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Paper 55

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PATRICK W. GRAY
and
ERNST H. RINDERKNECHT
(Patent No. 4,855,238)

v.

NORMAN K. ALTON,
MARY A. PETERS, YITZHAK STABINSKY,
and DAVID L. SNITMAN
Senior Party,
(Application 06/483,451 and 06/462,022).

Patent Interference No. 104,762

Before LEE, LANE, and MEDLEY, Administrative Patent Judges.

LANE, Administrative Patent Judge.

DECISION ON MOTION AND FINAL JUDGMENT

I. Background

A decision on preliminary motions was entered in the interference on 28 January 2003

(Paper 47). As a consequence of the decision, the interference was redeclared with the following count ("Count 2") (Paper 48 at 2):

A composition according to claim 70 of Alton 06/483,451 or claim 64 of
Alton 08/462,022

or

A composition according to claim 13 of Gray et al. U.S. 4,855,238.

A conference call was scheduled with the parties for 26 February 2003 so that times could be set for completing the priority phase of the interference. However, during the call, the parties¹ indicated that they had reached agreement on all issues in the interference except the issue of conception. The parties asked that they be permitted to present Alton's testimony and supporting evidence on the issue of conception for a determination as to whether Alton had established a *prima facie* case of conception prior to Gray's earliest alleged conception date. Gray agreed that if it was determined that Alton had established a *prima facie* case of conception prior to Gray's alleged conception date, then Gray would request adverse judgment.

Subsequently, the parties filed a paper entitled "JOINT MOTION UNDER 37 C.F.R. § 1.635 FOR DETERMINATION ON ALTON PRIORITY PROOFS" (Paper 54). According to the parties, "[i]f the Board determines that the agreed Alton proofs establish such a *prima facie* case of conception, then Gray, as junior party, will submit to adverse judgment, terminating the interference" (Paper 54 at 2).

The procedure Gray has asked us to undertake is somewhat unusual since we ordinarily would receive all the evidence and arguments on priority, not just the evidence and arguments relating to conception, before rendering a final judgment. However, the parties have agreed that

¹ Michael Borun represented senior party Alton and R. Danny Huntington represented junior party Gray.

the only issue that needs to be decided to resolve the interference is whether Alton has established a *prima facie* conception prior to Gray's alleged conception date. Our rules provide for the Administrative Patent Judge ("APJ") taking appropriate action where the parties have agreed to simplify the issues in the interference. 37 CFR § 1.610(d). Moreover, the APJ may determine a proper course of conduct in an interference where unusual circumstances arise. 37 CFR § 1.610(e). Given the circumstances before us and in the interest of securing a just, speedy, and inexpensive determination of the interference (37 CFR § 1.601), we GRANT the "JOINT MOTION UNDER 37 C.F.R. § 1.635 FOR DETERMINATION ON ALTON PRIORITY PROOFS" (Paper 54) and enter final judgment against Gray.

Brief summary of the involved technology

The subject matter of the interference relates to the immunoregulatory hormone human interferon gamma (IFN- γ). IFN- γ is said to be expressed in cells with a signal polypeptide of 20 amino acids followed by a polypeptide of 146 amino acids, the latter constituting the "mature" hormone (Paper 34 at 4-5). For purposes of this decision, we understand IFN- γ to refer to the 146 amino acid polypeptide that is the "mature" hormone. The first three amino acids of the 146 amino acid polypeptide are cysteine ("Cys"), tyrosine ("Tyr"), and Cys (Paper 34 at 5). Count 2 is directed to IFN- γ where the first three amino acids of the 146 amino acid polypeptide are deleted and replaced with methionine ("Met"). A shorthand way of describing the resulting polypeptide is [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ .

II. Findings of fact

The record supports the following findings of facts and any findings of facts set forth in the discussion portion of this decision by at least a preponderance of the evidence.

The interference

1. The interference was declared on 2 November 2001 between junior party Gray, *et al.*, (“Gray”)² and senior party Alton, *et al.* (“Alton”).
2. Gray is involved in the interference on the basis of its 4,855,238 (“238”) patent, issued on 8 August 1989 from application 06/584,217, filed 27 February 1984.
3. Alton is involved in the interference on the basis of the following two applications:

08/462,022, filed 5 June 1995, and
06/483,451, filed 15 April 1983.

Benefit

4. The earliest priority benefit accorded to Gray for the subject matter of Count 2 is the 16 December 1983 filing date of application 06/562,009 (Paper 1 at 5).
5. The earliest priority benefit accorded to Alton for the subject matter of Count 2 is the 15 April 1983 filing date of the ‘451 application (Paper 1 at 3).

Count 2

6. Count 2 is as follows (Paper 48 at 2):

A composition according to claim 70 of Alton 06/483,451 or claim 64 of Alton 08/462,022

or

² Prior to the decision on preliminary motions (Paper 47), the junior party was referred to as Genentech, Inc.

A composition according to claim 13 of Gray et al. U.S. 4,855,238.

7. Claim 70 of '451 and claim 64 of '022 are set forth below:

70. [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ polypeptide produced by a DNA sequence coding therefore in a transformant organism, said product having substantially the characteristics of human immune interferon.

64. The analog polypeptide of claim 63 that is [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ .

8. Claim 13 of the '238 patent is set forth below:

13. A double stranded DNA according to claim 12 wherein the n amino acids are

GLY-LYS-AGR-LYS-ARG-SER-GLY-MET-LEU-
127 128 129 130 131 132 133 134 135
-PHE-ARG-GLY-ARG-ARG-ALA-SER-GLN
136 137 138 139 140 141 142 143

9. When claim 13 of the '238 patent is read in view of the claims it depends upon the polypeptide encoded by the DNA of the claim is [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ .

Claim designations

10. The following claims are designated as corresponding to Count 2 (Paper 48 at 2-3):

Alton '022: 63 and 64

Alton '451: 70

Gray: 1-5 and 8-13.

Preliminary statements

11. According to the Alton preliminary statement, as to Count 2, the invention was first conceived by Alton "at least as early as October 4, 1982" (Paper 49 at 2).
12. According to the Gray preliminary statement, as to Count 2, the invention was first conceived by Gray "on or about February 25, 1983" (Paper 52 at 2).

The Alton testimony

13. The affidavit testimony of inventor Dr. Norman K. Alton (Exh. 1)³ has been submitted as evidence of Alton's conception.
14. According to the parties, the affidavit was submitted in a conflict proceeding in Canada concerning a Canadian counterpart patent application of the involved Alton applications (Paper 54 at 2).
15. The parties have agreed that Dr. Alton would testify as he did in the submitted affidavit (Exh.1)⁴ if called to do so in this interference proceeding. 37 CFR § 1.672(h).
16. Dr. Alton's testimony indicates that:
 - (a) The complete coding sequence of human IFN- γ , which had been shown to have anti-viral, anti-tumor, and anti-proliferative activities , was

³ The parties have submitted several exhibits with the joint motion (Paper 54). The exhibit numbering is not in compliance with the Standing Order (Paper 2 at § 39) and is confusing (e.g., there is more than one "exhibit 1"). We understand that part of the difficulty is that the affidavit exhibits presented by the parties were not prepared in preparation for this interference.

⁴ The parties have submitted more than one exhibit that is labeled as "Exhibit 1". Whenever we refer to exhibit 1, we are referring to Dr. Alton's affidavit.

published in 1982 by Gray *et al.* According to the Gray publication, the first four amino acids of IFN- γ are Cys, Tyr, Cys, Glutamine (“Gln”).

(Exh. 1 at ¶ 3).

(b) “Around 1982”, “we” began constructing IFN-gamma analogs by either omitting or substituting certain amino acids. The analogs were to be analyzed for their specific anti-viral and anti-proliferative activities. (Exh. 1 at ¶ 4).

(c) On 18 October 1982, Dr. Alton described a procedure for the construction of [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ requiring a synthetic linker. (Exh. 1 at ¶ 5).

(d) Dr. Alton recorded the procedure in his notebook. (Exh. 1 at ¶ 5).

(e) At some time prior to recording the procedure in his notebook, Dr. Alton had discussed preparation of the linker with Dr. Zippora Stabinsky.⁵ (Exh. 1 at ¶ 5).

17. A copy of what is said to be a page from Dr. Alton’s notebook, dated “10/18/82” and signed “[illegible] Alton” (Exh. 2)⁶, states:

⁵ We note that there is an inventor having the surname Stabinsky. The parties inform us that Dr. Zippora Stabinsky is not an inventor (Paper 54 at 7) and thus we understand inventor Yitzhak Stabinsky and Zippora Stabinsky to be different people.

⁶ The notebook page is referred to as “Exhibit 2” where it is attached to Dr. Alton’s affidavit and “Exhibit A” where it is attached to Dr. Stabinsky’s affidavit. We will use the term “Exh. 2” to refer to the notebook page.

Purpose: To construct a gene which will delete the first three amino acids of mature human gamma interferon. A synthetic linker for this purpose was constructed by Zippora Stabinsky,

and that

The sequence of the linker is as follows:

5' CTAGAAATGCAG
TTTACGTCCTAG 5',

and that

Z. Stabinsky provided 500 [illegible] of this linker unphosphorilated [sic].

18. Under the portion of the notebook page reading “Witnessed & Understood by me”, no signature appears. Moreover, we see no witnessing signature elsewhere on the notebook page. Accordingly, it does not appear that the notebook page was witnessed.
19. As noted in Dr. Alton’s testimony (Exh. 1 at ¶ 5), the linker set forth on his notebook page would encode Met (from the codon ATG) followed by Gln (from the codon CAG).

Dr. Stabinsky's testimony

20. The affidavit of Dr. Zippora Stabinsky ("Stab. Aff.")⁷ has been submitted as evidence of Alton's conception.
21. According to the parties, Dr. Stabinsky's affidavit was submitted in a conflict proceeding in Canada concerning a Canadian counterpart patent application of the involved Alton applications (Paper 54 at 2).
22. The parties have agreed that Dr. Stabinsky would testify as she did in the submitted affidavit if called to do so in this interference proceeding. 37 CFR § 1.672(h)
23. According to Dr. Stabinsky's testimony:
 - (a) She was a colleague of Dr. Alton in 1982. (Stab. Aff. at ¶ 2).
 - (b) She prepared a linker as shown in Dr. Alton's notebook which was used to make [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ . (Stab. Aff. at ¶ 3).
 - (c) Her notebook shows the linker and states that the linker is to be used to express an interferon gene that deletes the first three amino acids from the N-terminus. (Stab. Aff. at ¶ 3).
24. A copy of what is said to be a page from Dr. Stabinsky's notebook ("Stab. Nbk.")⁸ dated "10.04.82" and having a signature that is said to be Dr. Stabinsky's

⁷ The document having the heading "AFFIDAVIT OF ZIPPORA STABINSKY, Ph.D" is labeled "EXHIBIT 2". Dr. Alton's notebook page is also labeled exhibit 2. To avoid confusion, we will refer to Dr. Stabinsky's affidavit as the "Stab. Aff." and not as exhibit 2.

⁸ The notebook page is labeled as "Exhibit B" where it is attached to Dr. Stabinsky's affidavit and "Exhibit 3" where it is attached to Dr. Alton's affidavit. We will refer to the exhibit as the "Stab. Nbk".

signature is referred to in Dr. Stabinsky's testimony. The notebook page has the heading "Synthesis of Tac II promoter and linker for Immune Interferon (For K. Alton)" and states that:

This linker will be used to express the Immune interferon gene that lack the first three amino acids (from the N-terminus) through the Trp control region.

25. Under the portion of the notebook page reading "Witnessed & Understood by me", no signature appears. Moreover, we see no witnessing signature elsewhere on the notebook page. Accordingly, it does not appear that the notebook page was witnessed.
26. A linker sequence set forth on the notebook page (at FF 24) is the same as the linker sequence found in the notebook page referred to in Dr. Alton's testimony (at FF 17).

The Gray et. al publication

27. Dr. Alton refers to a publication by Gray *et al.* ("Gray")⁹ (Exh. 1011) in his testimony. (Exh. 1 at ¶ 3).
28. According to the Gray publication, IFN- γ has anti-viral and anti-proliferative effects. (Exh. 1011 at 503).
29. The publication date of Gray is prior to Dr. Alton's work in October of 1982.

⁹ Gray *et al.*, Nature, 295:503-508 (Feb. 1982).

III. Discussion

A rebuttable presumption exists that the inventors made their invention in the chronological order of their effective filing dates. The burden of proof shall be upon the party that contends otherwise. 37 CFR § 1.657(a). Alton argues that it conceived the invention prior to its accorded benefit date (Paper 1 at 3). Thus, Alton has the burden of proof.

Conception is the formation in the inventor's mind of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). "An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). The conception must show possession of every limitation of the count and must be sufficient to enable one of ordinary skill in the art to make the invention without extensive experimentation. *Sewall v. Walters*, 21 F.3d 411, 415, 30 USPQ2d 1356, 1359 (Fed. Cir. 1994).

An inventor's testimony used to establish conception must be corroborated by independent evidence. *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d at 1228, 32 USPQ2d at 1919. All pertinent evidence must be evaluated when determining the credibility of an inventor's testimony. For example, under a "rule of reason" analysis, circumstantial evidence of an independent nature may satisfy the corroboration requirement. *Reese v. Hurst v. Wiewiorowski*, 661 F.2d 1222, 1230, 211 USPQ 936, 940 (CCPA 1981); *Cooper v. Goldfarb*, 154 F.3d at 1330, 47 USPQ2d at 1903. "However, the 'rule of reason' does not dispense with

the requirement for some evidence of independent corroboration.” *Coleman v. Dines*, 754 F.2d, 353, 360, 224 USPQ 857, 862 (Fed. Cir. 1985).

Dr. Alton’s testimony

Dr. Alton’s testimony indicates that he came up with a procedure for constructing [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ and recorded the procedure in his notebook on 18 October 1982. (FFs 16(c) and (d)). Dr. Alton testified that he had discussed the preparation of a linker to be used in the procedure to construct [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ with Dr. Stabinsky prior to recording the procedure in his notebook (FF 16(e)).

Dr. Alton’s notebook page states a plan to construct a gene that will delete the first three amino acids of IFN- γ (FF 17). According to the notebook page, the linker to be used to construct the gene was prepared by Dr. Stabinsky. The linker set forth on the notebook page would encode Met (from the codon ATG) followed by Gln (from the codon CAG) (FF 19). Met-Gln are the first two amino acids of [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ (FF 16(a)). Thus, Dr. Alton’s testimony and the notebook page are consistent with one another. We give Dr. Alton’s notebook page no more weight than Dr. Alton’s testimony as the notebook page does not appear to have been witnessed (FF 18). See *Reese v. Hurst v. Wiewiorowski*, 661 F.2d at 1231, 211 USPQ at 945.

Corroboration of Dr. Alton’s testimony and notebook page

Dr. Stabinsky’s testimony indicates that she prepared a linker for the purpose of producing [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ (FF 23(a)). Dr. Stabinsky’s notebook page indicates that a linker for immune interferon for “K. Alton” was synthesized (FF 24). The linker recorded on Dr. Stabinsky’s notebook page is the same as the linker recorded on Dr.

Alton's notebook page (FF 26). Thus, both Dr. Stabinsky's testimony and the notebook page are consistent with Dr. Alton's testimony and vice versa.

While Dr. Stabinsky has not explicitly testified that Dr. Alton told her of his plan for constructing [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ , when we consider all the pertinent evidence, we determine that Dr. Alton's testimony is credible. We note for instance, that:

(1) Dr. Stabinsky's notebook page indicates that she prepared a linker for "K. Alton" for use in expressing immune interferon lacking the first three amino acids on 4 October 1982,

(2) Dr. Alton's testimony and notebook page indicate that Dr. Stabinsky provided him with the linker he needed to construct [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ on 18 October 1982,

(3) the linker Dr. Stabinsky recorded in her notebook is the same as the linker that Dr. Alton recorded in his notebook, and

(4) it appears that the linker found in both Dr. Alton's and Dr. Stabinsky's notebook would have been useful in constructing [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ (FF 19).

Thus, the evidence before us sufficiently establishes that as of at least 18 October 1982, Dr. Alton had both the idea of [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ and an idea of how to produce [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ (i.e., using the synthetic linker produced by Dr. Stabinsky). However, to complete conception of the invention, it is necessary that Alton conceived of a utility for [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ .

Utility

Count 2 does not specify a use for the [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ and thus the conception of any use would result in conception of a complete and operative invention

of the count. Dr. Alton's testimony states that IFN- γ had been shown to have anti-viral, anti-tumor, and anti-proliferative properties (FF 16(a)). Dr. Alton testified that "we"¹⁰ prepared IFN- γ analogs with a view toward testing the analogs for their anti-viral and anti-proliferative properties (FF 16(b)). Thus, Dr. Alton's testimony indicates that his plan was to use the [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ as an anti-viral or anti-proliferative agent.

Dr. Stabinsky's testimony does not explicitly address the intended use of the [Met⁻¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ . However, "[u]nder a rule of reason analysis, an inventor's uncorroborated testimony that he conceived a utility for his invention may be accepted if there exists other corroborated evidence to indicate that the inventor's testimony is credible...The utility of the invention need not always be explicitly corroborated. Circumstances may make a utility implicit." *Kridl v. McCormick*, 105 F.3d 1446, 1451, 41 USPQ2d 1686, 1690 (Fed. Cir. 1997).

Like the Court in *Kridl*, we determine that the evidence before us indicates that a person of ordinary skill in the art would have accepted Dr. Alton's testimony of intended use of his invention at the time of his conception. The evidence before us is consistent with Dr. Alton's testimony indicating that he conceived the utility of his invention when he conceived its other features. In particular, the state of the art was such that one of ordinary skill in the art would have accepted Dr. Alton's testimony indicating that the IFN- γ analogs were being prepared for use as anti-viral and anti-proliferative agents. For example, the Gray publication, which was published prior to Dr. Alton's work in October of 1982, acknowledges the anti-viral and anti-proliferative effects of IFN- γ (FFs 28 and 29).

¹⁰ We understand "we" to refer to Dr. Alton and unspecified others.

IV. Conclusion

The evidence pointed out to us by the parties is sufficient to show that Dr. Alton formed a definite and permanent idea of [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ , including how it was to be used in practice. We have been directed to no evidence establishing that Dr. Alton's plan for constructing [Met¹, des-Cys¹, des-Tyr², des-Cys³]IFN- γ was insufficient to enable one of ordinary skill in the art to make the invention without extensive experimentation. Thus, we determine that, on the record before us, *prima facie* conception by Alton has been established. Accordingly, it is appropriate to enter judgment against Gray.

V. Order

Upon consideration of the record of the interference and for reasons given, it is

ORDERED that the JOINT MOTION UNDER 37 C.F.R. § 1.635 FOR DETERMINATION ON ALTON PRIORITY PROOFS (Paper 54) is GRANTED;

FURTHER ORDERED that, on the record before us, a *prima facie* showing of conception by Alton has been made;

FURTHER ORDERED that judgment on priority is awarded against PATRICK W. GRAY and ERNST H. RINDERKNECHT as to Count 2;

FURTHER ORDERED that PATRICK W. GRAY and ERNST H. RINDERKNECHT is not entitled to a patent containing claims 1-5 and 8-13 of US 4,855,238;

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative records of Gray's 4,855,238 patent and Alton's 06/483,451 and 08/462,022 applications; and

FURTHER ORDERED that, if there is a settlement agreement in the interference, the parties are directed to 35 USC § 135(c) and 37 CFR § 1.666.

_____)	
JAMESON LEE)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
_____)	APPEALS AND
SALLY GARDNER LANE)	INTERFERENCES
Administrative Patent Judge)	
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