnuk was the only expert with fluorination experience at the relevant time. Further, Idenix impugns the judge's reliance on Dr. Wnuk's expert reports despite Dr. Wnuk allegedly having changed his testimony during cross-examination. I would not accede to these arguments.
- [35] First, the judge was entitled to prefer one witness over the other (*Actavis Pharma Company v. Alcon Canada Inc.*, 2015 FCA 192 at para. 13, 476 N.R. 309). He rejected Gilead's argument that Drs. Damha and Barrett should not be qualified to give opinion evidence on the fluorination of nucleosides, but "weighed as a factor in the evidence of the contending experts that favours Gilead" Dr. Wnuk's particular expertise (Reasons at para. 61). For example, it was open to the judge to consider and weigh the evidence that, although Dr. Damha published a paper on the topic in 2002, he did not have first-hand experience with the fluorination of nucleosides in 2003-04 (Reasons at para. 62) as did Dr. Wnuk. I note that the judge found that "Dr Wnuk focused his career on the synthesis of nucleosides, including an extensive amount of time dealing with the fluorination of nucleosides."

The judge recognized that Idenix was able to extract certain concessions from Dr. Wnuk on cross-examination. It was for the judge to assess the impact of these concessions. He found that Dr. Wnuk's evidence reflected his role as an expert attempting to assist the Court, nor did it undermine the essential points of his testimony regarding the common general knowledge at the relevant time (Reasons at para. 535). This conclusion was open to him to draw. It must be remembered that the judge had the benefit of observing, first-hand, the testimony of the witness in direct and cross-examination, and was in a position to draw the inferences and conclusions that he did (*Housen*, at para. 25).

# (c) Dr. Stewart

- [37] Idenix alleges that the judge erred in admitting into evidence a witness statement and transcript of cross-examination of Dr. Stewart from parallel proceedings in the United Kingdom. Gilead sought leave to admit these documents at the end of the trial. The judge determined that the transcripts constituted hearsay, and although he found them to be unnecessary under the principled approach, he ultimately determined that they were admissible under the common law exception of admissions against interest (Reasons at para. 737).
- [38] While it is clear to me that the judge did not follow the proper analysis for admitting the transcripts, I will not address the admissibility of this evidence here, as nothing turns on this point. The judge noted, at para 740 of his Reasons, that neither the evidence of Dr. Stewart or Ms. Wang would have affected his conclusion, already drawn, that the 191 Patent did not disclose the fluorination step in the synthesis of the Claimed Compound.

### (d) Ms. Wang

- [39] Idenix submits further that the judge erred in finding that Ms. Wang did not make the Claimed Compound before learning how to do so from a Pharmasset Inc. (now Gilead) employee or the Clark publication. According to Idenix, the judge was not entitled to rely on Dr. Wnuk's report to find that Ms. Wang did not make the claimed compound because of his admission on cross-examination that, on reviewing her lab notes, he "[couldn't] really tell" whether she made the compound in an experiment conducted in December 2005.
- [40] Essentially, Idenix asks this Court to reweigh the evidence. Dr. Wnuk's admission is not sufficient to support the conclusion that Ms. Wang made the Claimed Compound prior to receiving information regarding Mr. Clark's method. The burden to establish this rested with Idenix.
- [41] It was established in the evidence that Dr. Stewart received information on Mr. Clark's method prior to the publication of the 657 Patent, and that he and Ms. Wang were working together on the project for Idenix. It was open to the judge to find on a balance of probabilities that Dr. Stewart conveyed this information to Ms. Wang, who then altered her experiments to incorporate it.

# (4) Errors relating to synthesis of the Claimed Compound

[42] It is not contentious that the 191 Patent does not teach the fluorination step necessary to synthesize the Claimed Compound. However, Idenix alleges that it would have been

straightforward to the skilled person in light of the common general knowledge. Idenix alleges that the judge erred in his analysis related to the fluorination step.

- [43] Specifically, Idenix submits that the judge mistakenly understood that specific reaction conditions were required for methylation, leading him to believe that methylation required more experimentation to achieve than the evidence showed. Nothing turns on this point, given the judge's finding that the skilled person was not directed by the 191 Patent or the common general knowledge to either the Intermediate Compound, or the methylation step necessary for making the Intermediate Compound (Reasons at paras. 457-58, 469, 483-84, 491). The difficulty of carrying out the methylation step is irrelevant if the skilled person would not know that methylation was the next step towards creating the Claimed Compound.
- [44] As noted above, Idenix argued that the 191 Patent either taught the skilled person to begin the synthesis process by selecting the nucleoside or sugar ring pathways or that it would have been apparent to do so, given the references in the 191 Patent directing the skilled person to the Intermediate Compound. The judge rejected these submissions. At paragraph 509 of the Reasons, the judge accepted the evidence of Dr. Wnuk that:

the skilled person would have had multiple different starting materials to choose from, multiple reagents to choose from, multiple possible routes that could have been tried, multiple protecting groups available, and multiple possible reaction conditions that could have been attempted for each step in the chosen route.

[45] The judge found that Idenix was attempting to read something into the 191 Patent that was not there (Reasons at paras. 491, 494, 512).

- [46] Since the filing date, all three synthesis pathways (nucleoside, sugar ring and Gemcitabine) have been proven to work (Reasons at para. 512). According to Idenix, this fact supports the sufficiency of its disclosure because no matter which pathway the skilled person chose, they would arrive at the Claimed Compound. Though reversed on other points, this Court held in *Novopharm Limited v. Pfizer Canada Inc.*, 2010 FCA 242 at paragraph 79, [2012] 2 F.C.R. 69, that courts must "determine whether the disclosure was sufficient as of the date of filing. As a result, anything which occurred subsequent thereto is of no relevance." In my view, Idenix's argument reflects the benefit of hindsight rather than the knowledge of the skilled person at the relevant date.
- [47] Although dealing with the question of sufficiency of disclosure, analogy may be made to the Supreme Court of Canada's decision in *Teva*. The Supreme Court held that, since Pfizer's patent disclosed two compound claims, only one of which worked, the skilled person would have had to "undertake a minor research project to determine which claim is the true invention" (*Teva* at paras. 74-75). The Supreme Court held that Pfizer had not met its obligation to fully disclose the invention.
- I agree with the judge and Dr. Wnuk that "the fact that, in hindsight, individual steps in a chemical synthesis have some precedent in the literature does not mean that the overall sequence of steps for making a new compound was easy to determine" (Reasons at para. 548). In the case at bar, since at the date of filing the skilled person would not have known which pathway, along with the associated choices of reagents and reaction condition, would successfully lead to the claimed invention, the skilled person was faced with a similar task, at a conceptual level, as in *Teva*.

[49] Rather than leading the skilled person step by step through the synthesis of the Claimed Compound, the specification "necessitates the working out of a problem" (*Pioneer*). The judge accepted the evidence of Dr. Wnuk at paragraph 516 of his Reasons that:

there was no teaching as to how to fluorinate a tertiary carbon at a nucleoside's 2' position in a stereoselective manner. I also accept his evidence that it was not common general knowledge that using a nucleophilic fluorination approach, or indeed any fluorination approach, would successfully synthesize a 2'-C-Me/F compound.

- [50] In the absence of any teaching from the 191 Patent, this constituted a burden beyond that borne by the text of paragraph 27(3)(b) of the *Patent Act* as interpreted and applied in the jurisprudence. I would uphold the judge's finding that the disclosure of the 191 Patent was insufficient.
- [51] Further, I note that the judge found that neither the 191 Patent nor the common general knowledge directed the skilled person to the Intermediate Compound. Even if the fluorination step was disclosed, and even if the skilled person was directed to either the nucleoside or sugar ring approach, a step necessary for sufficient disclosure of how to make the Claimed Compound using either of those methods remained missing. In the event that Idenix was able to satisfy this Court that the judge made numerous errors with respect to the fluorination step, unless these errors also go to identification of the Intermediate Compound, and I find that they do not, the judge's conclusions on this point stand.

Page: 18

B. Sound prediction of utility

[52] Idenix next challenges the judge's finding that the 191 Patent was invalid for lack of

sound prediction. Having found no reversible error in the judge's conclusion that the 191 Patent

was invalid due to insufficiency of disclosure, it is not necessary for this Court to deal with

Idenix's submissions on utility. However, I do not wish for these reasons to be taken as

endorsing the judge's approach to sound prediction.

C. The 657 Patent

[53] Having found no reversible error in the judge's conclusion that the 191 Patent is invalid

due to insufficiency of disclosure, the 657 Patent was not anticipated nor did it infringe the 191

Patent.

V. Conclusion

[54] For the reasons above, the appeal should be dismissed with costs.

"Donald J. Rennie"
J.A.

"I agree

J.D. Denis Pelletier J.A."

"I agree

D.G. Near J.A."

# FEDERAL COURT OF APPEAL

# NAMES OF COUNSEL AND SOLICITORS OF RECORD

# APPEAL FROM A JUDGMENT OF THE FEDERAL COURT FOR REASONS DATED October 9, 2015 (confidential) and November 2, 2015 (public) No. T-1156-12 (2015 FC 1156)

DOCKET:	A-483-15

STYLE OF CAUSE: IDENIX PHARMACEUTICALS,

INC. v. GILEAD PHARMASSET LLC, GILEAD SCIENCES, INC.

and GILEAD SCIENCES

CANADA, INC.

PLACE OF HEARING: TORONTO, ONTARIO

**DATE OF HEARING:** JANUARY 17, 2017

**REASONS FOR JUDGMENT BY:** RENNIE J.A.

**CONCURRED IN BY:** PELLETIER J.A.

NEAR J.A.

**DATED:** JULY 24, 2017

## **APPEARANCES:**

Patrick S. Smith FOR THE APPELLANT

Christopher C. Van Barr

Alex Gloor Marc Crandall

Jason C. Markwell FOR THE RESPONDENTS

Jordana Sanft Amy Grenon Jillian Hyslop

# **SOLICITORS OF RECORD:**

Gowling WLG (Canada) LLP Ottawa, Ontario

Norton Rose Fulbright Canada LLP Toronto, Ontario

Belmore Neidrauer LLP Toronto, Ontario FOR THE APPELLANT

FOR THE RESPONDENTS