

United States Court of Appeals for the Federal Circuit

95-1329

PAUL SCHEDEL,

Appellant,

v.

BENSON M. CURTIS, LINDA S. PARK,
and DAVID J. COSMAN,

Appellees.

Bruce M. Collins, Mathews, Woodbridge & Collins, of Princeton, New Jersey, argued for appellant. With him on the brief was Scott N. Bernstein.

John P. Isacson, Jr., Foley & Lardner, of Washington, D.C., argued for appellees. With him on the brief were Stephen A. Bent and Lawrence M. Sung.

Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

95-1329

(Interference No. 103,443)

PAUL SCHENDEL,

Appellant,

v.

BENSON M. CURTIS, LINDA S. PARK,
and DAVID J. COSMAN,

Appellee.

DECIDED: May 14, 1996

Before NEWMAN, LOURIE, and BRYSON, Circuit Judges.

Opinion by the court filed by Circuit Judge LOURIE. Dissenting opinion filed by Circuit Judge NEWMAN.

LOURIE, Circuit Judge.

Paul Schendel appeals from the April 19, 1995 decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences ("board" or "PTO") granting summary judgment in favor of Benson M. Curtis, Linda S. Park, and David J. Cosman (collectively "Curtis") in Interference No. 103,443. Because the board did not err in granting summary judgment, we affirm.

BACKGROUND

This appeal concerns an interference between the parties Schendel and Curtis. Schendel, the junior party, is the applicant of U.S. Patent Application 08/057,198.¹ The application was assigned to Genetics Institute. Curtis is the senior party, Curtis, Park, and Cosman being the inventors of U.S. Patent 5,073,627, assigned to Immunex Corporation.²

The invention at issue is a fusion protein, which is a molecule that contains the amino acid sequences of two different proteins.³ Specifically, the invention is a fusion protein of interleukin-3 ("IL-3") and a hematopoietin, which may be granulocyte colony

¹ The application was filed on May 5, 1993 and accorded the benefit of the August 29, 1990 filing date of U.S. Patent Application 07/575,003.

² The '627 patent issued on December 17, 1991, based on U.S. Patent Application 07/567,983, filed August 14, 1990. It was accorded the benefit of the August 22, 1989 filing date of U.S. Patent Application 07/397,146, now abandoned.

³ A fusion protein may be prepared by inserting a plasmid containing DNA encoding both proteins into a bacterial host, and expressing the fusion protein in the host. For a discussion of recombinant DNA technology, see Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re O'Farrell, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988).

stimulating factor ("G-CSF") or granulocyte-macrophage colony stimulating factor ("GM-CSF"). The count of the interference requires that the fusion protein components be linked together either directly or through a peptide linker.

Schendel sought to provoke an interference with Curtis by presenting in his application claims corresponding substantially to the claims of the '627 patent. Schendel's effective filing date, however, was more than three months after Curtis's effective filing date. Therefore, before the interference could be declared, the patent examiner required Schendel to submit evidence showing that he was "prima facie entitled to a judgment" relative to Curtis, together with "an explanation stating with particularity" why he was "prima facie entitled to the judgment." See 37 C.F.R. § 1.608(b) (1994).⁴

⁴ 37 C.F.R. § 1.608, entitled "Interference between an application and a patent; prima facie showing by applicant," provides:

When the earlier of the filing date or the effective filing date of an application is more than three months after the earlier of the filing date or the effective filing date under 35 U.S.C. 120 of a patent, the applicant, before an interference will be declared, shall file (1) evidence which may consist of patents or printed publications, other documents, and one or more affidavits which demonstrate that [the] applicant is prima facie entitled to a judgment relative to the patentee and (2) an explanation stating with particularity the basis upon which the applicant is prima facie entitled to the judgment. Where the basis upon which an applicant is entitled to judgment relative to a patentee is priority of invention, the evidence shall include affidavits by the applicant, if possible, and one or more corroborating witnesses, supported by documentary evidence, if available, each setting out a factual description of acts and circumstances performed or observed by the affiant, which collectively would prima facie entitle the applicant to judgment on priority with respect to the earlier of the filing date or effective filing date of the patent. . . . If an examiner finds an application to be in condition for declaration of an interference, the examiner will consider the evidence and explanation only

Accordingly, Schendel stated that he was prima facie entitled to a judgment based on his actual reduction to practice of an IL-3/G-CSF fusion protein before Curtis's effective filing date. In support of his contention, he submitted six declarations describing acts that he and other Genetics Institute employees allegedly performed before Curtis's effective filing date. In particular, Schendel submitted the following declarations:

1. A declaration of Paul Schendel describing his alleged preparation of an IL-3/G-CSF fusion protein;

2. A declaration of Steven C. Clark stating that Schendel discussed with him Schendel's idea of preparing a molecule in which two lymphokines, IL-3 and another hematopoietin, would be linked to form a covalent dimer;

3. A declaration of Hemchand Sookdeo stating that he prepared two 10-base oligonucleotides for Schendel's use "in sequencing second generation lymphokines;"

4. A declaration of JoAnn Giannotti stating that she received from Schendel a sample identified by Schendel as an IL-3/G-CSF fusion protein; this sample exhibited G-CSF activity when she subjected it to a murine bone marrow assay;

5. A declaration of Agnes B. Ciarletta stating that she received from Schendel a sample labelled by Schendel as an IL-3/G-CSF dimer; this sample exhibited IL-3 activity when she subjected it to an M07e assay; and

to the extent of determining whether a basis upon which the applicant would be entitled to a judgment relative to the patentee is alleged and, if a basis is alleged, an interference may be declared.
37 C.F.R. § 1.608(b).

6. A declaration of Frances Bennett stating that she received from Schendel samples identified by Schendel as IL-3/G-CSF fusion proteins; these samples exhibited G-CSF activity when she subjected them to 32D and DA2 assays.

The board accordingly declared the interference between Schendel and Curtis.⁵ Concurrently with the Declaration of Interference, an Administrative Patent Judge ("APJ") ordered Schendel to show cause why judgment should not be entered against him. See 37 C.F.R. § 1.617(a) (1994).⁶ In the "show cause" order, the APJ asserted that there was insufficient corroboration of Schendel's statements concerning his alleged reduction to practice of the invention. In addition, the APJ asserted that the evidence did not establish that Schendel had reduced to practice a fusion protein meeting every limitation of the count. Schendel responded that there was adequate corroboration to support the statements in his declaration and that the evidence showed an actual

⁵ Count 1, the only count in the interference, reads as follows:

1. A fusion protein of the formula IL-3/X or X/IL-3 substantially free from association with other proteinaceous materials, wherein X is a hematopoietin selected from the group consisting of G-CSF and GM-CSF, and wherein IL-3 and X are linked either directly or through a peptide linker.

⁶ 37 C.F.R. § 1.617, entitled "Summary judgment against applicant," provides:

An [APJ] shall review any evidence filed by an applicant under § 1.608(b) to determine if the applicant is prima facie entitled to a judgment relative to the patentee. If the [APJ] determines that the evidence shows the applicant is prima facie entitled to a judgment relative to the patentee, the interference shall proceed in the normal manner under the regulations of this part. If in the opinion of the [APJ] the evidence fails to show that the applicant is prima facie entitled to a judgment relative to the patentee, the [APJ] shall, concurrently with the notice declaring the interference, enter an order stating the reasons for the opinion and directing the applicant, within a time set in the order, to show cause why summary judgment should not be entered against the applicant.

37 C.F.R. § 1.617(a).

reduction to practice of an IL-3/G-CSF fusion protein meeting every limitation of the count.

In accordance with 37 C.F.R. § 1.617(g), the board then reviewed the case to determine whether summary judgment should be granted against Schendel. After considering Schendel's evidence and arguments, the board held that Schendel had not established an actual reduction to practice of a fusion protein within the scope of the count before Curtis's effective filing date. The board, like the APJ, found that there was inadequate corroboration of Schendel's statements to support his alleged actual reduction to practice. The board also found that the evidence did not establish that Schendel had made a fusion protein meeting all the limitations of the count. Therefore, the board held that Schendel was not prima facie entitled to a judgment of priority and entered a decision granting summary judgment against Schendel. See 37 C.F.R. § 1.617(g). One board member dissented, arguing that the majority had applied too high a burden of proof. This appeal followed.

DISCUSSION

The issue before us is whether the board erred in holding that Schendel was not prima facie entitled to a judgment of priority against Curtis based upon Schendel's submitted evidence and arguments, which alleged an actual reduction to practice of the invention before Curtis's effective filing date. We review de novo the board's legal conclusion concerning an alleged reduction to practice. See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). We review the board's underlying factual findings for clear error. Id.

To establish priority based upon an alleged actual reduction to practice, Schendel was required to prove, inter alia, that he prepared a fusion protein meeting every limitation of the count. See Newkirk v. Lulejian, 825 F.2d 1581, 1582, 3 USPQ2d 1793, 1794 (Fed. Cir. 1987) ("[E]very limitation of the interference count must exist in the embodiment and be shown to have performed as intended."); Hahn v. Wong, 892 F.2d 1028, 1032, 13 USPQ2d 1313, 1317 (Fed. Cir. 1989) ("To establish reduction to practice of a chemical composition, it is sufficient to prove 'that the inventor actually prepared the composition and knew it would work.'") (quoting Mikus v. Wachtel, 542 F.2d 1157, 1159, 191 USPQ 571, 573 (CCPA 1976)).

Schendel's burden of making a prima facie showing of priority required him to prove so much of his case as to entitle him to an award of priority if Curtis were to rely only on his filing date and were not to rebut any of Schendel's case. See Hahn, 892 F.2d at 1032, 13 USPQ2d at 1317; Kistler v. Weber, 412 F.2d 280, 285, 162 USPQ 214, 218 (CCPA 1969). Count 1 requires, among other limitations, a "fusion protein" in which the specified components "are linked either directly or through a peptide linker." The board concluded that Schendel had not made a prima facie showing that he had actually prepared a fusion protein, i.e., a molecule containing the component proteins linked either directly or through a peptide linker. We agree with the board's conclusion.

Schendel did not provide direct evidence that he prepared a fusion protein having the structure required by the count. Schendel's declaration describes the process he purportedly used to prepare an IL-3/G-CSF fusion protein. Specifically, Schendel's declaration states that he constructed a plasmid containing IL-3 and G-CSF genes joined together by a linker, and verified the junctions between those genes. The Sookdeo

declaration suggests that Schendel obtained primers to sequence the linker junctions between the IL-3 and G-CSF coding regions of the plasmid, and Schendel's laboratory notebook entries suggest that he may have constructed portions of that plasmid. Significantly, however, Schendel's laboratory notebook does not show that the complete plasmid was actually constructed or that its structure was identified (such as by DNA sequencing). In addition, Schendel's declaration does not allege that he or anyone else at Genetics Institute ever sequenced the coding region of the plasmid allegedly used to prepare the relevant fusion protein. Most particularly, he provided no data showing that what he obtained was the purported fusion protein. He did not determine the sequence or the molecular weight of the purported fusion protein, each of which might have indicated preparation of the protein. He clearly had the capability to determine molecular weight; the declaration describes how he performed such an analysis for an IL-3/IL-3 dimer not within the scope of the count. The absence of corresponding molecular weight or other information for the purported IL-3/G-CSF fusion protein, or even any data confirming the coding sequence of the plasmid, leaves unproved the question whether Schendel ever successfully prepared the fusion protein specified by the count.

Schendel's declaration asserts that the final plasmid was transformed into an E. coli cell line. The declaration cites a laboratory notebook page containing a graph and Schendel's statement in the notebook that "[a]ll cultures induced well." The declaration asserts, in conclusory fashion, that "[t]his indicates that [Schendel] detected protein being made by [the] plasmids." It does not explain, however, what the data in the graph mean or how Schendel could have known from the data that he had successfully made the claimed fusion protein. Curtis argues that the graph depicts optical density data

that indicate only the rate and level of host bacterial growth, not the amount of protein produced or, most importantly, the identity of the resulting protein. Schendel provides no persuasive response to this argument.

The Giannotti, Ciarletta, and Bennett declarations do not overcome the deficiencies of the Schendel declaration. As the board found, none of these declarants had any first-hand knowledge of the composition or structure of the proteins contained in Schendel's samples; they all derived their understanding from Schendel's labelling of the samples as fusion proteins. None of the declarants stated that their tests showed that the samples were IL-3/G-CSF fusion proteins. Thus, there is no proof that any of these declarants knew what was actually in the samples provided to them by Schendel. See Frilette v. Kimberlin, 412 F.2d 1390, 1398, 162 USPQ 148, 155 (CCPA 1969) ("Of course, the designation of the material involved in the . . . tests in Lago's records as 'Linde Molecular Sieve 13X calcined ammonium exchange' cannot establish identification since that designation was merely copied by Lago from the label on the bottle in which the sample was given to him by Frilette and was not based on either knowledge or analysis by Lago."), cert. denied, 396 U.S. 1002 (1970).

The biological activity data discussed in these declarations do not show that Schendel prepared an IL-3/G-CSF fusion protein. That evidence establishes, at most, that certain tested samples exhibited biological activity characteristic of IL-3 and G-CSF proteins. Schendel's declaration asserts, again in conclusory fashion, that the samples exhibited both IL-3 and G-CSF activity. Even accepting this argument as true, however, as the board stated in its opinion, Schendel did not prove or explain why samples exhibiting biological activity characteristic of IL-3 and G-CSF were more likely to be IL-3/G-CSF fusion proteins than a mixture of the component proteins. On the contrary,

the record is devoid of any explanation or evidence linking the biological activity data to the composition or structure of the purported fusion protein. No declarant asserted that a conclusion of chemical composition or structure could be drawn from the biological activity data, let alone explain why.

On appeal, Schendel has not persuasively explained why his samples could not have contained a mixture of IL-3 and G-CSF proteins. Moreover, it is not our function to second-guess the board's interpretation of technical data, particularly when a party provides no compelling reason why the board's analysis thereof was incorrect. Thus, given Schendel's failure to explain the relevance of the biological activity data to the identity of the prepared material, it was not unreasonable for the board to conclude that the data did not establish that he actually prepared an IL-3/G-CSF fusion protein.⁷

In addition, while the Clark declaration states that Schendel discussed with him Schendel's idea of preparing a molecule in which two lymphokines would be linked to form a fusion protein, it provides no evidence that Schendel actually prepared such a molecule. Similarly, the Sookdeo declaration only suggests that Schendel obtained sequencing primers; it provides no indication that Schendel used the primers to show that he succeeded in preparing the necessary plasmid or the claimed fusion protein recited in the count.

Thus, the evidence is critically deficient on the question whether Schendel actually prepared a fusion protein. In particular, without any molecular weight or

⁷ Schendel argues that the board did not apply the "rule of reason" in its analysis. We disagree. Under the "rule of reason" standard, "the Patent and Trademark Office [must] examine, analyze, and evaluate reasonably all [the] pertinent evidence." Holmwood v. Sugavanam, 948 F.2d 1236, 1239, 20 USPQ2d 1712, 1714 (Fed. Cir. 1991). But a rule of reason analysis cannot overcome a lack of meaningful evidence that a claimed substance was obtained.

other probative data relevant to the composition or structure of the molecule he allegedly prepared, there is insufficient evidentiary support for Schendel's conclusory assertion that he made an IL-3/G-CSF fusion protein. Schendel's subjective belief that he prepared the fusion protein is inadequate to carry his burden of proof because it does not consist of evidence that a composition having the particular structure of the count was obtained. The fact that several co-employees of Schendel may have believed that he had made the claimed fusion protein, while perhaps relevant to the issue of corroboration, see Berges v. Gottstein, 618 F.2d 771, 205 USPQ 691 (CCPA 1980), does not supply the crucial missing proof that the claimed protein was prepared. This is a separate matter from the question of corroboration; no one, not even the inventor, provided proof constituting a prima facie case that the claimed fusion protein was obtained. Thus, we conclude that the board did not err in determining that Schendel failed to show that he actually prepared a fusion protein meeting all the limitations of the count. We therefore affirm the board's determination that Schendel was not entitled to a judgment of priority and its entry of summary judgment against him pursuant to 37 C.F.R. § 1.617(g). See Frilette, 412 F.2d at 1392, 1396-98, 162 USPQ at 150, 153-55 (affirming the board's determination that a junior party did not establish an actual reduction to practice because its tests did not show a "crystalline" metallic aluminosilicate catalyst "having uniform pore openings between about 6 and about 15 Angstrom units," as required by the count). We need not consider Schendel's argument that the board erred in holding, alternatively, that his testimony lacked adequate corroboration; the board's determination that the evidence did not show a fusion

protein meeting all the limitations of the count mandates that we affirm the decision. See Newkirk, 825 F.2d at 1582, 3 USPQ2d at 1794.⁸

We note that the board made two incorrect statements in its discussion of the corroboration issue. The board stated that the research project that Schendel participated in at Genetics Institute was not an organized research endeavor; this assertion lacked support in the record and seems extreme considering the size of the company and the multitude of scientists with whom Schendel was involved. The board also criticized Schendel for masking the dates on his documentary evidence, despite the fact that the PTO's own guidelines permit the masking of dates under the circumstances of this case. See Manual of Patent Examining Procedure § 2308.02 (6th ed., 1995). These

⁸ The dissent runs through all the data presented by Schendel and ends up concluding that "the analytical data confirmed that the expected linked product was obtained." That there were no analytical data is the nub of this case. The import of the dissent's extensive analysis of the facts is that the identity of the claimed product was proved and that the court has improperly assumed an "appellate role to devise experiments that the inventor did not deem it necessary to conduct."

As an appellate court, we are affirming the judgment of the expert agency because the agency did not apply an incorrect standard and did not make clear error in its evaluation of facts. Rather than weighing evidence and devising further experiments, we are affirming the board's determination that Schendel did not establish the structure or identity of the product of the count. Whether we might agree, as nonexperts, that Schendel may have obtained the product is not the point. Even a prima facie case requires some real proof, not just vague inference, based on surrounding circumstances that tangentially support the inventor's goal.

The question here is whether Schendel proved, irrespective of whether that proof was corroborated, that use of his starting gene fragments resulted in the synthesis of the fusion protein. We conclude that the PTO did not err in holding that he did not.

The dissent, citing Kahl v. Scoville, 609 F.2d 991, 203 USPQ 652 (CCPA 1979), also takes the position that, for summary judgment purposes, all of Schendel's allegations must be assumed to be true for purposes of determining whether he established a prima facie case of priority. Because Schendel did not argue for such a rule, either before the board or on appeal, we decline to decide whether such a rule is appropriate.

errors, however, do not undermine the board's correct (and dispositive) determination that Schendel did not show that he prepared a fusion protein meeting all the limitations of the count. See Newkirk, 825 F.2d at 1582, 3 USPQ2d at 1794.

Finally, Curtis moves for an award of attorney fees and costs as a sanction pursuant to Fed. R. App. P. 38, asserting that Schendel's appeal is frivolous as argued.⁹ Curtis contends that in a related interference between the parties ("the DNA interference"), in which the count was directed to a DNA molecule encoding the fusion protein at issue here, the board determined that Schendel "never had possession of" the DNA that Schendel now argues was used as a starting material to produce the alleged fusion protein. Curtis contends that Schendel is collaterally estopped from relitigating his "possession" of the DNA because the board already decided that issue and therefore that Schendel violated his duty of candor to this court by failing to advise us of the DNA interference.

We disagree with Curtis. Curtis's theory of frivolousness depends on an allegation of collateral estoppel (issue preclusion). For issue preclusion to apply here, (1) an identical issue must have been present in the two interferences, (2) that issue must have been litigated by the parties in the first interference and actually decided by the board, (3) resolution of the issue must have been essential to the board's judgment in the first interference, and (4) the party against whom the estoppel is asserted, Schendel, must have had a full and fair opportunity to litigate the issue in the first interference. See In re Freeman, 30 F.3d 1459, 1465-67, 31 USPQ2d 1444, 1448-50 (Fed. Cir. 1994).

⁹ The distinction between an appeal that is frivolous as argued and one that is frivolous as filed is discussed in Finch v. Hughes Aircraft Co., 926 F.2d 1574, 1578-80, 17 USPQ2d 1914, 1918-19 (Fed. Cir. 1991).

Significantly, at least two of these four requirements were not met here. The parties did not litigate, and the board did not actually decide in the DNA interference the factual question whether Schendel "had possession of" the relevant DNA molecule. Rather, the board entered judgment for Curtis based on Schendel's voluntary abandonment of the DNA application (and interference) one month after the interference was declared. Manifestly, resolution of the factual question of "possession" of DNA was not essential to the board's judgment. Thus, the principle of issue preclusion is clearly inapplicable. See Restatement (Second) of Judgments §27 cmt. e (1982) ("In the case of a judgment entered by confession, consent, or default, none of the issues is actually litigated" and thus issue preclusion does not apply absent an agreement between the parties.). Moreover, the board presumably did not believe that the prior interference was relevant to the issue of priority concerning the fusion protein; it knew of Schendel's abandonment of the DNA interference¹⁰ but did not even mention that fact in its opinion in this interference. If the board did not deign to even mention it in its opinion in this case, Schendel could hardly be faulted for failing to mention it to this court.

As an apparent backup position, Curtis argues that "[t]he doctrine of issue preclusion aside," Schendel's failure to mention the DNA interference "clearly repudiates Schendel's allegations before this court." We fail to see how this is so, because determination of the facts relating to the DNA invention did not finally occur. Schendel abandoned his DNA claims and placed his bet on winning priority to the protein claims. We therefore reject Curtis's contention that "Schendel has misstated by

¹⁰ The two decisions were authored by the same APJ.

omission the complete nature and state of his case." Schendel did not violate his obligation to this court and his appeal is not frivolous as argued.

Since Curtis's assertion of frivolousness depends upon an allegation of issue preclusion that is badly flawed, we consider it appropriate to caution Curtis and his counsel that "[u]nfounded requests for sanctions are themselves frivolous and sanctionable." Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 835 n.1, 23 USPQ2d 1481, 1482 n.1 (Fed. Cir. 1992). A baseless sanctions motion unfairly forces an opponent into satellite litigation while diverting attention away from the real issues in a case. It also unjustly challenges the integrity of the accused party and the professionalism of its counsel, and it wastes judicial resources. Assertion that an appeal is frivolous should be based on clear-cut grounds, not tenuous argument.

CONCLUSION

The board correctly held that Schendel did not make a prima facie showing of entitlement to priority because he did not establish that he prepared a fusion protein meeting all the limitations of the count. We therefore affirm the board's decision granting summary judgment in favor of Curtis. Further, Schendel's appeal was not frivolous; Curtis's motion for an imposition of sanctions is denied.

AFFIRMED

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

95-1329

PAUL SCHENDEL,

Appellant,

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BENSON M. CURTIS, LINDA S. PARK,
and DAVID J. COSMAN,

Appellee.

NEWMAN, Circuit Judge, dissenting.

The issue at this threshold stage is not priority of invention: it is the right to contest priority. The only issue is whether the junior party Schendel made a *prima facie* case that he was in possession of the subject matter of the count, for the purpose of determining whether there should be an interference proceeding. As discussed in Kahl v. Scoville, 609 F.2d 991, 995, 203 USPQ 652, 656 (CCPA 1979), at this stage of the proceedings "[a]ppellants are only required to establish a *prima facie* case; that is, it is assumed that the allegations in appellants' affidavits are true." The evidence supporting the allegations

on behalf of Schendel was extensive, and was *prima facie* probative of conception and reduction to practice of the subject matter of the count. Thus I must, respectfully, dissent from the ruling of the panel majority that summary judgment was properly granted against Dr. Schendel.

The record evidence of conception, disclosure, synthesis, and assay meets the requirements of the *prima facie* case. The testimony and the documentary records are

unambiguous and straightforward. The scientific sufficiency of this evidence has not been challenged by persons of skill in this field of science; indeed, both sides followed similar synthesis and assay procedures, to the same effect. The ruling of the majority of a three-member Board of Patent Appeals and Interferences¹¹ that more laboratory work was needed implements an incorrect standard at this stage of the proceedings. For this court to hold by summary judgment that the scientific record is insufficient, when the scientists themselves deemed it sufficient, is an improper judicial role.

The quality of the evidence on behalf of Schendel has not been seriously challenged by the party Curtis. The Board's summary disposition under 37 C.F.R. §1.617 was necessarily based on the premise that there is no genuine issue as to any material fact and the party Curtis is entitled to judgment as a matter of law. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The grant of summary judgment is reviewed de novo on appeal to the Federal Circuit, without deference to the Board's conclusions of law, and "assum[ing] that the allegations in appellants' affidavits are true." Kahl, 609 F.2d at 995, 203 USPQ at 656.

The interference count is as follows:

1. A fusion protein of the formula IL-3/X or X/IL-3 substantially free from association with other proteinaceous materials, wherein X is a hematopoietin selected from the group consisting of G-CSF and GM-CSF, and wherein IL-3 and X are linked either directly or through a peptide linker.

The record shows that Dr. Schendel described the fusion protein of the count in written memoranda to Dr. Stephen C. Clark and also to Dr. Kamen, both research managers at Genetics Institute. The record contains a declaration by Dr. Clark describing discussions with Dr. Schendel of the products that Dr.

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The Board was constituted in a curious manner: first an administrative patent judge, in his role as examiner, made the decision; then it was reviewed by a three-member Board presided over by the same administrative patent judge, who wrote an opinion sustaining his action, quoting himself with approval. One member of the Board dissented, stating that the Board had applied an incorrect standard.

Schendel proposed to make and the method of their preparation. Conception of the subject matter of the count was found by the Board, and is not at issue.

Dr. Schendel's declarations describing the various procedures involved, and notebook records showing the experiments that he conducted, are in evidence, as are the declarations and notebook records of others who conducted various phases of the work. The procedures are unchallenged as established modes of carrying out the reactions described. Plasmids containing the known DNA sequences for IL-3 and G-CSF were cleaved at known restriction sites and combined with a peptide linker of known structure. The Board did not dispute the materials used and the reactions conducted, leaving me somewhat surprised that the majority of this panel holds that Dr. Schendel should have re-proved the basic structures, for example by DNA sequencing. As discussed in Berges v. Gottstein, 618 F.2d 771, 774, 205 USPQ 691, 694 (CCPA 1980), "a reasonable analysis of the evidence in toto" is required in determining whether there was a reduction to practice of the count, with reasonable inferences drawn from the scientific tests and data. Similarly, a reasonable an analysis of all the evidence is required in determining whether a *prima facie* case has been made.

Dr. Schendel, on a form entitled "Requisition for Synthetic Oligodeoxyribonucleotides," ordered the synthesis of two oligonucleotides to be used as primers, in order to verify the junctions between the known linker sequence and the known protein-encoding genes. In evidence are the declaration and records of the person who performed the synthesis, Mr. Sookdeo, using an automated commercial nucleotide synthesizer for this routine procedure. Schendel tested the junctions by standard procedure, described in his declaration, and confirmed that the IL-3 vector and G-CSF gene fragment had been linked via the peptide linker. The resulting combination was transformed into a standard *E. coli* cell line which then expressed the molecule of the count, a fusion protein containing both IL-3 and G-CSF.

The tests and data well support the reasonable inference that these standard reactions proceeded in a standard way to produce the intended product. The IL-3 and G-CSF are known proteins, and the identity of the starting materials is not disputed. The DNA sequences encoding for these proteins are known, the plasmids were cleaved at known sites, and the fusion was conducted by a known procedure using a peptide linker of known structure. No scientific challenge to these procedures was raised. The

junctions between the DNA sequences in the recombinant plasmid were verified by known techniques. This standard procedure for linking the expression plasmids for IL-3 and G-CSF was followed by a standard procedure for transformation into a cell line. There is no evidence or suggestion, by Curtis or by the Board, that the procedures were unreliable or flawed. The panel majority criticizes the terseness of Dr. Schendel's laboratory record that the transformation was successful, by showing data in graphical form and stating that "all cultures induce well." However, the Board did not dispute that this procedure was routine to scientists skilled in this field, and there is no suggestion that a scientist of similar skill would have deemed these entries and observations unreasonable.

The product was analyzed using standard bioassay procedures. The tests were conducted by analysts experienced in these bioassays. Their declarations and notebook records are in evidence, and the scientific validity of their assays is unchallenged. Analyst JoAnn Giannotti tested for the G-CSF component by Murine Bone Marrow Assay, using the procedure that is described in her declaration. This is an established method of G-CSF analysis, and was not challenged by Curtis or the Board or the majority of this panel. Ms. Giannotti found G-CSF activity. She also recorded in her notebook that the same protein was found by Ms. Ciarletta, another analyst, to have IL-3 activity.

Agnes B. Ciarletta analyzed for the IL-3 component using the MO7e Assay, an established technique for this analysis. Her declaration states the details of the procedure, and copies of her laboratory records are in evidence. Analyst Frances Bennett also analyzed for the G-CSF component, using the 32D Proliferation Assay and the DA2 assay, two additional established methods for such analysis. Her notebook pages, and details of the tests and how they were performed, are in the record.

The Board found that these were "positive tests." The Board held, however, that they did not establish that these proteins "were either IL-3 or G-CSF." The Board stated that "A sample exhibiting G-CSF activity would not have necessarily had the amino acid sequence of G-CSF." I don't know the absolute scientific correctness of this statement as applied to random samples of unknown provenance, but the undisputed facts make the statement extremely unlikely to be correct, or even reasonable, in this case. These scientists started with the known nucleotide sequences for G-CSF and IL-3; they followed standard procedures that do not disrupt the amino acid sequences of G-CSF or IL-3; and the bioassays

established that G-CSF and IL-3 activities were present in the proteins that were expressed by standard procedures. It is surely more likely than not that the products were the G-CSF and IL-3 proteins and not some heretofore unknown mimics. Other than a general nay-saying, the Board offered no basis whatsoever for its finding, on summary judgment, that the known IL-3 and G-CSF nucleotide sequences could reasonably be expected to be transformed into something other than the IL-3 and G-CSF proteins.

The Board also held that "there is no evidence that the IL-3 and G-CSF of that sample are linked directly or through a peptide linker." That is incorrect, and untenable on summary judgment. The evidence was that known starting materials were subjected to known chemical reactions by procedures that were standard, and that the analytical data confirmed that the expected linked product was obtained. Neither the Board, nor Curtis, nor the majority of this panel, has challenged the efficacy of the synthesis to produce the intended molecule. The starting materials contained the known IL-3 and G-CSF sequences and the assays were positive for both IL-3 and G-CSF. The Sookdeo declaration and records showed the synthesis of oligonucleotides of a known sequence, complementary to the IL-3/G-CSF recombinant plasmid linker sequences, and Dr. Schendel testified that these oligonucleotides verified the junctions between the linker and the IL-3 and G-CSF genes.

It is always possible to devise an additional experiment, as does the panel majority in its criticism of the absence of a direct molecular weight determination. However, even if such a test would be interesting to this court, it has not been shown to be critical. In addition, molecular weight was not ignored by Dr. Schendel, who made a more complex type of analysis in calculating specific activity on a molar basis. The specific activity calculation when expressed as a ratio to molecular weight shows that the product had half the IL-3 specific activity of the IL-3 dimer, reinforcing the conclusion that the product was the IL-3/G-CSF linked protein:

When calculated on a molar basis, that is, when the raw data are expressed as a ratio of activity to molecular weight, the specific activity of the IL-3/G-CSF fusion protein was about one-half (46%) that of IL3. This is fully consistent with its purported structure (since roughly half the molecule was IL-3 and half was not). By contrast, the homodimer IL34 (with two units of IL3 fused together) was found to have approximately twice the activity as that of IL3 alone, again fully consistent with its purported structure (since both halves of the molecule were IL-3).

Appellant's brief at 39-40 (footnote omitted.)

Determination of whether the evidence is sufficient to make a *prima facie* showing that Schendel produced what he said he produced must be based on objective scientific standards, from the viewpoint of the scientists in the field of the invention. It is thus relevant whether the fusion reaction was scientifically routine and reliable, or exotic and unreliable; whether the bioassays were scientifically routine and professionally performed, or whether they were unusual or performed by amateurs. All of the procedures and data together present a *prima facie* case that Dr. Schendel had produced the molecule of the count. There was no contrary evidence. Although our standard of review of the Board's grant of summary judgment is plenary, at this stage of the proceedings neither the Board nor we can weigh evidence; to the contrary, reasonable factual inferences must be drawn in favor of the party Schendel. Kahl, 609 F.2d at 995, 203 USPQ at 656; see Anderson, 477 U.S. at 255.

It is not our appellate role to devise experiments that the inventor did not deem it necessary to conduct, and then to hold that the judges' choice of experiments is dispositive of the issue. The criteria for the grant of summary judgment, a procedure expressly authorized in 37 C.F.R. §1.617, are not isolated from the law governing summary dispositions. As the law requires, unsupported or conclusory averments are insufficient. Celotex v. Catrett, 477 U.S. at 322-23. Further, the truth of the factual evidence adduced is not determined in summary proceedings. Anderson v. Liberty Lobby, 477 U.S. at 255; Kahl, 609 F.2d at 995, 203 USPQ at 656.

The grant of summary judgment under 37 C.F.R. §1.617 requires that the evidence is insufficient, on its face, to make a *prima facie* case of possession of the subject matter of the count before the critical date. Hahn v. Wong, 892 F.2d 1028, 1032, 13 USPQ2d 1313, 1317 (Fed. Cir. 1989). The *prima facie* case, in turn, is based on whether it is more likely than not, on the evidence presented in the affidavits and documentary records, that the party was in possession of the invention of the count. Bosies v. Benedict, 27 F.3d 539, 542, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994). Schendel's evidence showed conception, disclosure, synthesis, and testing of the subject matter of the

count. This is not a matter of retrospective reconstruction of ambiguous experiments or vague theories. This is a case of hard evidence, straightforward testimony, and supporting documentation.¹²

The issue is the threshold question of the right to contest priority. When this right is denied summarily, the law requires that the procedure is fair, and fairly administered. This in turn requires that the rules of summary judgment be properly applied. Since on the evidence of record summary judgment was improperly granted, I respectfully dissent from the affirmance of the Board's decision.

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The majority opinion states at n.8 that "there were no analytical data," but simply "vague inference based on surrounding circumstances." These conclusions, respectfully, are contrary to the extensive record that was filed in accordance with 37 C.F.R. §1.608, including the declarations and documents of the analysts who obtained the data. Assuming that the majority is stating that it disbelieves the evidence that was provided, matters of truth and credibility and judicial determination of scientific significance contrary to the view of the scientists themselves, are not matters for summary adjudication.

