

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte BRIAN MATHUR and C. ALEXANDER TURNER, JR.

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Appeal No. 2003-2017  
Application No. 09/802,116

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 3, all of the claims remaining. Claims 1 and 3 read as follows:

1. An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1.
3. An isolated nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence shown in SEQ ID NO:2.

The examiner relies on the following references:

Van de Loo et al., "An Oleate 12-hydroxylase from Ricinus Communis L. is a Fatty acyl Desaturase Homolog," Proc. Natl. Acad. Sci., Vol. 92, pp. 6743-6747 (1995)

Smith et al., "The Challenges of Genome Sequence Annotation or 'The devil is in the details'," Nature Biotechnology, Vol. 15, pp.1222-1223 (1997)

Broun et al., "Catalytic Plasticity of Fatty Acid Modification Enzymes Underlying Chemical Diversity of Plant Lipids," Science, Vol. 282, pp. 1315-1317 (1998)

Seki et al., "Structure, Expression Profile and Chromosomal Location of an Isolog of DNA-PKcs Interacting Protein (KIP) Gene," Biochimica et Biophysica Acta, Vol. 1444, pp. 143-147 (1999)

Brenner, "Errors in Genome Annotation," TIG, Vol. 15, No.4, pp. 132-133 (1999)

Bork, "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," Genome Research, Vol. 10, pp. 398-400 (2000)

NCI-CGAP, National Cancer Institute, Cancer Genome Anatomy Project, AW295492 (2000)

Seki et al., GenEMBL accession number AB012955 (nucleotide), BAA33584 (polypeptide) (1999)

Saito et al., GenEMBL accession number AB016080 (1999)

Hayashi et al., GenBank accession number NM 054113 and NP 473454 (2002)

Claims 1 and 3 stand rejected under 35 U.S.C. § 101 as lacking patentable utility, and under 35 U.S.C. § 112, first paragraph, as nonenabled.

We affirm.

#### Background

The specification discloses a cDNA encoding a putative human protein, generically referred to as an NHP (for "novel human protein"), that "shares structural similarity with animal (DNA-dependent) protein kinase interacting

proteins (KIPs), including but not limited to KIP 1, KIP 2, and variants thereof. Like KIPs, the described protein also shares structural similarity with the phosphatase component . . . of calcineurin B. As such, the novel polynucleotides encode a new kinase interacting protein.” Page 2.

The specification also discloses that

[k]inases mediate phosphorylation of a wide variety of proteins and compounds in the cell. In conjunction with phosphatases, kinases are involved in a wide range of regulatory pathways and processes. Given the physiological importance of kinases, they and proteins with which they interact have been subject to intense scrutiny and are proven drug targets.

Page 1. The specification does not indicate what role kinase-interacting proteins play in any physiological process, but it does speculate that “[g]iven the strong homology to KIPs, the described NHP may mediate DNA repair.” Page 15.

The specification also suggests a number of potential uses for the claimed polynucleotides that do not depend on the function of the encoded protein. For example, the specification discloses that “knock-out” mice can be made that do not express the disclosed gene; “[w]hen the unique NHP sequences described in SEQ ID NOS:1-2 are ‘knocked-out’ they provide a method of identifying phenotypic expression of the particular gene as well as a method of assigning function to previously unknown genes.” Page 2. The specification also discloses that “the unique NHP sequences described in SEQ ID NOS:1-2 are useful for identification of coding sequence and the mapping [of] a unique polynucleotide to a particular chromosome.” Id.

The specification also discloses that “NHP oligonucleotides can be used as hybridization probes for screening libraries, and assessing gene expression patterns (particularly using a micro array or high-throughput ‘chip’ format).” Page 5. Such “[a]ddressable arrays comprising sequences first disclosed in SEQ ID NOS:1-2 can be used to identify and characterize the temporal and tissue specific expression of a gene.” Page 6.

Microarray-based analysis allows the discovery of broad patterns of genetic activity, providing new understanding of gene functions and generating novel and unexpected insight into transcriptional processes and biological mechanisms. The use of addressable arrays comprising sequences first disclosed in SEQ ID NOS:1-2 provides detailed information about transcriptional changes involved in a specific pathway, potentially leading to the identification of novel components or gene functions that manifest themselves as novel phenotypes.

Pages 6-7. According to the specification, the claimed polynucleotides are also useful in: “drug discovery” (page 7); “monitoring both drug action and toxicity” (id.); and “identify[ing] mutations associated with a particular disease” (id.).

The specification discloses that the polypeptide encoded by the claimed polynucleotides also has

a variety of uses. These uses include but are not limited to the generation of antibodies, as reagents in diagnostic assays, the identification of other cellular gene products related to the NHP, [and] as reagents in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders and disease.

Page 16. Finally, the specification discloses that antibodies that bind the polypeptide encoded by the claimed polynucleotides are useful. They

can be used, for example, in the detection of NHP in a biological sample and may, therefore, be utilized as part of a diagnostic or

prognostic technique whereby patients may be tested for abnormal amounts of NHP. Such antibodies may also be utilized in conjunction with, for example, compound screening schemes for the evaluation of the effect of test compounds on expression and/or activity of a NHP gene product. Additionally, such antibodies can be used in conjunction with gene therapy to, for example, evaluate the normal and/or engineered NHP-expressing cells prior to their introduction into the patient. Such antibodies may additionally be used as a method for the inhibition of abnormal NHP activity. Thus, such antibodies can, therefore, be utilized as part of treatment methods.

Page 23.

### Discussion

The claims are directed to a polynucleotide comprising the sequence of SEQ ID NO:1 (claim 1) and other polynucleotides encoding the same amino acid sequence (claim 3). The sole issue on appeal is whether the claims are supported by a disclosure of utility sufficient to satisfy 35 U.S.C. § 101.<sup>1</sup>

We note at the outset that we construe the claims to require the entire, specific amino acid or nucleotide sequence that is recited. Thus, claim 1 requires nucleotides comprising the entire sequence of SEQ ID NO:1 without substitutions, insertions, or deletions (although the open claim language permits additional sequences before and/or after the recited sequence). Likewise, claim 2 requires nucleotides encoding at least the entire, unaltered amino acid sequence of SEQ ID NO:2.

This interpretation of the claims is supported by their literal terms as well as by the prosecution history. As originally filed, the claims encompassed

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<sup>1</sup> While the examiner also rejected the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, that rejection is presented simply as a corollary of the finding of lack of utility. See

fragments of SEQ ID NO:1 (original claim 1) as well as polynucleotides that, among other things, hybridize to SEQ ID NO:1 under stringent conditions (claim 2). These claims were rejected as anticipated. See Paper No. 8, mailed Nov. 23, 2001. In response, Appellants cancelled claim 2 and rewrote claim 1 in its present form.. See Paper No. 9, filed Feb. 26, 2002. Appellants stated that

as claim 1 has been amended to recite the complete nucleotide sequence of SEQ ID NO:1 . . . and claim 2 has been cancelled without prejudice and without disclaimer, Applicants submit that the rejection of claims 1-2 under 35 U.S.C. § 102(a) has been overcome.

Id., page 10. Thus, as the prosecution history makes clear, the language of the claims on appeal does not allow for any variation in the recited sequences,<sup>2</sup> even though the open claim language allows for inclusion of additional sequence(s) at the 3' or 5' end of the claimed polynucleotides.

The examiner rejected all of the elected claims for lack of utility. The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (“Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility.”).

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the Examiner’s Answer, page 8. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

<sup>2</sup> Thus, to the extent that the specification discusses NHP “homologs,” “domains,” “mutant versions”, hybridizing sequences, and functional equivalents (e.g., pages 3-5, 10-11, and 16-17), the present claims do not encompass those embodiments.

The seminal decision interpreting the utility requirement of § 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). At issue in Brenner was a claim to “a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—ha[d] not yet been evidenced.” Id. at 529, 148 USPQ at 693. The Patent Office had rejected the claimed process for lack of utility, on the basis that the product produced by the claimed process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690. On appeal, the Court of Customs and Patent Appeals reversed, on the basis that “where a claimed process produces a known product it is not necessary to show utility for the product.” Id. at 522, 148 USPQ at 691.

The Brenner Court noted that although § 101 requires that an invention be “useful,” that “simple, everyday word can be pregnant with ambiguity when applied to the facts of life.” Id. at 529, 148 USPQ at 693. Thus,

[it] is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the “new and useful” phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man’s grasp and where little or nothing is wholly beyond the pale of “utility”—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.<sup>3</sup>

The Court, finding “no specific assistance in the legislative materials underlying § 101,” based its analysis on “the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the

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<sup>3</sup> The invention at issue in Brenner was a process, but the Court expressly noted that its holding

other.” Id. at 532, 148 USPQ at 695. The Court concluded that “[t]he 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. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” Id. at 534-35, 148 USPQ at 695.

The Court considered and rejected the applicant’s argument that attenuating the requirement of utility “would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge.” The Court noted that, while there is value to encouraging disclosure, “a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development.” Id. at 534, 148 USPQ at 695.

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“would apply equally to the patenting of the product produced by the process.” Id. at 535, 148 USPQ at 695-96.

The Court took pains to note that it did not “mean to disparage the importance of contributions to the fund of scientific information short of the invention of something ‘useful,’” and that it was not “blind to the prospect that what now seems without ‘use’ may tomorrow command the grateful attention of the public.” Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have added further layers of judicial gloss to the meaning of § 101’s utility requirement. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value “in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice.” Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly “show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests.” Id. at 939, 153 USPQ at 51.

The court held that “nebulous expressions [like] ‘biological activity’ or ‘biological properties’” did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants’ affidavit help their case: “the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know ‘how to use’ the compounds to find out in the

first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are.” Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. “There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of ‘useful in research’ or ‘useful as building blocks of value to the researcher’ was recognized, and clearly rejected, by the Supreme Court” in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

More recently, in In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. “In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was ‘plastic-like.’” Id. at 1203, 26 USPQ2d at 1605. “Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility.” Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26 USPQ2d at 1606. “[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at

the time of the filing of the German application; but in that application Ziegler had not yet gotten there.” Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were “well recognized in the art as valuable for use in cancer chemotherapy.” Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were “relevant to the treatment of humans and [were] not to be disregarded,” id. at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to show utility in the pharmaceutical context. The Cross court stated that “[it] is axiomatic that an invention cannot be considered ‘useful,’ in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious.” Id. at 1044, 224 USPQ at 742 (citing Brenner v. Manson). The court “perceive[d] no

insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question.” Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by “marshal[ing] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . . , analogous to the benefit provided by the showing of an in vivo utility.” Id. On the facts of that case – successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds – the court held that in vitro activity was sufficient to meet the requirements of § 101. See id.

The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The claimed compounds were disclosed to have higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from Brenner and its progeny. First, § 101’s requirement that an invention be “useful” is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack

utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every “use” that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound at issue in Brenner was useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, § 101 requires a utility that is “substantial”, i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442).

By contrast, Brenner’s standard has been interpreted to mean that “vague, general disclosures or arguments of ‘useful in research’ or ‘useful as building blocks of value to the researcher’” would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a “plastic-like” polypropylene capable of being pressed into a flexible film was held to show that the applicant was “at best . . . on the way to discovering a practical utility for

polypropylene at the time of the filing,” but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

In this case, the examiner found the specification’s disclosure that the claimed polynucleotides encode a kinase-interacting protein (KIP) was not sufficient to establish their utility, because the specification does not disclose

(1) the type of kinase interacting protein (KIP) being encoded by the claimed polynucleotides (i.e., which kinase or kinases will interact with the KIP of the instant application), (2) the biological processes or pathways in which the target kinases (i.e., kinases with which the KIPs interact) or the polypeptide of SEQ ID NO:2 are involved, [or] (3) the type of interaction (i.e., binding, phosphorylation, etc.) associated with the KIP of the instant application and how does this interaction change the target kinase.

Examiner’s Answer, page 7.<sup>4</sup> The examiner stated that such information would be required because, “[a]s known in the art and admitted by Appellants in the specification, kinases are active in many different biological processes.” Id.

Appellants argue that the examiner’s statement

that the claimed sequence lacks utility because the specification does not indicate “which type of KIP the polypeptide of SEQ ID NO:2 is” . . . is beyond belief, and completely misses the point of determining whether the instant sequence meets the utility requirement. First, the present specification does in fact indicate “which type of KIP the polypeptide of SEQ ID NO:2 is”, specifically, at least at page 2, lines 7-8 – “the novel polynucleotides encode a new kinase interacting protein.”

Appeal Brief, page 4 (emphasis in original).

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<sup>4</sup> The examiner also disputed the specification’s characterization of the claimed polynucleotides as encoding kinase-interacting proteins. See the Examiner’s Answer, pages 4-6. Appellants argue that the characterization would have been accepted by those skilled in the art, based on the degree of sequence similarity to known kinase-interacting proteins, and have submitted post-filing evidence that sequences nearly identical to SEQ ID NO:1 have been characterized by others in the field as kinase-interacting proteins. We agree with Appellants that the evidence of record would be accepted by those skilled in the art as establishing that the protein encoded by SEQ ID NO:1 is likely to be a kinase-interacting protein.

We do not agree with Appellants that the characterization of the protein encoded by the claimed polynucleotides as a “new” kinase-interacting protein is sufficient to establish patentable utility. Appellants’ specification discloses that the claimed polynucleotides encode a protein that “shares structural similarity with animal (DNA-dependent) protein kinase interacting proteins.” No further information is provided regarding the activity or function of the protein encoded by the claimed polynucleotides, the function of the proteins with which it “shares structural similarity”, the kinase(s) with which any of these proteins interact, or the nature of that interaction.

As the examiner pointed out, the evidence of record shows that kinases have widely varying activities in vivo. See, e.g., the instant specification, which admits that “kinases are involved in a wide range of regulatory pathways and processes.” Page 1. The specification provides no basis for concluding which of the “wide range of regulatory pathways and processes” involve kinases that interact with the putative kinase-interacting protein of SEQ ID NO:2, or how the protein of SEQ ID NO:2 affects the kinase(s) with which it interacts.

Thus, the evidence of record does not support Appellants’ position that the identification of SEQ ID NO:2 as a kinase-interacting protein, without more, provides a substantial utility for the claimed invention. In the terms used by the Brenner Court, such a characterization does not provide a specific utility in currently available form. We therefore reject Appellants’ argument that § 101 is satisfied by SEQ ID NO:2’s “structural similarity” to known kinase-interacting proteins.

Appellants also argue that the claimed polynucleotides are useful because they can be used for purposes that do not depend on the activity or function of the encoded polypeptide. Appellants argue, for example, that

knowledge of one or more particular kinase[s] with which the presently claimed sequence interacts is not required to track expression patterns using a DNA chip. . . . [T]hose skilled in the art would instantly recognize that the present nucleotide sequence would be an ideal, novel candidate for assessing gene expression using, for example, DNA chips. . . . Such “DNA chips” clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequence, must also be useful.

Appeal Brief, pages 4-5 (emphases in original).

Appellants argue that, in addition to their use in “DNA chips”, the claimed sequences are also useful “in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions,” and in “localizing the specific region of the human chromosome containing the gene encoding the given polynucleotide [sic, polypeptide].” Id., page 8. More particularly, Appellants argue that

[t]he presently claimed polynucleotide sequence provides biologically validated empirical data (e.g., showing which sequences are transcribed, spliced, and polyadenylated) that specifically define that portion of the corresponding genomic locus that actually encodes exon sequence.

Id. Appellants argue that “the described sequences are useful for functionally defining exon splice-junctions,” and that “the practical scientific value of expressed, spliced, and polyadenylated mRNA sequences is readily apparent to those skilled in the relevant biological and biochemical arts.” Id.

We are not persuaded by Appellants' argument. We find that the asserted uses of the claimed polynucleotides—as a component of a DNA chip for monitoring gene expression, as a marker for a given chromosomal locus, or for defining the exon splice-junctions of a gene—do not satisfy the utility requirement of § 101. Such uses do not provide a specific benefit in currently available form.

For example, with regard to the asserted “DNA chip” utility, we accept for argument's sake that a person skilled in the art could attach one of the claimed polynucleotides (or a part of it) to a solid substrate, in combination with other polynucleotides, to form a DNA chip. We can also accept that such a DNA chip could be used to monitor changes in expression of the corresponding gene. However, the specification provides no guidance to allow a skilled artisan to use data relating to the expression of the putative KIP gene in any practical way. The specification provides no guidance regarding what the KIP gene-specific information derived from a DNA chip would mean.

Assume, for example, that a fragment of SEQ ID NO:1 was attached to a DNA chip and the researcher observed that expression of the corresponding gene was increased when a cell was treated with a particular agent. The specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful. Maybe the meaning in a change in expression of the gene would depend on other factors, but again the specification provides no hint what other factors might be important. Would it depend on what agent is used, what cell type is used, the behavior of other genes (if so, which genes and what behavior is significant), the degree of increase? Because the

specification provides no information about the activity of the protein encoded by the claimed polynucleotides, it provides no guidance as to how to interpret the results of a DNA chip-based gene expression assay based on the claimed polynucleotides.

The same problem afflicts Appellants' assertions that the claimed polynucleotides can be used to map a particular chromosomal locus or to define the exon splice-junctions of the genomic gene. The specification provides no meaningful guidance regarding how to use such information in any practical way. Assume, for example, that SEQ ID NO:1 hybridizes to a specific part of human chromosome 3, or that SEQ ID NO:1 can be used to show that the chromosomal gene has an exon splice junction between nucleotides 103 and 104: the specification provides no guidance on how such information would allow those skilled in the art to use the claimed polynucleotides in a specific, substantial way. By contrast, if the specification disclosed, for example, that SEQ ID NO:1 hybridized adjacent to a chromosomal locus associated with a known disease (e.g., a locus susceptible to a cancer-causing translocation), the sequence would have an apparent utility in disease diagnosis. However, without disclosure of a specific use for the resulting data, using the claimed sequences for mapping or determining exon splice-junctions amounts to research on the claimed polynucleotides themselves.

In effect, Appellants' position is that the claimed polynucleotides are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. We do not

agree that such a disclosure provides a “specific benefit in currently available form.” Rather, the instant case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, Appellants claim a product asserted to be useful in a method of generating gene-expression or gene-mapping data, but the specification does not disclose how to interpret those data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the end-product, the product claims here lack utility, based on their use in, e.g., DNA chips, because the specification does not disclose how to use the KIP gene-specific gene expression data generated by a DNA chip.

Appellants argue that the claimed polynucleotides could potentially be part of a DNA chip; since DNA chips have utility, compounds that “enhance the utility of such DNA chips, such as the presently claimed nucleotide sequence, must also be useful.” Appeal Brief, page 5 (emphasis in original). We disagree.

Assuming arguendo that a generic DNA chip—one comprising a collection of uncharacterized or semi-characterized gene fragments—would provide a useful tool for, e.g., drug discovery, it does not follow that each one of the polynucleotides represented in the DNA chip individually has patentable utility. Although each polynucleotide in the DNA chip contributes to the data generated by the DNA chip overall, the contribution of a single polynucleotide—its data point—is only a tiny contribution to the overall picture.

The Brenner Court held that § 101 sets more than a de minimis standard for utility. Therefore, the patentable utility of a DNA chip, for example, does not necessarily mean that every one of the components of the DNA chip also has patentable utility. A patentable utility divided by a thousand does not necessarily equal a thousand patentable utilities. Each claimed invention must be shown to meet § 101's utility requirement in order to be patentable; it must provide a specific benefit in currently available form. Providing a single data point among thousands or millions, even if the thousands or millions of data points collectively are useful, does not meet this standard.

The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, an inventor discloses his invention to the public. See Brenner, 383 U.S. at 534, 148 USPQ at 695. The Brenner Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure that justifies granting him the right to exclude others. See id.

In this case, Appellants seek the right to exclude others from using any polynucleotide encoding the sequence of SEQ ID NO:2. In return, Appellants contend that they need not disclose the biological role or activity of the encoded protein. See the Appeal Brief, pages 4-5 (“[K]nowledge of one or more particular kinase[s] with which the presently claimed sequence interacts is not required to

track expression patterns using a DNA chip.”). We do not agree that such a disclosure satisfies § 101. The basic quid pro quo of the patent system, as interpreted by the Brenner Court, is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention. The generic utilities disclosed for the claimed products in this case do not entitle Appellants to the legal right they claim.

We note that this application is one of several on appeal that share the same assignee.<sup>5</sup> In each of these cases, regardless of the specific facts of the case, the appellants have argued that the claimed polynucleotide can be used in DNA chips. It would therefore appear that Appellants are using the asserted DNA chip utility as a stalking horse, to provide a utility that can be asserted for any cDNA they isolate, regardless of how little is known about it, which (they hope) will nonetheless serve as a basis for patent protection of all related products and methods and secure for Appellants any value that might become apparent in the future, after they or others have further characterized the claimed products. This is precisely the type of result that the Brenner Court sought to avoid by requiring disclosure of a substantial utility to satisfy § 101. See 148 U.S. at 535-36, 148 USPQ at 696: [The Court was not] “blind to the prospect that what now seems without ‘use’ may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” Id.

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<sup>5</sup> The applications referred to are: 09/460,594 (Appeal No. 2003-1528), 09/804,969 (2003-1794); 09/802,116 (2003-2017); 09/822,807 (2003-2028); and 09/564,557 (2004-0343).

The polynucleotides of the instant claims may indeed prove to be useful (and valuable), after the in vivo role of the encoded protein is discovered. The work required to confer value on the claimed products, however, remains to be done. The instant specification's disclosure does not justify a grant of patent rights. See Brenner, 383 U.S. at 534, 148 USPQ at 695: “[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development.” We consider the Brenner Court's concern about the “power to block off whole areas of scientific development” to be equally applicable here.

Finally, in addition to being contrary to controlling case law, the per se rule that Appellants seek—that any expressed human gene has utility because it can be used in a DNA chip—would disserve the patent system. In the first place, it is unclear what, if anything, limits Appellants' proposed rule. Appellants have asserted that this rationale would apply to polynucleotides that encode a polypeptide with an unknown biological role. See the Appeal Brief, pages 4-5. It is also apparent that it applies not only to intact genes, but to fragments of them as small as eight nucleotides long. See the specification, page 6, lines 10-17.

Nor can the rationale be confined to expressed human genes. We can take judicial notice of the fact that other organisms are of interest for many different reasons, such that gene expression assays could conceivably be used in their research. For example, some organisms are of interest to researchers because they have been historically well-studied (e.g., yeast, Arabidopsis, C. elegans, Drosophila). Other organisms are of interest because they are used as animal models for testing pharmaceuticals (e.g., mice, chimpanzees, rhesus monkeys, rabbits), or because they are commercially valuable (e.g., pigs, cows, corn, rice, tomatoes), or because they are pests (e.g., fungi such as Fusarium, common weeds like ragweed, insects such as corn borers, nonnative invaders such as zebra mussels, etc.), or because they are pathogens (e.g., Candida, various bacteria, tapeworms, etc.). Under Appellants' proposed rule, every eight base pair-long fragment of any gene of any of these organisms—and probably most other organisms—would be found to have patentable utility because it could be attached to a chip and used in “research” to see what happens to expression of that gene under various conditions.

Appellants' reasoning would also vitiate the enablement requirement, since “[t]he enablement requirement is met if the description enables any mode of making and using the invention.” Johns Hopkins Univ. v. CellPro Inc., 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1714 (Fed. Cir. 1998) (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991)). If we were to agree with Appellants that any expressed gene and any eight base pair-long fragment thereof is useful in a DNA chip, then we would also

have to hold that the specification has taught those skilled in the art one mode of using the invention. Thus, Appellants' rule of per se utility would also require a corresponding rule of per se enablement.

Under Appellants' rule, therefore, it would seem that a polynucleotide would be patentable if it was adequately described in the specification and was not disclosed or suggested in the prior art. This standard, however, is not the one set by Congress, which requires that a patentable invention also be useful and fully enabled, nor is it the standard that has been consistently applied by the courts.

#### Summary

The patent system is based on a balancing of interests. "Patents . . . are meant to encourage invention by rewarding the inventor with the right, limited to a term of years fixed by the patent, to exclude others from the use of his invention. . . . But in rewarding useful invention, the 'rights and welfare of the community must be fairly dealt with and effectually guarded.' Kendall v. Winsor, 21 How. 322, 329 (1859). To that end the prerequisites to obtaining a patent are strictly observed. . . . To begin with, a genuine 'invention' or 'discovery' must be demonstrated 'lest in the constant demand for new appliances the heavy hand of tribute be laid on each slight technological advance in an art.'" Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230, 140 USPQ 524, 527 (1964).

The basic quid pro quo of the patent system requires disclosure of an invention having substantial utility. Appellants' disclosure in this case does not provide a specific benefit in currently available form, and therefore lacks the

substantial utility required by 35 U.S.C. § 101. The examiner's rejections under 35 U.S.C. §§ 101 and 112, first paragraph, are affirmed.

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

AFFIRMED

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
William F. Smith	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Eric Grimes	)	
Administrative Patent Judge	)	

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