

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARTIN J. CLINE and DENNIS J. SLAMON

Appeal No. 94-3341
Reissue Application 07/885,142¹

ON BRIEF

Before SCHAFER, *Vice Chief Administrative Patent Judge*, and
WINTERS and GRON, *Administrative Patent Judges*.

GRON, *Administrative Patent Judge*.

¹ Application filed May 18, 1992, for reissue of U.S. Patent 4,699,877. According to applicants, this application is a continuation of Application 07/421,096, filed October 12, 1989, for reissue of the same patent. U.S. Patent 4,699,877 issued October 13, 1987, from Application 06/673,469, filed November 20, 1984; which is a continuation-in-part of abandoned Applications 06/439,252, filed November 4, 1982, and 06/496,027, filed May 19, 1983.

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DECISION ON APPEAL UNDER 35 U.S.C. § 134

1. Introduction

This is an appeal of rejections of Claims 10 to 15, 33, and 34, all claims pending in this application. Claim 34 stands rejected under 35 U.S.C. § 112, first paragraph, as based on a specification which purportedly does not provide a written description of the claimed invention. Claims 10 to 15, 33, and 34 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a specification which purportedly would not have enabled persons skilled in the art to make and use the full scope of the claimed invention. Claims 10 to 15, 33, and 34 stand rejected under 35 U.S.C. § 101 as drawn to inventions which lack practical utility. Claims 10 to 15, 33, and 34 stand rejected under 35 U.S.C. § 251 as based on a defective reissue oath.

Claims 10² and 14 read:

10. A method for substantially eliminating human malignant cells from a combination of human malignant and normal cells, which comprises:

combining under cytotoxic conditions said combination of cells with an antibody specific for an expression product of a DNA sequence present in a retrovirus genome or substantially complementary to said DNA sequence, which sequence is expressed in said malignant cells as a surface protein; and

² The examiner incorrectly indicated on page 5 of her Answer (Ans) that Claim 10 of appellants' Appendix to the brief is correct.

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isolating normal cells, substantially free of malignant cells.

14. A method for treating a human host suspected of having malignant cells, which comprises:

administering to said human host under cytotoxic conditions antibodies to the expression product of a gene, which gene is part of a retrovirus genome capable of inducing malignancy in a normal cell or which gene is substantially complementary to said gene of said retrovirus genome.

Dependent Claim 13 further limits the antibodies employed in the method of Claim 10 to those specific to the expression product of the v-myb or c-myb gene. Independent Claim 33 limits the antibodies administered in accordance with the method of Claim 14 to those specific to a cell surface protein expressed by a c-onc gene substantially complementary to a v-onc gene of a retrovirus which is capable of inducing malignancy in a normal cell.

Independent Claim 34 limits the antibodies administered in accordance with the method of Claim 14 to those specific to an expression product of c-erb.

We are confused by the examiner's statement that "claims 10-15, 33 and 34 stand or fall together" (Examiner's Answer (Ans), page 5). The examiner apparently recognizes that Claims 10 to 13 are directed to selective elimination of malignant cells in vitro while Claims 14, 15, 33, and 34 are directed to in vivo therapeutic methods and acknowledges that method Claims 13 and 34

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use antibodies to expression products of c-myb and c-erb. She nevertheless finds that "the issues are the same for all of the claimed invention" (Ans 4-5, bridging sentence). The examiner's finding disregards the different scope of enablement, utility and description required of the specification under the first paragraph of 35 U.S.C. § 112 for subject matter encompassed by claims which differ in scope. We will not blindly follow the examiner down the path of least resistance. The claims in this case do not stand or fall together.

2. The claimed methods

Common to all claimed methods is the step of combining an antibody to the expression product of a retroviral DNA sequence which induces malignancy in normal human cells, with a combination of human malignant and normal cells so to selectively eliminate only the malignant cells. The combining step of method Claims 10 to 13 is performed in vitro. The combining step of Claims 14, 15, 33, and 34 occurs in vivo following administration of an antibody to a human host.

The expression products of Claims 10 to 13 and 33 are cell surface proteins. Consistent therewith, the specification suggests that the expression product of the myb gene of Claim 13 appears to be a surface membrane protein (Specification (Spec.), page 13, lines 58 to 60). We find implicit that the expression

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products of Claims 14, 15 and 34 also are surface membrane proteins which act as antigenic markers on malignant human cells for the antibodies administered to a human host and in vivo cytotoxic activity. The specification teaches (Spec.14, lines 24 to 26), "The oncogenic proteins are found to be available for binding to antibodies as surface membrane proteins."

The basis for our decision on the patentability of the subject matter claimed in this case is not confined to the four corners of this application, i.e., the Appeal Brief, the Examiner's Answer, the Langton Declaration under 37 CFR § 1.132 (Paper No. 7), all supporting publications including those published after November 20, 1984, and the prosecution history of rejections entered in Reissue Application 07/885,142. We have considered the prosecution history of this case in its entirety, including arguments made and the evidence of record in the patented file and its parent applications relative to prosecution of prior rejections under 35 U.S.C. §§ 112 and 103 of the subject matter claimed in those applications.

3. Discussion of the Rejections

A. Rejections under 35 U.S.C. § 112, 1st paragraph

(1) The Written Description Requirement

Claim 34 stands rejected for noncompliance with the written description requirement of 35 U.S.C. § 112, first paragraph.

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We affirm.

Whether or not the specification contains a written description of the subject matter claimed is a question of fact. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). We find no literal support in the specification for the Claim 34 "method for treating a human host suspected of having malignant cells" which comprises the single step of "administering to said human host under cytotoxic conditions antibodies to the expression product of a gene substantially complementary to v-erb." However, the claimed invention need not be described ipsis verbis to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. In re Lukach, 442 F.2d 967, 969, 169 USPQ 795, 796 (CCPA 1971). Revisiting the specification, we find in Table 1 an express teaching that the v-erb oncogene can be found in chickens (Spec.3) and a positive indication for mRNA in Table 4 allegedly establishing that an expression product of c-erb is detectable in embryo/fetuses of mice, i.e., evidence that an expression product of c-erb is detectable in an animal species other than chickens (Spec. 11, lines 9 to 41; Spec. 12, lines 6 to 7). However, Claim 34 is drawn neither to the expression product of c-erb in chickens or mice nor to a method of treating chickens or mice with malignancy. The examiner argues that the specification does

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not recognize "a human cellular counterpart to v-erb" (Ans 9).

The specification reports that no expression of c-erb in human malignancy was detected on the basis of DNA-RNA hybridization techniques (Spec. 8, Table 2 and lines 1 to 39). That artisans later found c-erb in human malignancy does not remedy the deficiencies of appellants' patent specification as originally filed. The specification itself must satisfy the written description requirement of Section 112. Information which is necessary to satisfy 35 U.S.C. § 112, first paragraph, that cannot be gleaned from the original specification may not be added later. In re Buchner 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); In re Brandstadter, 484 F.2d 1395, 1404-1405, 179 USPQ 286, 293-294 (CCPA 1973); In re Smyth, 189 F.2d 982, 990, 90 USPQ 106, 112 (CCPA 1951).

Moreover, even if the specification were to establish that persons skilled in the art reasonably could have predicted from appellants' specification that a human cellular counterpart to chicken v-erb exists, we would still find that the patent specification would not have conveyed to persons skilled in the art as of the filing date of the patent application that appellants invented the method of new Claim 34. See In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989); In re Wilder, 736 F.2d 1516, 1520, 222 USPQ 369, 372

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(Fed. Cir. 1984); In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)(while appellant does not have to describe exactly the subject matter claimed, the description must clearly allow persons skilled in the art to recognize that appellant invented what is claimed).

Claim 34 is drawn to a method of treating a human host suspected of having malignant cells. The method comprises "administering to the human host under cytotoxic conditions an antibody to the expression product of a gene [(c-erb)] substantially complementary to v-erb." According to the specification, in vivo treatment of the human host is effected when (Spec. 14, lines 24 to 29) "[t]he oncogenic proteins are found to be available for binding to antibodies as surface membrane proteins." While the patent specification states that "myb protein appears to be a surface protein which is available for binding to antibodies" (Spec 13, lines 58 to 60),³ it does not teach or even suggest that the expression product of c-erb is a surface membrane protein. Therefore, the patent specification does not describe the specific method of Claim 34, i.e., a method

³ Table 24-1 at page 986 of Darnell, James, et al., Molecular Cell Biology, Second Edition, Scientific American Books, New York (1990)(attached) indicates that myb is located in the nuclear matrix of leukemia cells.

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of treating human malignancy in vivo with antibodies to an expression product of c-erb.

The specification does not provide a written description of the method of Claim 34 which is sufficient to allow persons skilled in the art to recognize that appellants invented what is specifically claimed. The specification does not describe the two characteristics of c-erb which it deems essential to possession of the invention. The required characteristics are: (a) recognition that the expression product of c-erb is a cell surface membrane, and (b) evidence that c-erb is expressed in human malignancy. Consequently, while we find a general written description of a method for treating human malignant cells in vivo comprising administering antibodies to a cell surface protein of a gene (v-onc) which is part of a retrovirus genome capable of inducing malignancy in a normal cell or of a gene (c-onc) substantial complementary to the v-onc, we find no recognition or suggestion that the expression product of c-erb is a protein which can be found in a surface membrane of human malignant cells.

(2) The Enablement Requirement

Claims 10 to 15, 33, and 34 stand rejected under 35 U.S.C. § 112, first paragraph. According to the examiner, the patent specification would not have enabled persons skilled in the art

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to make and use the full scope of the claimed inventions claimed. To sustain this rejection, the examiner must provide sufficient reasons to doubt the objective enablement of the invention appellants describe. See In re Marzocchi, 439 F.2d 220, 223-224, 169 USPQ 367, 369-370 (CCPA 1971)(when the PTO rejects claims under the first paragraph of 35 U.S.C. § 112, it must explain why it doubts that the asserted scope of the objective enablement is commensurate with the scope of the protection sought). Enablement is a matter of law. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). We affirm.

Claims 10 to 13 are claims to in vitro methods. Claims 14, 15, 33 and 34 are directed to in vivo processes. To enable persons skilled in the art to use the full scope of the claimed in vivo methods for cytotoxically treating malignant human cells without affecting normal cells under the first paragraph of Section 112, in vitro test results will rarely suffice. The art of treating human malignancy in vivo is highly unpredictable. Where physiological activity is concerned, one skilled in the art reasonably would not and properly should not accept in vitro results as support for in vivo activity. Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1216-1217, 18 USPQ2d 1016, 1030 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

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Therefore, to enable one skilled in the art to use a method of treating human malignancy in vivo based solely on in vitro testing, as is here the case, some evidence correlating in vivo results to in vitro testing at the pertinent time is required. See In re Brana, 51 F.3d 1560, 1565 USPQ2d 1437, 1442 (Fed. Cir. 1995)(to enable one skilled in the art to use a clinical method based on preclinical testing, the preclinical testing must be shown to be statistically significant) and Cross v. Iizuka, 753 F.2d 1040, 1050-1051, 224 USPQ 739, 747-748 (Fed. Cir. 1985) (preclinical testing activity must at least reasonably correlate to clinical activity to establish utility). We find no evidence of record correlating successful treatment of human malignancy in vitro to successful treatment of human malignancy in vivo at the time appellants' application was first filed.

While appellants point to the Langton Declaration and later publications to affirm the teachings in their specification (Appeal Brief, pages 9, 11 to 13, and 17 to 18; Hancock, M.C., et al., Cancer Research, Vol. 51, pages 4575-4580 (1991), referred to on page 2 of the Langton Declaration, and a poster presentation at the AACR/JCR meeting on February 10-14, 1992, referred to on page 3 of the Langton Declaration), we reiterate that the specification as originally filed must satisfy 35 U.S.C. § 112, first paragraph. In re Buchner, supra; In re

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Brandstadter, supra; In re Smyth, supra. Ex post facto affirmations of practical utility, not previously disclosed in the specification, are irrelevant. In re Kirk, 376 F.2d 936, 941-942, 153 USPQ 48, 52-53 (CCPA 1967).

Appellants reason that the added evidence shows the skill in the art at the time of appellants' invention. Appellants therefore adhere to their argument that, given the teaching of their specification, persons skilled in the art would have been able to practice the full scope of the claimed inventions at the time their application was filed without undue experimentation.

Our reviewing court rejected similar arguments in Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) and stated at 1366, 42 USPQ2d at 1005:

Genentech's arguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

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In this case, we scrutinized the original specification for some tangible evidence of an in vivo method of selectively treating malignant cells with antibodies to the expression product of a gene of a retrovirus which is capable of inducing malignancy in a normal cell or a gene substantially complementary to the retrovirus gene. We find none. Rather, we conclude, as did the court in Genentech Inc. v. Novo Nordisk A/S, supra, that appellants' specification invites skilled artisans to experiment. It proffers no more than the germ of the claimed idea.

Appellants' specification lists various known oncogenes and their species of origin (Spec.3, Table 1). Having isolated any one of the known oncogenes, the specification suggests that its nucleotide sequence "may be determined by known means" (Spec.4, lines 27 to 30). The amino acid sequence of the expression protein of the oncogene can be determined from the nucleotide sequence (Spec.4, lines 30 to 32). Alternatively, "hybrid DNA technology may be employed for obtaining expression" (Spec.4, lines 37 to 38). The specification then teaches (Spec.4, lines 51 to 56):

Once the protein has been identified and verified, one can then use the protein or subunit peptides as an antigen for the production of antibodies for diagnosis and treatment. Antibodies can be prepared in a variety of ways, depending upon whether monoclonal or polyclonal antibodies are desired.

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We find no reason to doubt that procedures for isolation of corresponding human c-oncs are conventional in the art and would not require undue experimentation of persons skilled in this art. Thus, we accept the following statement at face value (Spec.5, lines 55 to 61):

In those situations where the human gene is different from the v-onc, e.g., c-ras, the above described techniques may be used for isolating the gene, mRNA or pseudo-gene and obtaining antibodies to the human expression product.

However, while the specification teaches that "[t]he antibodies may be used in a variety of ways" (Spec.6, line 3), the variety of useful ways may or may not apply to the expression products of each and every c-onc encompassed by the claims. Apparently, there are limitations or conditions precedent to each of the variety of uses contemplated. For example (Spec.6, lines 4 to 9):

In instances where the antigen may be found in a physiological fluid at an elevated concentration only when malignancy exists, the physiological fluid, such as serum, plasma, whole blood or cerebrospinal fluid may be assayed.

However, it is just as likely that an antigen may not be found in detectable amounts or findable at all in the physiological fluid (Spec.6, lines 33 to 34). The specification teaches that the antibodies may be labeled and introduced in vivo. However, if the antigens sought by the antibodies are either not present or

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undetectable in the human host, the antibodies will not direct the label to the malignant cell for diagnosis and/or treatment in vivo as the specification contemplates (Spec.6, lines 59 to 62). The specification teaches, "Usually, the antibodies will be formulated in a physiologically acceptable carrier . . . and injected into the host, when possible at the desired site, and when this is not possible, into a circulating system, such as blood" (Spec.6, line 66, to Spec.7, line 2).

The in vivo utility of antibodies for detection and treatment of human malignancy presumes the existence of human counterparts to recognized animal antigens. However, Tables 2 and 3 of the specification (Spec.8) indicate that a presumption that a human counterpart to the expression products of any specific animal cellular oncogene exists may not be reasonable.

Table 2 shows that "[n]o significant expression of mRNA sequences homologous to c-erb, c-yes, c-abl, c-mos, c-fms, or c-sis could be detected" in any form of human malignancy initially tested by DNA-RNA hybridization techniques (Spec.8, lines 32 to 34; emphasis added). Only "[f]our cellular oncogenes[; c-myc, c-fos, c-ras^{Ha}, and c-ras^{Ki} showed a consistent pattern of expression in a variety of human tumors" (Spec.8, lines 40 to 42). Moreover (Spec.8, lines 52 to 59):

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Messenger RNA sequences related to c-fes were detected in only 2 of 14 tumors examined, both of these were lung cancers.

C-myb expression was detected in only one of 14 tumors; this too, was lung cancer.

C-src messenger RNA sequences were observed only in circulating tumor cells of a patient with lymphosarcoma.

On further testing, c-myb, c-src, and c-fes were detected in some other human tumors, while c-myc, c-fos, c-ras^{Ha}, and c-ras^{Ki} were detected in all other human tumors examined (Spec.9, Table 3 and lines 48 to 53). Evidence of "c-rel, c-abl, and c-sis expression was not observed in any of the additional [human] tumor types examined" (Spec.9, lines 54 to 55). The specification reports that "none of the cellular oncogenes looked for were found to be expressed at any significant level in the single uterine carcinoma evaluated" (Spec.9, lines 56 to 58).

On the other hand, the specification reports that c-fos, c-abl, c-ras^{Ha}, c-myc, c-erb, c-src, and c-sis were detected in mouse embryonic tissue (Spec.11, Table 4). The relevance of the detectability of certain c-oncs in mouse embryonic tissue to the presently claimed subject matter escapes us. According to the specification, the antigen must be found in a physiological fluid or on the surface of human malignant cells at an elevated concentration relative the its concentration in normal fluid or cells in order to selectively eliminate human malignant cells from a combination with normal cells in vitro or treat the human

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body for malignancy in vivo without cytotoxicity to normal cells (Spec.6, lines 4 to 9). That c-oncs were detected in mouse normal embryonic tissue is irrelevant at best and at worst inconsistent with methods which require selective expression of the c-oncs in human malignant cells to mark and selectively eliminate human malignant cells from a combination of malignant and normal cells in vitro or in vivo.

The specification indicates that antibodies to c-myb reacted with "radioactively labeled cell lysates from a cell line containing multiple copies of the Avian myeloblastosis virus and with lysates from appropriate non-infected cell lines" (Spec.13, lines 9 to 12; we emphasize the reactivity with cell lysates rather than cells) and "the plasma of chickens bearing tumors induced by amv" (Spec.13, lines 16 to 17). More relevant to the methods presented by the appealed claims, anti-myb antisera also reacted with select proteins in lysates of the myeloid human leukemia cell line (HL-60) which is known to express messenger RNA transcripts of the c-myb gene (Spec.13, lines 20 to 27).

While the reactivity of antisera to cell lysates of a myeloid human leukemia cell line suggests that expression products of c-myb exist in one type of human malignancy, we note again the specification's teaching that in vivo treatment of the human host and in vitro elimination of malignant cells from

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combinations with normal cells is effected when "[t]he oncogenic proteins are found to be available for binding to antibodies as surface membrane proteins" (Spec. 14, lines 24 to 29). Thus, the reactivity of antisera to the lysate of one type of human malignant cell reasonably would not have suggested to persons skilled in the art that the expression products of that or any other c-onc are cell surface proteins which enable selective identification and treatment of human tumor cells in vivo or isolation of malignant cells from normal cells in vitro. With regard to human myb, the specification indicates that "myb protein appears to be a surface protein which is available for binding to antibodies" (Spec 13, lines 58 to 60; emphasis added). Whether or not myb or any other expression product of a c-onc is in fact a cell surface protein which is available for binding to antibodies in vivo or in vitro appears to be, based on appellants' patent specification, pure speculation.⁴ This is especially true for the expression products of c-oncs which were not detected in any type of human malignancy, e.g., the expression product of c-erb to which Claim 34 is limited. See Tables 2 and 3 on pages 8 and 9 of the specification.

We indicated in subparagraph (1) above that all claimed methods, whether they be methods of treating human malignancy in

⁴ See Footnote 3 on page 8 of this decision.

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in vitro or in vivo, require selective binding of antibodies to cell surface proteins of human malignant cells. Hence, we need not dwell on any specific evidence of record which might suggest a correlation between in vitro and in vivo reactivity. Even presuming evidence of a statistically significant correlation between in vitro and in vivo test results, undue experimentation still would have been required to use the full scope of all claims for selectively locating, treating, or eliminating human malignant cells from a combination of human malignant and normal cells. According to the specification, myb is the only human cell protein which appeared to be a cell surface protein. No other cellular expression products are so labeled. Appellants point to no evidence of the cell surface reactivity of expression products of any other c-onc encompassed by appellants' broad claims which would have been accessible to persons skilled in the art at the time appellants' invention was made. Only Claim 13 is directed to eliminating human malignant cells from normal human cells in vitro or treating human malignancy based on evidence which no more than suggests that the expression product of c-myb might be a cell surface protein.

But for Claim 13, none of appellants' claims are limited to elimination or treatment of only those malignant cells which the specification indicates are likely to carry a cell surface

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expression product of a c-onc. Moreover, but for Claim 13, none of appellants' claims are limited to elimination or treatment of only those human malignant cells for which evidence of c-onc expression products has been detected. Alas, no claim on appeal is limited to elimination or treatment of only those specific human malignant cells which have been shown to have a cell surface c-onc expression product. Rather, the claims are generally directed to a broad concept which, based on additional experimentation, may or may not prove valuable to some extent.

Doubtless, persons skilled in the art would have been well able to determine which human malignancies carry those cell surface proteins which would enable their in vitro elimination from combinations with normal human cells and selective in vivo treatment of human malignancy. However, we repeat the wisdom espoused in Genentech Inc. v. Novo Nordisk A/S, 108 F.3d at 1366, 42 USPQ2d at 1005 (Fed. Cir. 1997):

[A]rguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)(stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have

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been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

Here, the best that can be said for appellants' patent specification is that it provides an invitation to experiment in an art where a ounce of hope is enough to incite a ton of experimentation. In this highly unpredictable art, the scant information, guidance and direction this specification would have provide persons skilled in the art does not justify the broad patent protection appellants seek. The later publications appellants cite support the argument that the "germ of an idea" is likely to lead to great discoveries. However, we repeat that ex post facto affirmations of practical utility, not previously disclosed in the specification, are not particularly relevant. In re Kirk, 376 F.2d at 941-942, 153 USPQ at 52-53.

The art published prior to the filing date of the patent application, the art published contemporaneous to appellants' filing date, the later published art, and the complete history of prosecution help us to understand just how unpredictable this art is and how much additional experimentation would have been required for persons skilled in the art to determine the practical scope of the invention appellants here broadly claim. We find from the collective information that the amount

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experimentation required for this specification to satisfy the enablement provision of 35 U.S.C. § 112, first paragraph, for the full scope of the subject matter encompassed by the claims before us would have been undue at the time appellants' patent application was filed. While we find that the procedures persons skilled in the art would have been required to perform would have been conventional, we also find, based on the specification and the published art, no reasonable expectation of success using an antibody after the preliminary stages of isolating the antibody. Thus, we find that the additional experimentation which would have been required at the pertinent time to enable one skilled in the art to use the full scope of the claimed subject matter would have been undue in kind and amount. In our view, appellants' specification is an invitation to persons skilled in the art to find out just how practical the concept they describe in their specification is.

Our findings with respect to unpredictability in the art and undue experimentation are buttressed by appellants' arguments in traverse of rejections of their claims under 35 U.S.C. § 103 over cited prior art. Appellants proffered the following response to the examiner's final rejection of March 17, 1987, in Application 06/673,469, now U.S. Patent 4,699,877, the subject of this

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reissue application (Paper No. 10, pages 2 to 3, of the patented application responding to Paper No. 9):

[T]o this day there has been no human virus associated with an oncogene . . . [(page 2, third ¶)].

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[T]here were a substantial number of bird and animal retroviruses. These retroviruses were found to occasionally carry a gene, the oncogene, which would transform the host cell which was the natural target of the retrovirus. As the literature shows, some of these retroviruses when used in culture with cells from other species, including humans, were also found to transform the cells in culture to tumorous cells . . . [(pages 2-3, bridging ¶)].

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One can never be certain in operating in culture that the events which are observed can be translated to a bird or animal host from which these cells were obtained. The fact is that cells in culture are substantially different from cells in the live host, as to conditions, environment, and also as to the fact that cells in culture are compromised as compared to their natural environment. . . . [U]ntil evidence in the live host establishes the correctness or erroneous nature of the observations in culture, there can be no proof that the theory is correct [(page 3, first full ¶)].

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Arguing against there being a relationship between oncogenes observed with retroviruses associated with other than humans and cancer in humans was the fact that retroviruses were extremely rare for humans and the two that had been discovered did not carry oncogenes. Secondly, while oncogenes could be shown to transform human cells in culture, no one [sic, no one] had ever established that these oncogenes had

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any relationship to the situation in human cancer cells. There was also the problem that the mechanism for cancer is still somewhat elusive and in order to establish relationships, it is desirable, if not necessary, that there be some understanding of the interaction between a specific material and its effect, in this case initiating a tumor. Therefore, while it might have seemed that there was a relationship between oncogenes which had been found with other species, the fact was that until the subject discovery there was insufficient evidence to warrant the conclusion that the same mechanism was operative with humans [(page 3, last ¶)].

Brenner v. Manson, supra, instructs us not to reissue appellants a hunting license based on this specification. Where there is uncertainty as to the potential utility of vaccines for treating or eliminating human maladies related to viral activity, the specification must in most cases provide more than a single embodiment to enable broad claims. Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d at 1209-1210, 1214, 18 USPQ2d at 1024, 1028. Accord In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1515 (Fed. Cir. 1993). Interestingly, here we have what appears at best to be one, and based on more recent evidence⁵, wha appears now to have been no working examples. We will follow the wisdom of Brenner v. Manson, 383 U.S. at 534-535:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.

⁵ Revisit Footnote 3 on page 8 of this decision.

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Unless and until a process is refined and developed to this point--where specific benefit exists in current available form--there is insufficient justification for permitting an applicant to engross . . . a broad field.

Accordingly, we affirm.

B. Rejections under 35 U.S.C. § 101

Claims 10 to 15, 33, and 34 stand rejected under 35 U.S.C. § 101. We affirm this rejection for the same reasons we affirmed the examiner's rejection of Claims 10 to 15, 33, and 34 under 35 U.S.C. § 112, first paragraph. In our view, the basis for the examiner's rejections of the claimed subject matter under 35 U.S.C. §§ 101 and 112, first paragraph, is substantially the same. The examiner so indicated in the Answer by grouping the rejections under 35 U.S.C. §§ 101 and 112, first paragraph, under a single issue, i.e., "does the specification as originally filed provide . . . an enabling disclosure for those skilled in the art at the time the invention was made to practice the invention for the utility claimed or disclosed . . ." (Ans 3-4, bridging ¶). We hold that appellants' specification does not establish a practical utility for the full scope of the methods claimed and accordingly would not have enabled persons skilled in the art to use the full scope of the methods claimed for the purpose indicated.

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Our view that the rejections under 35 U.S.C. §§ 101 and 112, first paragraph, here presented are substantially the same is supported by our reviewing court. In re Brana, teaches at 1564, 34 USPQ2d at 1439:

The requirement that an invention have utility is found in 35 U.S.C. §101: "Whoever invents . . . any new and useful . . . composition of matter . . . may obtain a patent therefor. . . ." (emphasis added). It is also implicit in § 112, ¶1

Brana also noted at 1564 n.12, 34 USPQ2d at 1439 n.12:

This court's predecessor has determined that absence of utility can be the basis of a rejection under both 35 U.S.C. § 101 and § 112, ¶1. In re Jolles, 628 F.2d 1322, 1326 n.11, 206 USPQ 885, 889 n.11 (CCPA 1980); In re Fouche, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971)

On review of the examiner's discussion of the merits of the two rejections at pages 8 to 12 of the Answer, we see only a panoramic difference. The examiner focuses on a claimed species under § 112, first paragraph, and on the claimed genus under § 101. Having considered support for both genus and species claims under 35 U.S.C. § 112, first paragraph, we affirm what we view as substantially the same rejections of identical claims under 35 U.S.C. § 101.

C. Rejections under 35 U.S.C. § 251

Claims 10 to 15, 33, and 34 stand rejected under 35 U.S.C.

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§ 251 as based on a defective reissue oath. We affirm.

A supplemental reissue oath or declaration is required for every change in the specification or claims of an application for reissue of a patent. In re Constant, 827 F.2d 728, 729, 3 USPQ2d 1479, 1480 (Fed. Cir. 1987). Accord Manual of Patent Examining Procedure (MPEP), § 1444 (5th ed., Rev. 2, December 1985).

"Applicants' attorney has withheld filing a reissue declaration until such time as the claims are otherwise in form for issuance" (Appeal Brief, page 5). Whether or not the examiner's requirement to satisfy 37 CFR § 1.175 every time an amendment is entered during prosecution of a reissue patent application is onerous, appellants appear to concede that they are required under 35 U.S.C. § 251 to file a supplemental reissue oath or declaration in this case. Accordingly, we pro forma affirm the examiner's rejection.⁶

4. Conclusion

A. The examiner's rejection of Claim 34 under 35 U.S.C. § 112, first paragraph (written description) is affirmed.

B. The examiner's rejection of Claims 10 to 15, 33, and 34 under 35 U.S.C. § 112, first paragraph (enablement) is affirmed.

⁶ Matters of procedure are not within the jurisdiction of this Board. In re Watkinson, 900 F.2d 230, 233, 14 USPQ2d 1407, 1409-1410 (Fed. Cir. 1990). See 37 CFR § 1.181.

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C. The examiner's rejection of Claims 10 to 15, 33, and 34 under 35 U.S.C. § 101 is affirmed.

D. The examiner's rejection of Claims 10 to 15, 33, and 34 stand rejected under 35 U.S.C. § 251 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

RICHARD E. SCHAFER, Vice chief)
Administrative Patent Judge)
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) BOARD OF PATENT
SHERMAN D. WINTERS)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
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TEDDY S. GRON)
Administrative Patent Judge)

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