UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CELL GENESYS, INC., Plaintiff	)	
v.	)	C.A. No. 05-12448-MLW
APPLIED RESEARCH SYSTEMS ARS HOLDING, N.V., Defendant	)	
APPLIED RESEARCH SYSTEMS ARS HOLDING, N.V., Plaintiff	)	
v.	)	C.A. No. 04-11810-MLW
CELL GENESYS, INC, and TRANSKARYOTIC THERAPIES, INC. Defendants	)	

MEMORANDUM AND ORDER

WOLF, D.J. August 13, 2007

I. SUMMARY

These consolidated cases are appeals from a decision of the Board of Patent Appeals and Interferences (the "Board"), which is part of the Patent and Trademark Office (the "PTO"), pursuant to 35 U.S.C. §146. Cell Genesys, Inc. ("CGI") asserts that the Board erred in finding that some of the claims in its U.S. Patent Application No. 08/102,390 (the "'390 application") were invalid and, therefore, Applied Research Systems ARS Holding N.V.'s ("ARS") U.S. Patent No. 5,272,071 (the "'071 patent") did not interfere with those claims. ARS asserts that the Board erred in finding any

of CGI's claims in the '390 application to be valid.

After the completion of discovery, the parties made written submissions to the court in support of their respective positions. ARS also filed motions in limine seeking to exclude: deposition testimony from witnesses who did not provide evidence to the Board by affidavit or deposition; documents that were not submitted to the Board; and expert opinions that were not disclosed in the report of Dr. Thea Tlsty ("Dr. Tlsty") which was provided to ARS during the period for discovery in this case. A hearing on the motions in limine was held on January 14, 2007.

For the reasons described in this Memorandum, ARS' motions in limine are meritorious. A §146 proceeding in a United States District Court is primarily intended to provide an opportunity for further, live testimony by witnesses who presented affidavits or depositions to the Board, which may not receive live testimony, so that the credibility of those witnesses can be better judged. As a §146 case is an equitable proceeding, the court has the discretion to allow testimony by witnesses who did not present evidence to the Board if it is in the interests of justice to do so. However, the relevant statutes generally require that all evidence available through the exercise of due diligence be presented to the expert Board, which has primary responsibility for determining interference issues.

In this case, the new witnesses proffered to the court, and

the related documents, would have been available to CGI for presentation to the Board if CGI had exercised due diligence in seeking them. However, CGI did not. Rather, it relied exclusively on an affidavit an attorney, which the Board, for well-articulated reasons, found not to be credible. In these circumstances, it would be contrary to the interests of justice to allow CGI to present the disputed new evidence to this court.

In addition, ARS correctly contends that CGI is seeking to introduce expert opinions of Dr. Tlsty that were not, as required by Federal Rule of Civil Procedure 26(a)(2)(B), disclosed during discovery, either initially or in any supplementary expert report. CGI has neither shown that this failure to disclose was substantially justified nor that it was harmless as required by Federal Rule of Civil Procedure 37(c)(1). Therefore, to the extent that Dr. Tlsty's opinions go beyond those that were timely and properly disclosed, they are being excluded.

In view of the foregoing, ARS' motions in limine are being allowed. As a result, the parties are being ordered to revise their submissions to address the merits of these cases based solely on the admissible evidence.

II. FACTS

This appeal arises from interference number 105,114 (the "'114 interference") before the Board. The 105,114 interference followed an earlier interference proceeding, number 103,737 (the "'737

interference"). Both interferences involve a dispute for priority between ARS and CGI.

ARS owns the '071 patent, which was issued on December 21, 1993, and consists of 58 claims. The '071 patent discloses and claims certain methods, constructs, and cell lines relating to recombinant proteins and covers methods of modifying the proteins encoded by, and synthesized from, genes.

CGI filed the '390 application consisting of 112 claims, on August 5, 1993. CGI alleges that the '390 application contains claims covering the same or similar methods as those claimed in ARS' '071 patent.

The parties' dispute was first presented to the Board in the '737 interference. That interference was never resolved. On March 28, 2003, the Board redeclared the '737 interference as the '114 interference. In the '114 interference, the Board addressed three issues: (1) what inventions, if any, ARS' '071 patent and CGI's '390 application actually claimed; (2) whether those inventions, once construed, were sufficiently similar as to "interfere;" and (3) who the rightful inventor or inventors were. The '114 interference proceeding lasted 15 months. Each party filed numerous motions, memoranda, and exhibits. Each party also submitted witness declarations, and transcripts and video of the cross-examination of its adversary's witnesses.

The Board held a hearing on February 26, 2004. It issued its

decision on June 24, 2004. Canvassing the prior art, the Board invalidated Claims 1, 2, 5-7, 9-20, 22, 23, 25, 26, 28-30, 32-39, 52-54 and 57 of ARS' '071 patent and Claims 105 and 107-112 of CGI's '390 application. See Opinion of the Board (hereinafter "Board") at 36-112. The Board then compared the remaining claims in ARS' '071 patent to Claim 106 of CGI's '390 application and found that they did not interfere with each other and, therefore, did not present an interference-in-fact. Id. at 126-40.

The Board reviewed various pieces of prior art, including matters referred to as: Japan,[1] Kaufman I,[2] Raibaud,[3] Nasmuth I,[4]

[1] Japan patent Publication 1-215280, published August 29, 1989.

[2] Kaufman, R., et al.,"Coamplification and Coexpression of Human Tissue-Type Plasminogen Activator and Murine Dihydrofolate Reducatse Sequences in Chinese Hamster Ovary Cells," Molecular and Cellular Biology, Vol. 5, No. 7, 1750-59 (1985).

[3] Raibaud, O., et al, "A Technique for Integrating Any DNA Fragment into the Chromosome of Escherichia coli," Gene, Vol. 29, 231-41 (1984).

[4] Nasmyth, K., "At Least 1400 Base Pairs of 5'-Flanking DNA Is Required for the Correct Expression the HO Gene in Yeast," Cell, Vol. 42, 213-23 (August 1985).

Nasmuth II,[5] Smithies,[6] Cid,[7] and Thomas.[8] See id. at 37-86. Of particular relevance to the instant proceeding is the Japan reference, a patent issued in Japan on August 29, 1989. The Japan reference describes a method for:

> activating a prokaryotic microorganism to express a gene of its genome encoding a protein not normally expressed by said prokaryotic microorganism, and/or for increasing the level of expression of a gene of a prokaryotic microorganism's genome encoding a protein normally expressed by said prokaryotic microorganism.

Id. at 80. The Board compared the Japan reference to Claims 107-109 of CGI's '390 application, which it construed as follows:

> The methods of Claims 107-109 comprise inserting a DNA construct by homologous recombination into the genome of a mammalian cell in proximity to a target gene within the genome of said cell to stimulate or enhance expression of the target gene,
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> wherein the target gene encodes (1) a protein not normally expressed in said cell (Claims 107 & 109), or (2) a protein normally expressed in said cell (Claim 108); and

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[5] Nasmyth, K., "The Determination of Mother Cell-Specific Mating Type Switching in Yeast by a Specific Regulator of HO Transcription," The EMBO Journal, Vol. 6, No. 1, 243-48 (1987).

[6] Smithies, O., et al., "Insertion of DNA Sequences into the Human Chromosonal β-Globin Locus by Homologous Recombination," Nature, Vol. 317, 230-34 (September 19, 1985).

[7] Cid, A., et al., "Replacement of the Promoter of the Yeast Plasma Membrane ATPase Gene by a Calactose-Dependent Promoter of its Physiological Consequences," Current Genetics, Vol. 12, 105-10 (1987).

[8] Thomas, K., et al., "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Steme Cells," Cell, Vol. 51, 503-12 (November 6, 1987).

> wherein said DNA construct comprises (a) an amplifiable gene (Claim 107, 108 and 109), a regulatory sequence (Claim 107, 108 and 109), or both (Claim 107, 108 and 109) and (b) DNA homologous with DNA in a region of the genome in proximity to the target gene (Claim 107, 108 and 109).

Board at 35-36 (emphasis in original).

Acknowledging that the Japan reference focused on prokaryotic cell lines and that Claims 107-109 referred to eukaryotic--mammalian--cell lines, id. at 80-82, the Board nevertheless concluded that applying the technique patented in the Japan reference to a eukaryotic cell line would have been obvious to an individual ordinarily skilled in the relevant art at the time of CGI's '390 application. Id. at 86.

Based on its review of the teachings of the prior art references, the Board concluded that:

> [P]ersons having ordinary skill in the art would have been motivated to make and use inventions encompassed by Claims 1, 2, 5-7, 9-20, 22, 23, 25, 26, 28-30, 32-39, 52-54, 56 and 57 of ARS's '071 patent and Claims 105 and 107-112 of Genesys's Application 08/102,390 with reasonable expectation of success. Therefore we conclude that the subject matter defined by Claims 1, 2, 5-7, 9-20, 22, 23, 25, 26, 28-30, 32-39, 52-54, 56, and 57 of ARS's '071 patent and Claims 105 and 107-112 of Genesys's Application 08/102,390 prima facie would have been obvious to persons having ordinary skill in the art and unpatentable under 35 U.S.C. § 103 in view of the combined teachings of Japan, Kaufman I, Thomas and Smithies, optionally further in view of Kaufman II.

Id. at 87 (emphasis in original).

Following the Board's decision that Claims 107-09 of its '390 application were anticipated by the Japan reference, CGI had two

options. It could have deferred contesting the decision that the Japan reference anticipated its claims until the "priority" phase of the proceeding or it could have sought to antedate the Japan reference pursuant to the procedures of 37 C.F.R. §1.131 ("Rule 131"). See LeVeen v. Edwards, 57 U.S.P.Q.2d 1416, 1420-21 (Bd. Pat. App. & Int. 2000). If a party invokes Rule 131 and does not succeed in antedating the prior art, its claims may be held unpatentable and its application may be adjusted by the PTO accordingly. Id.

CGI elected to attempt to antedate the Japan reference in an effort to save Claims 107-109. Board at 86. To antedate prior art a party must show that it conceived of and reduced to practice its patent claims prior to the effective date of the prior art reference, which is the date the prior art reference was conceived of and reduced to practice. See 37 C.F.R. § 1.131. The party seeking to antedate the prior art must also show that it diligently pursued patenting its invention from a time just before the prior art reference's effective date to the date the party filed its application. Id. By antedating prior art, a party can "push back" its effective date, thus narrowing the pool of prior art available to which the party's invention must be compared. In effect, antedating prior art makes it likelier that a patent claim is novel and nonobvious, as the claim is compared to the prior art available to one ordinarily skilled in the relevant field earlier in that

field's development. In this case, the effective date that CGI was attempting to push back is November 6, 1989, the date CGI filed the "parent" to its '390 application.[9] See Board at 90. The effective date of the Japan reference is August 29, 1989. See id. at 37, 74.

Rule 131 permits an applicant to challenge a rejection by the PTO by submitting a declaration from the inventor informing the Board of when the inventor in fact conceived of the invention. It states, in pertinent part:

> When any claim of an application . . . is rejected, the inventor of the subject matter of the rejected claim . . . or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.

37 C.F.R. §1.131. Sections 1.42, 1.43, and 1.47, referenced in §1.131, permit an applicant to submit the declaration of someone other than the inventor in certain specified situations. Sections 1.42 and 1.43 apply when the inventor is dead or legally incapacitated. Section §1.47 applies when the inventor refuses to file a declaration or cannot be found. More specifically, at the time of the interference, §1.47 stated, in pertinent part:

(b) Whenever all of the inventors refuse to execute an

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[9] A parent application is an earlier version of a patent application that a party may use, in certain circumstances, to push back its effective date. See 35 U.S.C. §120. If the parent application satisfied the requirements of 35 U.S.C. §112, the later patent application, evolving from the parent, receives the benefit of the earlier patent's filing date. Id.; see also Falkner v. Inglis, 448 F.3d 1357, 1362 (Fed. Cir. 2006).

> application for patent, or cannot be found or reached after diligent effort, a person to whom an inventor has assigned or agreed in writing to assign the invention, or who otherwise shows sufficient proprietary interest in the matter justifying such action, may make application for patent on behalf of and as agent for all the inventors. The oath or declaration in such an application must be accompanied by a petition including proof of the pertinent facts, a showing that such action is necessary to preserve the rights of the parties or to prevent irreparable damage, the fee set forth in § 1.17(h), and the last known address of all of the inventors.

See 65 Fed. Reg. 54604, 54662, Sept. 8, 2000.[10]

CGI did not submit an affidavit from the inventor of the '390 application, Arthur Skoultchi, to the Board. Instead, it submitted an affidavit from Bertram I. Rowland, its patent attorney from June, 1989 through February, 1990, along with five exhibits. See Board at 93-94. Nor did CGI submit to the Board a petition indicating the unavailability of Skoultchi, his last known location, or evidence of diligence in attempting to locate him. Id.

The Board presumed, without deciding, that Rowland's Declaration and the accompanying exhibits constituted "an appropriate oath or declaration" for the purposes of §1.131. Id. at 93. The Board did not find the evidence presented by Rowland to be persuasive.

Rowland's submission included his Rule 131 declaration, video-cross-examination of him, a transcript of that October 1, 2003

[10] The text of 1.47 was revised on September 21, 2004, effective as of November 22, 2004. See 69 Fed. Reg. 56482, 56538, Sept. 21, 2004.

testimony, and five exhibits. Those exhibits were: Exhibit A, CGI meeting minutes dated July 24 and 25, 1989; Exhibit B, a hand-edited and annotated printed draft of an incomplete, non-final specification for a patent application titled "Production of Proteins Using Homologous Recombination;" and Exhibits C-E, copies of invoices from the firm of Laydig, Voit & Mayer, LTD., dated September 25, 1989, October 25, 1989, and November 25, 1989. See Board at 94-108.

After analyzing the exhibits and Rowland's declaration, the Board concluded that the record as a whole did not establish that CGI reduced to practice the invention described in Claims 107-109 of the '390 application or that it conceived of that invention, prior to the August 29, 1989 effective date of the Japan reference, coupled with due diligence from a time prior to that date to a subsequent reduction to practice or to the November 6, 1989 filing date of CGI's application. Id. at 108.

The Board noted that paragraph two of Rowland's declaration was "replete with references to inventor Skoultchi's ideas, suggestions and statements," but that "there [was] no testimony by Dr. Skoultchi of record." Id. at 95. The Board also noted that CGI had provided no explanation for the absence of Skoultchi's testimony. Id.

The Board found "generally that Rowland's testimony [was] not particularly credible." Id. at 94. After reviewing the videotape

and transcript of Rowland's testimony, the Board wrote that it was "as impressed, if not more impressed, by Rowland's lapses of memory as [it was] impressed by Rowland's memory." Id. at 109. The Board compared numerous examples of Rowland's claim to recall the intricate details of Skoultchi's invention with Rowland's inability to recall who was present at the 1989 meetings, whether he took notes at the meetings, where important documents came from, or the names of people at CGI or his law firm that he worked with on the matter. Id. at 109-112. Rowland explained these lapses by claiming that Skoultchi's idea was so impressive that he could not help but remember it in all its detail. See id. at 110-12.

The Board found that Rowland's explanation was not credible. More specifically, it wrote:

> Rowland's testimony does not remedy the deficiencies in Rowland's declaration and supporting exhibits. Moreover, we are not satisfied with Rowland's explanation why he could recall the complex technology discussed at CGI's meetings on July 24-25, 1989, many years later. More importantly, Rowland's declaration that Dr. Skoultchi conceived of the invention of Claims 106-109 on Genesys's Application 08/102,390 at the time of CGI's meetings on July 24, 1989, and July 25, 1989, is not consistent with the recorded minutes of CGI's July 24-25, 1989 meeting. Morever, Rowland has not explained how and when the handwritten entries in the recorded minutes of CGI's July 24-25, 1989 meeting became part of the document

Id. at 112. Based in part on the foregoing, the Board concluded that CGI had not satisfied its burden of antedating the Japan reference. Id. at 108.

After finding that CGI did not antedate the Japan reference,

the Board examined whether the remaining claims of ARS' '071 patent and Claim 106 of CGI's '390 application interfered in fact.[11] Claim 106 of CGI's '390 application states:

> 106. A human 293 embryonal kidney cell, wherein the genome of the cell has inserted therein an enhancer and promoter of cytomegalovirus operatively associated with human erythropoietin gene, so that the cell expresses human erythropoietin.

See id. at 127. As interpreted by the Board, the remaining valid claims of ARS' '071 patent (Claims 3,4, 8, 21, 24, 27, 31, 40-51, 55, 58) "comprise, or insert within the genome of a cell line, a DNA construct comprising an expressible, amplifiable gene capable of amplifying a target gene when inserted in close proximity thereto." Id. at 127.

The Board compared ARS' '071 patent to Claim 106 of the CGI's '390 application and found that "the specific DNA construct inserted into the genome of a human 293 cell" as described in CGI's

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[11] "An interference in fact exists when at least one claim that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention." 37 C.F.R. § 1.601(j). "Same patentable invention" and "separate patentable invention" are defined in 37 C.F.R. § 1.601(n) as follows:

> (N) Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of the invention "B" assuming invention "B" is prior art with respect to invention "A." Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of the invention "B" assuming invention "B" is prior art with respect to invention "A."

Claim 106 is "patentably distinct in structure and function from any specific DNA construct" described in ARS' '071 claims." Id. at 128. The Board also found that the DNA inserts in ARS' disclosure do not suggest enhancers and promoters of cytomegalovirus, and that the enhancers and promoters relevant to CGI's Claim 106 did not constitute an "amplifiable gene capable of amplifying a gene silent in the genome of any other mammalian." Id. Finally, the Board found that ARS' claims would not have been obvious to persons having ordinary skill in the art in light of the subject matter defined in Claim 106, and that the subject matter of Claim 106 would not have been obvious to persons having ordinary skill in the art in light of the valid claims in ARS' '071 patent. Id. at 128-29. Therefore, the Board found that CGI's Claim 106 did not interfere with ARS' valid claims. Id. at 126-140.

III. PROCEDURAL HISTORY OF THESE CASES

Both parties were dissatisfied with the Board's decision on the foregoing issues, and others not relevant to the discrete questions presented in this case. Therefore, they filed appeals in federal courts. Usually, such appeals are heard in the Federal Circuit. However, the parties invoked 35 U.S.C. §146, which allows parties dissatisfied the Board's decision in an interference to challenge it in a United States District Court.

On August 18, 2004, CGI filed a complaint against ARS in the District Court for the District of Columbia, seeking reversal of

the Board's decisions that CGI did not antedate the Japan reference, that all but Claim 106 of CGI's application was unpatentable, and that no interference-in-fact existed. See Complaint, Cell Genesys v. Applied Research Systems, C.A. 04-1407. On August 19, 2004, ARS filed a complaint in this court, seeking to reverse the Board's decisions regarding ARS' priority date, that some of its claims were unpatentable, and that one claim in CGI's '390 application was valid. See Amended Complaint, C.A. 04-11810.

On August 30, 2004, ARS filed an Amended Complaint, which, in Count I, repeated and amplified its earlier request that the court reverse the PTO and, in Count II, added a second claim against Transkaryotic Therapies, Inc. ("TKT") for allegedly infringing ARS' '071 patent. See id., ¶¶13-16.

On August 29, 2005, this court severed Count II from Count I and stayed the infringement claim against TKT pending the outcome of the §146 appeals. In December, 2005, CGI's suit against ARS was transferred to this court, where the two cases have been consolidated.

Discovery concerning CGI and ARS' claims against each other was completed in June, 2006. ARS initiated the depositions of Skoultchi, as well as Dr. Raju Kucherlapati, a CGI founder, Mark Levin, former CEO of CGI, and Andy Thompson and George Savage, both management consultants at the Mayfield Fund, which had invested in CGI during its formative years. CGI did not make any effort to

depose these witnesses until after ARS contacted them. At the depositions, ARS developed the factual record by relying on the documents Rowland had submitted to the Board as a means of refreshing the deponents' memories. The deposition testimony revealed documents relevant to the interference proceeding that had not been presented to the Board.

At a hearing held August 8, 2006, as agreed by the parties, the court ordered a trial scheduled for January 16 and 17, 2007, to be focused on two issues: (1) whether the Board correctly found that CGI's Claims 107-109 were unpatentable over the Japan reference; and (2) whether the Board correctly held that there was no interference-in-fact between Claim 106 of CGI's '390 application and the 21 claims of ARS' '071 patent that the Board found patentable. See August 9, 2006 Order. The parties also agreed to a trial on the written record as to the first question. Id. at 2. At the August 8, 2006 hearing, the parties disagreed on whether the second question should be tried only on the written record. ARS preferred a trial on the written record, while CGI proposed the introduction of additional expert testimony. The court did not finally decide whether the second issue would be tried on January 16 and 17, 2007,or whether it would include live testimony on that question.

In support of its contention that the Board incorrectly found that CGI's Claims 107-109 were unpatentable over the Japan

reference, CGI now seeks to introduce evidence that was not presented to the PTO. More specifically, it asks the court to consider the depositions of Skoultchi, Kucherlapati, Levin, Savage, and Thompson, which were taken in this case, after the interference proceeding, and various documents that CGI had not previously presented to the PTO, particularly: (1) two pages from Skoultchi's notebook, dated February 15, 1989 and April 26, 1989, see Appendix to CGI's Memorandum In Support of Position That Claims 107-109 Are Not Unpatentable Over the "Japan" Reference ("CGI Record"), Docket No. 129-2 (at CGI 4004, 4025); (2) a July 10, 1989 memorandum, see Docket No. 129-6, at 6; (3) a July 24, 1989 fax from Levin to Rowland, see CGI Record, Docket No. 129-5 (at CGI 3650-53); (4) two versions of CGI business plans dated August 26 and September 20, 1989, see CGI Record, Docket No. 129-9 (at CGI 3260-3313) and No. 129-14 (CGI 4430-64); (5) a draft patent application dated August 29, 1989, see CGI Record, Docket No. 129-11 (page 10 of 17) to No. 129-12 (page 12 of 18); (6) and a cover letter to a draft patent application dated November 1, 1989, see Docket No. 129-26 (at CGI 3656-57). CGI contends that these documents were revealed as a result of information discovered in the depositions, and were not otherwise known or available to CGI during the Board proceeding.[12]

[12] CGI also seeks to introduce meeting minutes dated July 24 and 25, 1989. See CGI Record, Docket No. 129-6 (at CGI 3231). ARS objects. They were presented previously to the Board as part of the Rowland affidavit. They are, therefore, admissible in this proceeding.

In support of its position that the Board incorrectly held that there was no interference-in-fact between Claim 106 of CGI's '390 application and the 21 Claims of ARS' '071 patent that the Board found patentable, CGI also seeks to introduce additional documents and expert testimony not previously presented to the Board. Specifically, CGI now seeks to introduce: U.S. patent No. 5,024,939 (the "'939 patent"), assigned to Genentech, Inc.; a 1984 article written by Kucherlapati and others titled "Introduction of Purified Genes into Mammalian Cells" (the "Kucherlapati article"); and the testimony of Dr. Tlsty. See Docket Nos. 126 and 27.

In its motions in limine, ARS objects to the introduction of evidence not submitted to the PTO. See Docket Nos. 135-141. ARS makes three primary arguments: (1) that CGI either had in its possession, or could reasonably have obtained if it had been minimally diligent, the new evidence when it was before the Board and, therefore, the evidence should be excluded; (2) that much of CGI's new evidence is inadmissible hearsay; and (3) that, pursuant to Rule 26(a)(2) of the Federal Rules of Civil Procedure, CGI's expert, Dr. Tlsty, should not be permitted to testify on various matters that were not disclosed in her expert report.

In response, CGI has submitted an affidavit from its current counsel, Stephen Kelber. Kelber seeks to explain why CGI did not present to the Board any of the witnesses whose testimony it now proposes to introduce and why it did not obtain any of the new

documents for presentation to the Board. Specifically, Kelber states that he attempted to contact Levin on two occasions around March, 2003, when Levin was employed as the Chief Executive Officer of Millennium Pharmaceuticals, but was unable to reach him. Nov. 22, 2006 Affidavit of Stephen Kelber, ¶4. Levin is the only person Kelber expressly states he made any effort to contact before the Board rendered its decision. Id. Kelber also asserts that he spoke with Skoultchi and Kucherlapati prior to this action, and that neither of them had any pertinent documents or memory. Id., ¶2. Kelber also states that he was not in possession of Skoultchi's notebook, although he indicates that CGI was. Id., ¶3. In addition, Kelber claims that neither Skoultchi nor Kucherlapati were under any contractual obligation to provide testimony or evidence on behalf of CGI, and that Kelber was unaware of the existence of Savage or Thompson until they were identified by Levin in his deposition. Id., ¶¶5, 7.

CGI also claims that none of the documents it now seeks to introduce are hearsay and that Dr. Tlsty's expert report provides sufficient notice to permit her to testify concerning the state of the art during the late 1980s and early 1990s. See CGI's Opposition to ARS' Motion in Limine to Exclude Previously Undisclosed Evidence Relied on by CGI in its "Interference-In-Fact."

The court held a hearing on these issues on January 16, 2007.

For the reasons discussed below, the court has concluded that it is not appropriate to permit CGI to rely on any evidence not presented to the Board. Nor is it appropriate to permit the introduction of any opinion not previously disclosed in Dr. Tlsty's expert report.

IV. ANALYSIS

A. The Applicable Standard Concerning the New Evidence

The Federal Circuit has, in dicta, stated that "the statute [§146] authorizes the district court to accept all proffered testimony on issues raised by the parties during the proceedings below or by the [B]oard's decision." Case v. CPC International, 730 F.2d 745, 752 (Fed. Cir. 1984). The Federal Circuit has not decided whether in a §146 proceeding the district court may restrict the admission of testimony on an issue raised before the Board. See General Instrument Corporation, Inc. v. Scientific Atlanta, Inc., 995 F.2d 209, 214 (Fed. Cir. 1993) ("we again have no occasion to decide whether 'a district court may properly restrict the admission of testimony on an issue raised before the [B]oard.'") (quoting Case, 730 F.2d at 752).

As explained below, this court concludes that it has the discretion to restrict the testimony of new witnesses and related documents that CGI proposes to present, and in the circumstances of this case it is most appropriate to do so. Section 146 expressly states that the parties have a right to present to this court "further" testimony, which manifests a statutory intent that

district courts receive live testimony, and related documents, from witnesses who presented evidence to the Board by affidavit or deposition--the only form the PTO permits.

However, "[d]istrict court review of an interference proceeding under section 146 is an equitable remedy of longstanding." General Instrument, 995 F.2d at 214. Therefore, it is also permissible for the court to receive testimony from witnesses who did not present evidence to the Board if equity so requires. See Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994); see also Velsicol Chemical Corporation v. Monsanto Company, 579 F.2d 1038, 1043-47 (7th Cir. 1978).

The issue of whether the court should consider the new evidence CGI proffers is one of statutory construction. "As in all statutory construction cases, [the court must] begin with the language of the statute." Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002); see also Phillips v. Pembroke Realty Estate, Inc., 459 F.3d 128, 139 (1st Cir. 2006). The statutory language is accorded "its ordinary meaning by reference to the specific context in which the language is used, and the broader context of the statute as a whole." United States v. Robertson, 459 F.3d 39, 51 (1st Cir. 2006). This means that it is necessary to consider the statute's "overall purpose and policy." Rolland v. Romney, 318 F.3d 42, 48 (1st Cir. 2003). "[T]he congressional intendment conveyed by unclear statutory language may be discernable from its

legislative history." Id. at 48 (quotations and citations omitted).

Section 146 states, in pertinent part, that in cases brought in the district court:

> the record of the Patent and Trademark Office shall be admitted on motion of either party . . . without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record of the patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

(emphasis added). Viewed both in the context in which it is used and in the broader context of the statute as a whole, absent special circumstances, "further" testimony means that the parties have a right to present live testimony, and documents introduced as part of it, from witnesses who presented evidence by affidavit or deposition to the Board. See Velsicol 579 F.2d at 1043-47.

The relevant "language of §146 itself does not resolve the controversy" concerning the scope of the right to present further testimony. Id. at 1045; see also Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1345 (Fed. Cir. 2000). The meaning of the language at issue is best understood in the context of the law concerning patent interference practice, which the Federal Circuit has properly characterized as "highly arcane and specialized." Conservolite, 21 F.3d at 1100.

As indicated earlier, "[a] patent interference is designed to determine whether two patent applications (or a patent application

and an issued patent) are drawn to the same patentable invention and, if so, which of the competing parties was the first to invent the duplicative subject matter." Noelle v. Lederman, 355 F.3d 1343, 1350 (Fed. Cir. 2004) (citations omitted). It is a proceeding conducted by the Board pursuant to 35 U.S.C. §135 and the related regulations that the PTO has issued.

Live testimony may not be presented in a PTO interference proceeding. See 37 C.F.R. §§1.653(a), 1.677. As the Federal Circuit has explained:

> In an interference . . . the Federal Rules of Evidence apply. See 37 C.F.R. §1.671(b) (1998). In addition, both sides can submit testimony, initially in the form of affidavits, unless the testimony must be compelled. See 37 C.F.R. §1.672. A party may "cross-examine" an affiant through oral deposition. See 37 C.F.R. §1.672(d). Discovery, at least against the party opponent, is also available. See 37 C.F.R. §1.687. However, although the parties "will be given an opportunity to appear before the Board to present oral argument at a final hearing," 37 C.F.R. §1.654, at no point in the interference proceeding is a party allowed to present live testimony before the Board. The Board reviews testimony only in the form of affidavits and transcripts of depositions, and other facts in the form of responses to interrogatories and requests for admissions. See 37 C.F.R. §§1.653(a), 1.677(a).

Winner, 202 F.2d at 1347 (emphasis added).

As also discussed earlier, there are two means of challenging the Board's decision in an interference proceeding. A party may appeal that decision directly to the Federal Circuit. See 35 U.S.C. §141. In such an appeal, the parties are "limited to the evidentiary record before the Board." Winner, 202 F.3d at 1345.

The Federal Circuit then determines whether the Board's decision was supported by substantial evidence. See Dickinson v. Zurko, 527 U.S. 150, 161 (1999).

Alternatively, a Board determination in an interference proceeding may be challenged in a United States District Court, subject to appeal to the Federal Circuit. See 35 U.S.C. §146. As described earlier, §146 provides that the district court must admit the record of the Board proceeding and that doing so is: "without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit." (emphasis added).

Therefore, the Federal Circuit has "often described the district court proceeding as 'a hybrid of an appeal and a trial de novo.'" Winner, 202 F.3d at 1345 (citations omitted). If the district court does not receive any new evidence, or perhaps any live testimony, it applies the substantial evidence test. See Mazzari v. Rogan, 323 F.3d 1000, 1004 (Fed. Cir. 2003).[13] However, if the court receives live testimony, the court must make factual findings de novo at least with regard to the issues on which live testimony is taken. See Winner, 202 F.3d at 1347-48 and n.4. For

[13]Mazzari was a case brought in the district court pursuant to 35 U.S.C. §145. See 323 F.3d at 1003-04. However for the purposes of deciding whether a de novo trial, rather than substantial evidence review, is required, the Federal Circuit has characterized §§ 145 and 146 as "parallel provisions." Winner, 2002 F.3d at 1345.

example, in Genetech, Inc. v. Chiron Corporation, 220 F.2d 1345, 1351 (Fed. Cir. 2000), the Federal Circuit noted that the district court did not hear live testimony on all issues decided by the Board and stated that, "[u]nder Winner, live testimony on the issue of practical utility makes the district court a factfinder on that issue, and requires the court to decide that issue de novo. Id. (emphasis added).

Facts on which live testimony is taken must be found de novo "because the district court may observe witnesses under examination and cross-examination [and, therefore,] it can have a 'powerful advantage' over the Board which can never receive testimony in such a manner." Id. at 1347 (quoting Burlington Indus., Inc. v. Quigg, 822 F.2d 1581, 1582 (Fed. Cir. 1987)).

However, "as early as 1927 the Third Circuit in Barrett Co. v. Koppers Co., 22 F.2d 395 (3rd Cir. 1927) held that the right to offer new evidence [to the district court] was not unlimited." Velsicol, 579 F.2d at 1043-44. Deciding the limits on the live testimony that should be admitted requires a recognition and reconciliation of several important purposes manifest by the statutory scheme concerning patent interferences.

First:

> "In a contest between two claimants to the same invention on an issue of priority each is expected to produce all the testimony he has on that issue so that the Patent Office tribunals and the courts may make right decisions. If for some reason of his own a party withholds evidence which is available to him and which he can produce at

> will but does not produce, then he must be regarded as having abandoned that evidence in its bearing on the issue under trial. When that issue is decided it is somewhat in the nature of res judicata as to the evidence withheld."

Id. at 1044 (quoting Barrett, 22 F.2d at 397). Consistent with this reasoning, in Velsicol the Seventh Circuit wrote that:

> In seeking the proper standard for waiver of the right to present new evidence in a §146 proceeding, we must be guided by the strong policy considerations underlying the Barrett Co. v. Koppers Co. doctrine. We agree with the statement of the court in Kirschke v. Lamar, 426 F.2d 870, 874 (8th Cir. 1970), that "(t)he viability of the administrative process presupposes that pertinent and available testimony will be presented before the appropriate administrative body."

Id. at 1045.

This court agrees that it is important that the parties be required to present all available evidence to the Board at the outset of the patent interference process. The Board is an expert body and has the primary responsibility for deciding patent interferences. In recognition of this, deference is due to its decisions in appeals taken directly to the Federal Circuit. See Dickinson, 527 U.S. at 161.

Moreover, it is in the public interest that Board decisions be as reliable as possible. Patents are generally intended to give the public and the patentee's competitors clear notice of what is protected by a claimed invention and what areas for innovation remain open. See Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1563 (Fed. Cir. 1995) (Plager, J. concurring).

Uncertainty is generally damaging to competition and particularly costly where, as here, prescription drug sales involving millions of dollars are involved. As this court has previously observed:

> uncertainty [regarding the validity of a patent] might create difficulties in pricing [competing] products. It may also cause the drug companies to delay introduction of new products or needlessly invest money in efforts to design around an invalid patent. Such efforts are likely to be extremely costly in a highly regulated industry such as the one in which drug companies compete because changes in their product designs or manufacturing process may require regulatory approval.

In re Columbia University Patent Litigation, 330 F. Supp. 2d 12, 17 (D. Mass. 2004). It is evident to this court that uncertainty puts pressure on alleged infringers to settle disputes by making substantial licensing payments to which the purported patentee may not be legally entitled. This is unfair and ultimately expensive to the public.

The law aims to minimize uncertainty by authorizing actions for declaratory judgments. See 28 U.S.C. §2201, and by establishing a single court of appeals to decide patent cases. See In re: Columbia University Patent Litigation, 330 F. Supp. at 17. It is also appropriate that courts exercise their discretion to admit live testimony in §146 proceedings in a manner that will encourage, if not require, litigants to present all reasonably available evidence to the Board and thus maximize the likelihood that its fully informed decisions will prove to be reliable.

However, the ability of courts to receive certain live

testimony was evidently an important reason for the enactment of §146. As the Seventh Circuit has explained:

> Exactly what Congress might mean by [without prejudice to the right of the parties to take further testimony] is not entirely clear. However, there is some evidence in the legislative history that the Congressional concern was that admission of the Patent Office record should not impede the parties from replicating parts thereof by the means of the further "live" testimony of the witnesses whose depositions had already been made part of that record. The basis of this concern was a recognition of the relative inferiority of the Patent Office procedure for dealing with questions of witness credibility, since testimony could only be presented in deposition form. In contrast, in the district court the live witnesses' demeanor could also be considered. Thus we do not find in the "without prejudice" language a strong congressional intent in favor of the unlimited admission of evidence not previously presented to the Board which would hinder the courts from developing rules limiting the circumstances in which admission will be permitted.

Id., 579 F.2d at 1045 (footnotes omitted) (emphasis added).

The legislative history suggesting that §146 intended to authorize "further 'live' testimony of the witnesses whose depositions had already been made part of [the Board] record," id., is consistent with the express terms of the statute. As the Federal Circuit has characterized it, "the Board reviews testimony only in the form of affidavits and transcripts of depositions." Winner, 202 F.2d at 1347 (emphasis added). In the context of §146, "further" has its common meaning of "additional." See Webster's Third New International Dictionary 924 (1961). Therefore, this court finds that when the statutory language is "accorded its ordinary meaning by reference to the specific context in which the

language is used, and the broader context of the statute as a whole," Robertson, 459 F.3d at 57, it means additional, live testimony from witnesses who presented evidence by affidavit or deposition to the Board and additional documents introduced in the course of that testimony.

Nevertheless, the court recognizes that §146 supplanted "a remedy by a bill in equity" in the district courts. Velsicol, 579 F.2d at 1045. As indicated earlier, the Federal Circuit has characterized a §146 proceeding as an "equitable proceeding" as well. General Instrument, 995 F.2d at 214. Therefore, the Federal Circuit has repeatedly held that a district court has the authority to admit live testimony on issues that were not raised before the Board and "under appropriate circumstances may exercise its discretion" to do so. Conservolite, 24 F.3d at 1102 (citing General Instrument, 995 F.2d at 214).

This court understands that it has comparable equitable authority to admit live testimony from witnesses not presented to the Board on issues that the Board did decide. See Velsicol, 579 F.2d at 1045-47. However, generally "the parties to an interference must make a complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of the administrative and judicial resources." Conservolite, 21 F.3d at 1102. Similarly, in deciding whether to admit live testimony in this §146 proceeding, it is appropriate that the court

be guided by the policy manifest by the statutory scheme that all reasonably available evidence must in the first instance be presented to the expert Board, subject to possible further proceedings in the district courts of general jurisdiction. See Velsicol, 579 F.2d at 1045; Kirschke, 426 F.2d at 874; Barrett, 22 F2d at 397.

The Federal Circuit has summarized the various factors courts have considered in deciding whether it was appropriate to allow a litigant to present testimony on an issue not presented to the Board:

> [C]ourts have considered whether there was suppression, bad faith, or gross negligence on the part of the plaintiff in failing to raise an issue before the Board; whether the evidence was then reasonably available; and whether the issue has been or may be more conveniently and expeditiously raised in another judicial proceeding. See Standard Oil Co. v. Montedison, S.p.A., 540 F.2d 611, 617, 191 USPQ 657, 661 (3d Cir.1976). Other courts have applied a test of due diligence in identifying and procuring evidence, whether or not the failure to identify or procure the evidence was attended by bad faith motives or for tactical reasons. See Velsicol Chem. Corp. v. Monsanto Co., 579 F.2d 1038, 1046, 198 USPQ 584, 591 (7th Cir.1978). Examples of appropriate circumstances have been said to include an intervening change in the law, the presence of a new issue, or the admission of other new evidence deserving of a response or further elaboration. Id. at 1046 n. 10, 198 USPQ at 591 n. 10.

Conservolite, 23 F.3d at 1102. A similar range of tests has been used in deciding whether new evidence should be admitted on issues that were presented to the Board. See Velsicol, 579 F.3d at 1046; Kirschke, 426 F.2d at 874; Barrett, 26 F.2d at 387; California Research Corp. v. Ladd, 356 F.2d 813, 820 n. 18 (D.C. Cir. 1966).

In its analysis the Federal Circuit explained that "[a] proceeding under §146 is not a chance for a party to reconstruct its case, based on a new litigation strategy, leapfrogging the administrative process in the PTO." Conservolite, 21 F.3d at 1102. This consideration contributes to this court's conclusion that the "due diligence" standard described in Velsicol is the most appropriate standard to be applied in this case. See 579 F.2d at 1046. More specifically, this court too finds that:

> absent special circumstances, the proper question for the district court [is] whether the failure of the proponent of the additional evidence to uncover its existence earlier or to procure it for the interference proceeding occurred in spite of the proponent's diligence in preparing his case before the Board. We agree with the court in Kirschke that it makes no difference whether the failure to produce the evidence was "attended by reprehensible motives or not (or) whether it be for tactical or other reasons." 426 F.2d at 874. Moreover, we find that in terms of the policy of encouraging full disclosure it is not necessary that there have been an affirmative action or decision to suppress the evidence; it is enough that a reasonably diligent preparation of the proponent's case before the Board would have led to the discovery of the existence of the evidence and its production. Nor is it necessary that the evidence have been in the exclusive control and possession of the proponent, as long as it was procurable by him. Conversely, a litigant who has been reasonably diligent in identifying and procuring evidence for the interference proceeding will not be precluded from strengthening his presentation in the district court if new evidence should become available to him in the interim.

Id. at 1046; see also Brunswick Corp. v. Riegell Textile Corp., 627 F. Supp. 147, 150 (N.D. Ill. 1985) ("The proponent of new evidence not available during the interference proceeding must show that the

new evidence was unavailable in spite of the proponent's diligence in preparing its case"); Freeman v. Motorola, Inc., 209 U.S.P.Q. 829, *5-6 (N.D. Ill. 1980) (proponent of new evidence must "show that his failure to uncover its existence earlier, or to procure it for the interference proceeding, occurred in spite of his diligence in preparing his case before the Board."); accord California Research, 356 F.2d at 820 n.18 (although each party to a §145 proceeding "'may strengthen its case with additional material' the plaintiff may not submit for the first time evidence which he was negligent in failing to submit to the patent Office.") (quoting Killian v. Watson, 121 U.S.P.Q. 507 (D.D.C. 1958)); De Seversky v. Brenner, 424 F.2d 857, 859, n.5 (D.C. Cir. 1970) (same); Lemelson v. Mossinghoff, 225 U.S.P.Q. 1063, *2-3 (D.D.C. 1985) (finding that proponent of new evidence in a §145 action did not negligently withhold the evidence "during the PTO proceedings as it was not in his custody, control, or knowledge at that time.") MacKay v. Quigg, 641 F. Supp. 567, 570 (D.D.C. 1986) (finding that in a §145 proceeding, proponent may not introduce new evidence of fact in dispute if he was negligent in failing to submit it to the PTO); Holloway v. Quigg, 9 U.S.P.Q.2D 1751 (D.D.C. 1988) (noting that courts exclude new evidence that "was available to the plaintiff during the PTO proceeding but [] negligently withheld.").

In Conservolite, the Federal Circuit implicitly required the proponent of the testimony on a new issue to justify its admission

in the §146 proceeding. See 21 F.3d at 1102. This allocation of the burden of persuasion is also appropriate in the circumstances of the instant case. As the Seventh Circuit has explained:

> The policy of encouraging full disclosure supports this allocation. The proponent knows in advance if he plans to introduce evidence not previously presented to the Board. The proponent would be expected to know when he first became aware of the new evidence. If he did know of its existence, yet failed to produce it, he is in the best position to point to any justification for that failure. If he was unaware of its existence, he may also be expected to be in the best position to show that the lack of knowledge was in spite of his due diligence in marshalling evidence for his case before the Board. The opponent may, of course, introduce rebutting evidence showing that the evidence was clearly available at the time of the interference proceeding.

Velsicol, 579 F.2d at 1046.

B. CGI Did Not Exercise Due Diligence With Regard To The New Evidence It Seeks to Introduce

This court has considered the evidence concerning CGI's due diligence presented by CGI and the countervailing evidence emphasized by ARS. For the reasons described below, the court finds that CGI has not proven that it exercised due diligence with regard to the testimony of witnesses, and related documents, that it wishes to present for the first time to this court. Therefore, the court is not exercising its discretion to permit the introduction of that evidence in this case.

As indicated earlier, CGI seeks to introduce the deposition testimony of Dr. Skoultchi, Dr. Kucherlapati, Levin, Savage, and Thompson, taken in this case, and various documents that CGI did

not present to the PTO.[14] According to CGI, these documents were discovered in connection with depositions taken by ARS in this §146 proceeding.

Although at the August 8, 2006 hearing the court agreed to the parties' suggestion that it receive appropriate deposition testimony rather than live testimony, the court now understands that a §146 proceeding is an option intended to provide an opportunity to present live testimony on disputed issues to enhance judgments concerning credibility. Therefore, the court may prefer, if not require, that witnesses with admissible evidence whose credibility is being challenged, actually testify in court. However, as explained below, it is not appropriate for the court to allow any of the proffered witnesses to testify and most of the documents CGI seeks to present should be excluded as well.

CGI now wishes to present for the first time the testimony of

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[14] Once again, the document in dispute are: (1) two pages from Dr. Skoultchi's notebook, dated February 15, 1989 and April 26, 1989), see CGI Record, Docket No. 129-2 (at CGI 4004, 4025); (2) a memorandum dated July 10, 1989, see Docket No. 129-6, at 6; (3) a fax from Levin to Rowland dated July 24, 1989, see CGI Record, Docket No. 129-5 (at CGI 3650-53); (4) the meeting minutes dated July 24-25, 1989, which the Board assumed were in the record, see CGI Record, Docket No. 129-6 (at CGI 3232), Ex. A to Benton Decl., Ex. 2054 before the Board; (5) two versions of business plans dated August 26 and September 20, 1989, see CGI Record at Docket No. 129-9 (at CGI 3260-3313) and No. 129-14 (CGI 4430-64); (6) a draft patent application dated August 29, 1989, see CGI Record, Docket No. 129-11 (page 10 of 17) to No. 129-12 (page 12 of 18); (7) and a cover letter to a draft patent application dated November 1, 1989, see Docket No. 129-26 (at CGI 3656-57).

Dr. Skoultchi, the inventor, and two pages of his notebook. As explained earlier, PTO regulations state that a party attempting to antedate an alleged prior art reference must submit to the Board a declaration as to the date of the invention from the inventor, as well as any original, relevant records. See 37 C.F.R. §1.31. The PTO regulations permit reliance on the affidavit of someone other than an inventor only if all of the inventors refuse to execute a required document or "cannot be found or reached after diligent effort." 37 C.F.R. §147(b). Nevertheless, CGI presented neither Dr. Skoultchi's affidavit nor his notebook to the Board. Rather, it relied instead on an affidavit from its attorney, Rowland. CGI has not demonstrated that it exercised due diligence in attempting to present the Board either an affidavit from Dr. Skoultchi or his notebook. Rather, the evidence indicates that it made no effort to do so at all.

In opposing ARS' motion in limine, Kelber states that he spoke to Dr. Skoultchi prior to filing this §146 action. Kelber Aff. at ¶2. Kelber also represented CGI in the '114 interference. There is no evidence that he even tried to speak to Dr. Skoultchi in connection with the Board proceeding despite the regulations clearly requiring that the inventor submit an affidavit unless he cannot be found despite "a diligent effort." See 37 C.F.R. §§1.131(a) and 1.47(b).

In its decision, the Board noted this obvious deficiency in

CGI's presentation, writing:

> There is no testimony by Dr. Skoultchi of record. Nor is there any explanation why Dr. Skoultchi could not have testified. In this respect, Rule 131 indicates that inventor testimony is necessary.

Board at 93. The absence of Dr. Skoultchi's testimony contributed to the Board's conclusion that CGI had not proven the conception and diligence necessary to antedate the Japan reference. That decision included the strong critique of Rowland's credibility described earlier. Board at 109-112.

CGI has also not persuasively explained to this court why the necessary affidavit of Dr. Skoultchi, providing the testimony and notebook that CGI now proffers to this court, could not have been presented to the Board. Dr. Skoultchi was known to be the inventor. His name appears on the '390 application as the inventor. Indeed, CGI previously represented to this court that during the period of the '114 interference, Dr. Skoultchi was under contract to CGI as a consultant and would testify at CGI's behest. See Oct. 4, 2004 Kelber Aff., ¶8; CGI's Memorandum in Support of its Motion to Dismiss for Lack of Personal Jurisdiction or, in the Alternative, for Severance and Transfer of Count I of Plaintiff's First Amended Complaint at 5, 14. Therefore, it appears that Dr. Skoultchi would have been readily available to CGI if it had sought to present his testimony to the Board in the '114 proceeding.

In any event, it is evident that CGI knew where to find Dr. Skoultchi. If he had been approached and, surprisingly, proved to

be uncooperative, CGI could have asked the Board to authorize it to obtain a subpoena from the court. See 37 C.F.R. §1.28(c); Tropix v. Lumigen, 53 U.S.P.Q.2d 2018 2020 (Bd. Pat. App. & Int. 2000). A subpoena is authorized by the Board when "the interest of justice requires ordering the discovery sought." Tropix, 53 U.S.P.Q. 2d at 20020. In view of the essential importance of evidence from the inventor, it is foreseeable that the Board would have authorized CGI to seek a subpoena for Dr. Skoultchi in the unlikely event that it was necessary to compel his testimony.

CGI suggests that it would have been futile to have sought evidence from Dr. Skoultchi for the '114 interference proceeding because when contacted prior to the filing of this §146 action he did not have any relevant documents or any memory relating to the availability of the Japan reference as prior art. Rather, CGI argues that Dr. Skoultchi's memory was refreshed only when he was shown his notebook and other documents by ARS at his deposition in this case.

This argument is unpersuasive. Dr. Skoultchi testified that he had provided his notebook to the attorneys for CGI during the '737 interference conducted from 1996 to 2003. See Skoultchi Tr. at 167:13–168:3. ARS obtained the notebook and most of the other documents used to refresh Dr. Skoultchi's memory in discovery from CGI. That notebook and certain other relevant documents were in the possession, custody, and control of CGI during the pendency of

the '114 proceeding. CGI found them to produce to ARS in discovery in this case. If CGI had been duly diligent it would have found them during the '114 proceeding before the Board. It could then have used them to refresh Dr. Skoultchi's recollection, and provided the Board with the affidavit from the inventor and related documents that the PTO regulations require.

With regard to Dr. Skoultchi, this case is analogous to Velsicol, 579 F.2d at 1047, in which the Seventh Circuit affirmed a district court's finding that the required due diligence had not been demonstrated. In Velsicol, the plaintiff sought to present to the district court the testimony of its former employees, Barnas and Berliner, who had not presented affidavits to the Board. Id. Velsicol had presented the testimony and notebooks of the inventor. Id. The PTO rules then required independent corroboration of that testimony. Id. The testimony of Barnas and Berliner who had signed the notebooks, was "the most logical source of corroboration." Id. However, Velsicol made no effort to contact the former employees and chose to rely instead on the more convenient testimony of a supervisor. Id.

The Seventh Circuit wrote that:

> [W]e find that Velsicol failed to meet its burden with respect to the justification of its failure to present the testimony of Barnas and Berliner in the interference proceeding. Velsicol claimed that it was unaware of the evidence in question at the time of the interference proceeding in that neither Barnas nor Berliner, both former employees, had been contacted by anyone associated with Velsicol with respect to the subject of the patent

> proceeding. Monsanto countered by offering evidence showing that Velsicol clearly should have been aware of the possibility of having Barnas or Berliner testify, and that their testimony was in fact easily procurable. The evidence before the district court strongly suggests that Velsicol was grossly negligent in not procuring their testimony.

Id. at 1046-47. Therefore, the Seventh Circuit held that, "the lack of any effort on the part of Velsicol to contact Barnas or Berliner demonstrates a lack of due diligence . . . [T]here was ample support for the trial court's finding that Velsicol had waived its right to introduce the testimony of these two witnesses." Id. at 1047.

Similarly, in Piher v. CTS Corporation, 664 F.2d 122, 124-26 (7th Cir. 1981), the Seventh Circuit affirmed a district court's denial of a request to present evidence not submitted to the Board. Piher sought to impeach an attorney, Gaydos, whose testimony CTS had presented to the Board, because the Board had, to Piher's surprise, credited that testimony. Id. 125. The Seventh Circuit wrote that:

> Piher was well aware of CTS's position on these issues and had full opportunity at that time to introduce experts to refute Piher's arguments. Having failed to take advantage of the opportunity to present evidence, it cannot now assert that right merely because it was surprised that the Board credited Gaydos' testimony and ruled in favor of CTS. An adverse decision after full opportunity to present evidence is not a special circumstance within the scope of Velsicol Chemical giving the party an absolute right to present additional evidence.

Id. at 125-26. See also Aqua-Chem, Inc. v. Baldwin-Lima-Hamilton Corp., 167 U.S.P.Q. 257 (N.D.Ill. 1970) (district court excluded

testimony by an expert who was available to provide testimony to the Board); Brunswick, 627 F.Supp. at 152-53; California Research, 356 F.2d at 820 n.18 (in a §145 proceeding before the district court "the plaintiff may not submit for the first time evidence which he was negligent in failing to submit to the patent Office."); MacKay, 641 F. Supp. at 570 (bald assertion that proponent did not intentionally or negligently fail to submit proffered evidence to PTO is insufficient to justify admission by district court).

The analysis and conclusion in Velsicol and comparable cases is equally applicable to the proffered testimony of Dr. Skoultchi, and the related documentary evidence, in the instant case. It is also applicable to the proffered testimony of Dr. Kucherlapati. Dr. Kucherlapati was well-known to CGI at the time of the '114 interference. He was a founder of CGI and, like Dr. Skoultchi, had a consulting contract with it. Dr. Kucherlapati had submitted an affidavit to the Board in connection with the earlier interference proceeding.

Once again, Kelber asserts that he contacted Dr. Kucherlapati prior to filing this §146 proceeding, but provides no evidence that he or anyone on behalf of CGI tried to contact him while the '114 interference proceeding was pending before the Board. Similarly, while Kelber asserts that Dr. Kucherlapati initially had no memory of relevant events or documents. His recollection has evidently been refreshed by documents produced by CGI in this case. Thus, he

could have reviewed those documents in connection with the '114 interference proceeding and provided evidence to the Board if CGI had been duly diligent in seeking the documents and his testimony.

Levin too was well-known because he was the Chief Executive Officer of CGI during the relevant period. Kelber represents that he tried twice to contact Levin, who was the CEO of Millennium Pharmaceuticals. These contacts were evidently telephone calls. CGI has introduced no evidence that it ever wrote to Levin to explain its need for his testimony. If necessary, CGI could have asked the Board to authorize a subpoena for Levin. If he was perceived by CGI to have valuable information that he was reluctant to provide to CGI, the court expects that the Board would have deemed it to be in the interests of justice to have granted a request to authorize the required subpoena. Thus, the court concludes that the two unsuccessful attempts to contact Levin did not constitute the required due diligence.

Savage and Thompson worked with the venture capital firm that invested in CGI. Kelber represents that he did not know of their existence or location until ARS deposed Levin. However, Dr. Kucherlapati also discussed them in his deposition. In addition, they are identified in at least one of the belatedly discovered documents CGI has proffered to this court, the July 10, 1989 memorandum. If CGI had exercised due diligence in speaking to Dr. Kucherlapati and Levin in connection with the '114 proceeding, and in collecting the documents it produced to ARS in this case, it

would have identified Savage and Thompson in time to present the evidence to the Board. Therefore, CGI's failure to present Savage and Thompson resulted from its lack of due diligence.

The foregoing analysis also applies to evidence CGI seeks to introduce for the first time in support of its claim that the '071 patent interferes in fact with the '390 application. In support of its interference argument, CGI seeks to introduce U.S. Patent No. 5,024,939 (the "'939 patent") and the 1984 Kucherlapati article, "Introduction of Purified Genes into Mammalian Cells" (the "Kucherlapati article"). According to CGI, it did not have these documents in its possession at the time initial discovery disclosures were made in this case. CGI does not address why these documents were unavailable during the Board proceedings. The Kucherlapati article was first published in 1984 and the '939 patent was filed in September, 1987, and issued in June, 1991. Had CGI exercised due diligence in speaking to Dr. Kucherlapati it would have identified his article in time to present it to the Board. The fact that both documents have each been in the public record for over 15 years similarly suggests that some modicum of diligence would have revealed their existence. Therefore, the court finds that CGI's failure to make an effort to present the Kucherlapati article and the '939 patent to the Board resulted from lack of due diligence.

In view of the foregoing, none of the disputed evidence not previously presented to the Board will be admitted in this case.

C. Dr. Tlsty May Not Testify To Matters Not Disclosed In Her Expert Report

CGI also proposes to introduce the expert report or testimony of Dr. Tlsty to support its claim that there is an interference-in-fact between ARS' '071 patent and CGI's '390 application. More specifically, CGI proposes to rely on Dr. Tlsty to prove: (1) the state of the art during the 1980s; (2) that it would have been obvious in 1989 to modify Claim 106 of CGI's '390 application to include a selectable amplifiable gene; and (3) that Claim 106 of CGI's '390 application renders Claim 24 of ARS' '071 patent obvious, and that they interfere in fact. CGI's Interference-in-Fact Memorandum at 9-10.

ARS objects to the scope of Dr. Tlsty's proposed evidence on these issues. It argues that her expert report does not disclose opinions concerning CGI's interference-in-fact claim generally or CGI's Claim 106 and ARS' Claim 24 particularly as required by Federal Rule of Civil Procedure 26(a)(2)(B).

Rule 26(a)(2)(B) expressly requires that an expert's report contain, among other things, "a complete statement of all opinions to be expressed and the basis and reasons therefor," and "the data or other information considered by the witness in forming the opinions." Rule 26(e)(1) requires that a party submitting an expert report supplement that report, among other things, where the "party learns that in some material respect the information disclosed is incomplete or incorrect."

Dr. Tlsty's report was submitted to ARS in April, 2006, which was within the period the court provided for discovery. It discusses the state of the art in the 1980s and early 1990s as to selectable, amplifiable genes and sets out the bases for her opinion on what would have been obvious to those skilled in the art at the time. She also focuses on Claim 3 of ARS' '071 patent, opining that as late at 1992, one skilled in the art would not have known how to render the method described in Claim 3 operative. Her report does not include the opinions that Claim 106 of CGI's '390 application renders Claim 24 of ARS' '071 patent obvious or that CGI's Claim 106 and ARS' Claim 24 interfere in fact. Indeed, she does not mention ARS' Claim 24 at all. Nor does Dr. Tlsty's report reference Claim 106 of CGI's '390 application as something she relied on in forming her opinions.

Except in certain, specified circumstances, an expert may not provide evidence or opinions that were not disclosed as required by Rule 26(a)(2)(B). See Gagnon v. Teledyne Princeton, Inc., 437 F.3d 188, 191 (1st Cir. 2005). More specifically, a party proposing to rely on evidence or testimony which it did not properly disclose to its adversary in discovery bears the burden of demonstrating a "substantial justification" for the failure to disclose or that such failure was "harmless." Fed. R. Civ. P. 37(c)(1) ("unless such failure is harmless," the offending party is not "permitted to introduce as evidence at trial, at a hearing, or on a motion, any witness or information not so disclosed."); see also Alves v. Mazda

Motor of Am., Inc., 448 F. Supp. 2d 285, 293 (D. Mass. 2006).

As the First Circuit has explained, "expert preclusion order[s] . . . fall[ ] in the heartland of case management decisions--the area where a trial judge has the remorseless responsibility, evenhandedly and efficiently, to govern, monitor, and police the progress of an endless line of cases through the court." Gagnon, 427 F.3d at 191. The First Circuit went on to explain that:

> In Primus v. United States, 389 F.3d 321 (1st Cir. 2004), we stressed that "[t]he adoption of Rule 37(c)(1) in 1993 'gave teeth to a significantly broadened duty' to comply with case management orders." Id. at 234 (citations omitted). Our view of the effect of this rule is well stated in Klonosski v. Mahlab, 156 F.3d 255, 269 (1st Cir. 1998), where we declared that it "clearly contemplates stricter adherence to discovery requirements, and harsher sanctions for breaches . . . , and the required sanction in the ordinary case is mandatory preclusion."

Id.; see also Primus, 389 F.3d at 235 ("Mandatory preclusion [is] the required sanction in the ordinary case.").

CGI has not shown that there is a substantial justification for its failure to disclose Dr. Tlsty's proposed opinions on ARS' Claim 24 and whether an interference-in-fact between ARS' Claim 24 and CGI's Claim 106 exist. Nor has CGI shown that admitting her opinions on Claim 24's obviousness and the possible interference-in-fact would be harmless.

CGI filed its complaint in 2004. It included a claim that the Board incorrectly found that there was no interference-in-fact between ARS' Claim 24 and CGI's Claim 106. See Complaint ¶23.

Therefore, it is clear CGI was aware that these issues were presented in this case. CGI provided ARS Dr. Tlsty's Rule 26 report in April, 2006. CGI did not amend or supplement that report to disclose Dr. Tlsty's opinions regarding Claim 24 and a possible interference-in-fact based on the theory of double obviousness--disputed issues on which CGI now proposes Dr. Tlsty provide evidence. When the court, on August 9, 2006, ordered CGI to identify the evidence on which it would rely at trial to prove an interference-in-fact, it did not alter the period previously provided for discovery or relieve CGI of the obligations under Rules 26(a)(2) and 26(e)(1) which it had during that period. In these circumstances, CGI has failed to show a substantial justification for its failure to disclose during the period for discovery that Dr. Tlsty intended to provide opinion evidence regarding Claim 24's obviousness and the possible interference-in-fact.

CGI has also not shown that its failure to include the opinions at issue in Dr. Tlsty's report was harmless. As the First Circuit wrote in Gagnon, 437 F.3d at 197:

> The Advisory Committee notes to the 1993 amendments to the rules state that the harmlessness provision is intended 'to avoid unduly harsh penalties in a variety of situations.' Illustrative examples are late disclosures of a potential witness known to all parties, a trial witness already listed by the adverse party, or a witness on behalf of a pro se litigant ignorant of the requirement. These suggest a fairly limited concept of "harmless."

CGI is represented by counsel, who knew of the requirements of Rule

26(a)(2). While Dr. Tlsty had previously been identified as an expert witness, as of August 9, 2006 the disputed opinions were not disclosed in the manner required by Rule 26(a)(2) or, indeed, disclosed at all.

This does not end the inquiry however. As the First Circuit has explained:

> "[T]rial judges must work a complicated equation, balancing fairness to the parties with the need to manage crowded dockets." This means that
>
> > [Courts] must consider a multiplicity of pertinent factors, including the history of the litigation, the proponent's need for the challenged evidence, and the opponent's ability to overcome its adverse effects. Surprise and prejudice are important integers in this calculation. So too is an assessment of what the late disclosure portends for the court's docket.

Gagnon, 437 F.3d at 197-98 (quoting MaCaulay v. Anas, 321 F.3d 45, 51 (1st Cir. 2003)).

The operation of these factors in this case does not persuade the court that Dr. Tlsty's previously undisclosed opinions should be deemed admissible. As indicated earlier, the disputed issues on which CGI proposes she opine have been in the case since CGI filed its Complaint. Thus, they were well-known to CGI before Dr. Tlsty produced her report. If those opinions had been disclosed during the period provided for discovery, ARS could have deposed Dr. Tlsty and had its own experts address her opinions in their reports.

ARS has been unnecessarily and unfairly surprised by the additional opinion evidence CGI proposes to introduce. It would be prejudiced if it were not given an opportunity to depose Dr.

Tlsty and have its own experts respond to her new opinions. This would require the reopening of discovery and prolong this already long pending case. Doing so would not only disrupt this court's busy docket. More importantly, it would extend the uncertainty concerning the validity of the patents at issue, which, as explained earlier, injures the public interest. See In re Columbia University Patent Litigation, 330 F.Supp. 2d at 17.

Accordingly, Dr. Tlsty may provide evidence on the matters properly disclosed in her Rule 26(c)(2) expert report, particularly on the questions of whether Claim 3 of ARS' '071 patent is obvious and concerning the state of the art from 1980 to the early 1990's. The court will not receive or consider evidence on any additional issues from her.

V. ORDER

In view of the foregoing, it is hereby ORDERED that:

1. ARS' Motion in Limine to Exclude New Evidence Offered by CGI in Support of Its "Japan" Memorandum (Docket No. 135) is ALLOWED in part and DENIED in part. Because CGI failed to exercise due diligence in securing certain evidence it seeks to introduce, particularly the testimony of Dr. Skoultchi, Dr. Kucherlapati, Levin, Savage, Thompson, and Dr. Skoultchi's notebook, such evidence, and any other documents not previously presented to the Board, is excluded. However, because the meeting minutes dated July 24 and 25, 1989 were previously submitted to the Board, they are admissible in these cases.

2. ARS' Motion in Limine to Exclude Hearsay Relied on by CGI in its "Japan" Memorandum (Docket No. 138) is MOOT because all of the documents ARS seeks to exclude as hearsay are excluded pursuant to paragraph 1 herein above.

3. ARS' Motion in Limine to Exclude Previously Undisclosed Evidence Relied on by CGI in its "Interference-In-Fact" Memorandum (Docket No. 140) is ALLOWED in part and DENIED in part. As CGI did not exercise due diligence in obtaining the Kucherlapati article and the '939 patent, and improperly failed to present them to the Board, they are inadmissible in these cases. Dr. Tlsty may provide evidence on the questions of whether Claim 3 of ARS' '071 patent is obvious and concerning the state of the art from 1980 to the early 1990's. She may not provide evidence on any other issues.

4. The parties shall, by September 31, 2007:

a. Revise their submissions in response to the August 9, 2006 Order to address, based solely on the admissible evidence, the merits of the issues of: (i) whether the Board correctly found that CGI's Claim 107-109 are unpatentable over the "Japan" reference; and (ii) whether the Board correctly held that there is no interference-in-fact between CGI's '390 application and the 21 claims of ARS' '071 patent.

b. State whether further live testimony should be taken from any witnesses who presented evidence to the Board and, if so, identify each such witness and the reasons why his or her live testimony should be taken.

c. State whether any admissible expert evidence should be taken by live testimony or in written form.

d. Estimate the length of time the trial of each issue should take.

5. A scheduling conference will be held on November 1, 2007, at 3:00 p.m.

/s/ MARK L. WOLF
UNITED STATES DISTRICT JUDGE

Publisher Information

Note* This page is not part of the opinion as entered by the court.

The docket information provided on this page is for the benefit

of publishers of these opinions.

Cell Genesys, Inc. v.

Applied Research

Systems ARS

Holding, NV

Assigned to: Chief

Judge Mark L. Wolf

Case in other court: USDC District of Columbia, 04-01407

JDB

Cause: 35:145

Patent Infringement

Date Filed: 12/07/2005 Jury Demand:

None Nature of Suit: 830 Patent

Jurisdiction: Federal Question

Plaintiff

Cell Genesys, Inc. represented by Steven B. Kelber Jagtiani + Guttag 10363-A Democracy Lane Fairfax, VA 22030 703-563-2011 Fax: 703-591-5907 Email: Steven.Kelber@Jagtiani.com LEAD ATTORNEY ATTORNEY TO BE NOTICED Jill Brenner Meixel Donnelly, Conroy & Gelhaar, LLP One Beacon Street 33rd Floor Boston, MA 02108 617-720-2880 Fax: 617-720-3554 Email: jbm@dcglaw.com ATTORNEY TO BE NOTICED T. Christopher Donnelly

	Donnelly, Conroy & Gelhaar, LLP One Beacon Street 33rd Floor Boston, MA 02108 617-720-2880 Fax: 617-720-3554 Email: tcd@dcglaw.com ATTORNEY TO BE NOTICED
V. Defendant Applied Research Systems ARS Holding, NV	represented by Bradford P Lyerla Marshall, Gerstein & Borun 6300 Sears Tower 233 S. Wacker Drive Chicago, IL 60606 312-474-6300 Fax: 312-474-0448 Email: BLyerla@marshallip.com LEAD ATTORNEY ATTORNEY TO BE NOTICED Charles L. Gholz Oblon, Spivak, McClelland, Maier & Neustadt, P.D. 1940 Duke Street Alexandria, VA 22314 703-413-3000 Fax: 2220 LEAD ATTORNEY ATTORNEY TO BE NOTICED Cullen N. Pendelton Marshall, Gerstein & Boron LLP 6300 Sears Tower 233 South Wacker Drive Chicago, IL 60606-6367 312-474-6300 LEAD ATTORNEY ATTORNEY TO BE NOTICED Frank J. West Oblon,Spivak,Mcclelland,Maier & Neustadt 1940 Duke Street Alexandria, VA 22314 703-412-7049 Fax: 703-413-2220 LEAD ATTORNEY ATTORNEY

TO BE NOTICED Kevin M Flowers Marshall Gerstein & Borun 6300 Sears Tower 233 S. Wacker Drive Chicago, IL 60606-6402 312-474-6300 Fax: 312-474-0448 Email: KFlowers@marshallip.com LEAD ATTORNEY ATTORNEY TO BE NOTICED Mathew C. Nielson Marshall, Gerstein& Borun LLP 6300 Sears Tower 233 South Wacker Drive Chicago, IL 60606-6367 312-474-6300 LEAD ATTORNEY ATTORNEY TO BE NOTICED Michael F. Borun Marshall, Gerstein & Borun LLP 233 South Wacker Drive 6300 Sears Tower Chicago, IL 60606 312-474-6300 Fax: 312-474-0448 Email: MBorun@marshallip.com LEAD ATTORNEY ATTORNEY TO BE NOTICED Sandip H. Patel Marshall, Gerstein & Bourn 6300 Sears Tower 233 S. Wacker Drive Chicago, IL 60606-6367 312-474-6300 Fax: 312-474-0448 Email: SPatel@marshallip.com LEAD ATTORNEY ATTORNEY TO BE NOTICED William K. Merkel Marshall, Gerstein & Borun 6300 Sears Tower 233 S. Wacker Drive Chicago, IL 60606 312-

474-6300 Fax: 312-474-0448 Email: WMerkel@marshallip.com LEAD ATTORNEY ATTORNEY TO BE NOTICED Jill E. Uhl Nixon Peabody, LLP 100 Summer Street Boston, MA 02110 781-345-1254 Fax: 866-456-8580 Email: juhl@nixonpeabody.com ATTORNEY TO BE NOTICED