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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte Y. TOM TANG, PREETI G. LAL, JENNIFER L. JACKSON, HENRY YUE, KARL J. GUEGLER, NEIL C. CORLEY, OLGA BANDMAN, CHANDRA S. ARVIZU, GINA A. GORGONE, MATTHEW R. KASER, MARIAH R. BAUGHN, and JANICE K. AU-YOUNG

Appeal 2017-003227
Application 14/471,727[1]
Technology Center 1600

Before JOHN G. NEW, JOHN E. SCHNEIDER, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an antibody that specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:74, which have been rejected as not being supported by a specific and substantial asserted utility, failing to meet the how to use enablement requirement, and as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Appellants identify the real party in interest as Incyte Corporation. (Appeal Br. 2.)

We affirm.

STATEMENT OF THE CASE

Appellants' have substantially purified 79 polypeptides that they refer to as "human transmembrane proteins" (HTMPN). (Spec. 10–11, 23.) They have derived the nucleic sequence encoding these polypeptides and predict transmembrane sequences. (Spec. 14, 23–24, *see also* Tables 1 and 2.) SEQ ID NO: 153 is the polynucleotide sequence encoding the polypeptide of SEQ ID NO: 74. (Spec at 77 (Table 1).) Appellants have also detected tissue categories expressing these HTMPNs using northern analysis. (Spec. 24, 60, 93 (Table 3).) SEQ ID NO: 153 was found to be expressed in reproductive, nervous, and gastrointestinal tissue. (Spec. 93 (Table 3).) The Specification does not disclose any biological function or activity for any of these HTMPNs. Table 3 of the Specification simply lists, in the third column, diseases, disorders, or conditions associated with the tissues in which the HTMPN was found to be expressed. (Spec. at 23–24.)

Claims 21 and 23–33 are on appeal.[2] Claim 21 is representative and reads as follows:

> 21. An isolated antibody or fragment thereof that specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO: 74.

(Appeal Br. 12.)

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[2] Claims 34–37 are directed to a non-elected invention and have been withdrawn. (Final Action 2.)

The following grounds of rejection by the Examiner are before us on review:

Claims 21 and 23–33 under 35 U.S.C. § 101 as not being supported by a specific and substantial or credible real world asserted utility.

Claims 21 and 23–33 under 35 U.S.C. § 112, 1st paragraph as the specification fails to adequately teach how to use the claimed invention.

Claims 21 and 23–33 under 35 U.S.C. § 102(b) as anticipated by McNagny.[3]

DISCUSSION

§101 Lack of Utility and §112, ¶ 1 Lack of Enablement

There is a common issue presented with regard to the rejections under 35 U.S.C. § §101 and 112, ¶ 1, which is whether the claimed antibody has a specific and substantial utility. We treat both rejections together. Furthermore, because Appellants have not argued the claims separately, we focus our analysis on representative claim 21. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner finds that the Specification discloses that the inventors "are in possession of a novel protein of SEQ ID NO: 74." (Final Action 5.) The Examiner, further finds, however, that the Specification has only provided a partial description of the protein "in the form of a predicted amino acid sequence" to which the claimed antibody is to specifically bind, and "does not disclose the physical or structural properties of that protein," or "the biological role" of it, "or its significance." (Final Action 3.) The Examiner notes that, while the Specification indicates that analytical methods have shown that the claimed antibody that binds to the polypeptide

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[3] McNagny et al., US 7,833,733 B2, issued Nov. 16, 2010.

of SEQ ID NO:74 "has consensus sequences or specific domains that are *homologous* to 2-membrane spanning signal peptide containing transmembrane protein[,]" "there is no actual and specific significance that can be attributed to said novel polypeptides identified in the specification, except the prophetic recitation of potential uses, which include the use in diagnosis, treatment, or prevention of immune, reproductive, smooth muscle, neurological, gastrointestinal, developmental, and cell proliferative disorders (page 23, lines 26-30)." (*Id.* at 3–4.) The Examiner finds that "[t]he instant specification fails to make any assertions regarding biological activity or asserted uses based on this statement of structural similarity." (*Id.* at 4.)

The Examiner further finds that signal peptide containing transmembrane proteins are noted in the Specification to include a wide range of proteins as follows: "G-protein coupled receptors, scavenger receptors, tetraspanins, tumor antigens, ion channels, proton pumps, ABC transporters, membrane proteins associated with intracellular communications, endoplasmic reticulum membrane proteins, mitochondrial membrane proteins, lymphocyte and leukocyte membrane proteins, apoptosis-associated membrane proteins, and tumorgenesis (see pages 3–10 of the specification)." (*Id.* at 6.) And the Examiner further finds that "[t]he specification does not assert that the protein encoded by the claimed polynucleotide is a member of a protein family." (*Id.*) The Examiner points to articles that postdate the earliest claimed effective filing date of the present Application on appeal (e.g., May 29, 1998) that state that the type of similarity of structure described in the Specification does not support assigning any particular function to the novel polypeptide SEQ ID NO: 74.

(*Id.* at 6–7 (citing Attwood[4] and Skolnick[5]).) Indeed, finds the Examiner, the relevant scientific publications indicate that "[e]ven in situations where there is some confidence of a similar overall structure between two proteins, [which is not the case here] only experimental research can confirm the artisan's best guess as to the function of the structurally related protein." (*Id.*)

Moreover, the Examiner finds that "the antibodies of the instant invention cannot be linked to a disease state or treating diseases listed in page 37, line 25 to page 40, line12." (*Id.* at 4.) That is "[i]n the absence of knowledge of what the protein of SEQ ID NO: 74 is, what function the protein has, or the biological significance of this protein, there is no immediately obvious patentable use for the antibody of the instant invention." (*Id.* at 7.) The Examiner concludes that "[s]ince the instant specification does not disclose a credible 'real world' use for claimed antibody to [the] protein of SEQ ID NO: 74, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful." (*Id.*)

The Examiner further addresses the assertion during prosecution that "the claimed antibody has a specific, substantial and credible utility as a tissue marker in applications such as forensic work, stem cell differentiation, or biopsy sample analysis." (*Id.* at 8–11.) The Examiner notes that there is no assertion in the Specification that "the claimed antibody that specifically

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[4] Attwood, *The Babel of Bioinformatics*, 290 Science, 471–473 (2000)
[5] Skolnick et al, *From Genes to Protein Structure and Function: Novel Applications of Computational Approaches in the Genomic Era*, 18(1) Trends in Biotech., 34–39 (2000)

binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 74 can be used or should be used as tissue markers for any particular tissue." (*Id.* at 9.) That is so, finds the Examiner, even though the Specification states: "Northern analysis shows the expression of this sequence in reproductive, nervous, and gastrointestinal cDNA libraries. Approximately 88.5% of these libraries are associated with cell proliferation, and 15.4% with inflammation." (*Id.*) The Examiner notes that because the polynucleotide encoding the polypeptide of SEQ ID NO: 74 (i.e., SEQ ID NO: 153) is found in each of reproductive, nervous, and gastrointestinal libraries, it cannot be used as a marker for tissue in a single one of those categories. (*Id.*) The Examiner finds that the claimed antibodies "could be used to determine what kind of tissue a sample is NOT (based on lack of expression from certain libraries) [.]" (*Id.*) The Examiner notes that "there is no evidence or line of reasoning" in support of the assertion that the specific binding of the claimed antibody to a polypeptide of SEQ ID NO: 74 that is selectively expressed in reproductive, nervous, and gastrointestinal provides for the claimed antibody having a specific, substantial and credible utility as a tissue marker in applications such as forensic work, stem cell differentiation, or biopsy sample analysis. (*Id.* at 10.) The Examiner notes that the Specification does not provide "guidance on how assessment of an unknown tissue sample as being one of reproductive, nervous and gastrointestinal tissues would provide immediate benefit to one of ordinary skill in the art at the time the invention was made." (Ans. 11.) The Examiner further finds that "[t]he expression data presented in the instant application does not even permit the skilled artisan to make a determination that a particular tissue type was in hand; in that 'reproductive' includes

several different tissue types such as uterine and ovarian. This is also true for gastrointestinal and nerve tissues[.]" (*Id.* at 11–12.) The Examiner further explains that "[t]he prophetic examples [of use in forensic work, stem cell differentiation, or biopsy sample analysis] find no support in [the] art at the time of the instant invention." (*Id.* at 12.) The Examiner concludes that in light of the fact that the antibody "cannot be used to determine a tissue type, but rather, only a subset of potential tissues from a list of 11 tissue types[,]" that there is not a specific or substantial utility. (Ans. 13–15, Final Action at 10–11.)

We agree with the Examiner's factual findings and conclusion that the claimed invention lacks utility.

Related Case Discussion

We note that utility is an issue that has been raised in application's from which this application claims continuity, and also in a similar application with similar disclosure and overlapping inventorship. Appellants direct our attention to one of them, *Ex parte Tang*, Appeal No. 2011-002119 (November 30, 2011) (Appeal Br. 6) (the 2119 Appeal), and the Examiner refers us to another *Ex parte Lal*, Appeal No. 2011-005611 (August 29, 2012) (Ans. 9). We find there is at least one other appeal of relevance.

In particular, Application 09/700,590, to which the present application on appeal claims continuity from, whose claims were directed to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 22, was rejected for lack of utility. *Ex Parte Lal*, Appeal No. 2006-1274 (the 2006 Appeal). In that case, one assertion of utility was premised on similarity of SEQ ID NO:22 to mouse Ring3 protein—a protein with a known role in cell proliferative and immune disorders—, based on 57% homology over 548

amino acid residues and the presence of a bromodomain—a domain found in various transcriptional regulators. (2006 Appeal at 6–7.) The panel explained that the fact of 57% homology over part of the mouse Ring3, where human Ring3 and mouse Ring3 are known to be 96.4% identical over the entire 805 amino acid sequence, demonstrates that the claimed polypeptide is not human Ring3. (*Id.* at 8.) The panel explained that while "it is reasonable to conclude that" the polypeptide "is somehow related[, e.g., shares an ancestral gene at some point in the past,] to mouse Ring 3, the sequence similarity and relatedness does not establish patentable utility". (*Id.* at 7–8.) Appellants in that case also asserted utility that was not premised on how the polypeptide functions: that utility was premised on "numerous practical, beneficial uses in [gene expression monitoring applications, e.g.,] toxicology testing, drug development, and the diagnosis of disease, none of which requires knowledge of how the polypeptide coded for by the polynucleotide actually functions." (*Id.* at 8–9.) Appellants provided a declaration in support of such utilities. (*Id.* at 9.) The panel explained that such generic utilities "are 'merely hypothetical possibilities, objectives with the claims [cDNAs] . . . could possibly achieve, but none for which they have been used in the real world.'" (*Id.*) The panel determined that the asserted utilities were not, therefore, substantial. Moreover, the panel explained that any cDNA transcribed from any gene in the human genome could be used in the same way, and thus the utilities were not specific. (*Id.* at 10.)

In Application 11/594,148 (the application at issue in *Ex parte Tang*, the 2119 Appeal), to which the present application on appeal claims priority, and whose claims were directed to an isolated polynucleotide encoding a

polypeptide comprising an amino acid sequence having at least about 95% sequence identity to the full-length of SEQ ID NO: 74 was also rejected for lack of utility. 2119 Appeal at 1. In a split decision, the utility rejection was reversed. A majority of the panel found that the assertion of utility as a tissue marker for nervous, reproductive, and gastrointestinal tissue in forensic work, stem cell differentiation, or to confirm the identity of biopsy tissue or what the tissue is not, was not rebutted by the Examiner, and was sufficient to meet the low utility threshold. (2119 Appeal at 7.) The dissenting judge, however, pointed out where the Examiner explained with scientific reasons why the tissue marker use is not specific or substantial and that Appellants' did not provide counter evidence or reasoning why a marker which does not uniquely identify a tissue but rather only identifies a tissue as one out of three possibilities would be useful in forensic work, stem cell differentiation or biopsy confirmation. (2119 Appeal (Fredman dissent) at 12–13.) The dissent poses the question "how many tissues can a polynucleotide be expressed and remain viable as a 'tissue marker'"? (*Id.* at 14.) The dissenting judge noted that Appellants asserted that β-actin, which is expressed in multiple tissues, but not all tissues, lacks utility as a tissue marker. (*Id.*)

Appeal No. 2011-005611, (the 2012 *Ex parte Lal* case to which the Examiner refers in the present appeal), concerned claims in Application 11/386,937, with claims to a polypeptide similar to those in the 2119 Appeal and with a Specification having the same minimal disclosure as to function and structure for such a polypeptide as in the 2119 appeal. (Application 11/386,937 Ans. 4 ("The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The

instant application does not disclose the biological role of this protein or its significance. . . The specification states that the claimed polynucleotide encodes a protein which shares 24% identity with rat OX-45 antigen preprotein, but makes no further statement or assertion regarding this structural relationship.").) Appellants in that case, just as in the present appeal and the 2119 Appeal, asserted utility of the invention as a tissue marker. (Application 11/386,937 Appeal Br. 10, Ans. 10.) In a unanimous opinion post-dating the 2119 Appeal, the same panel as that in the 2119 Appeal affirmed the lack of utility for the reasons asserted by the Examiner. (Appeal No. 2011-005611 Decision at 2.) Those reasons were the same as discussed by the dissent in the 2119 Appeal. (Application 11/386,937 Ans. at 10–13.)

Appellants argue that, in light of the decision in the 2119 appeal, we should find "an antibody that specifically binds to the same polypeptide (SEQ ID NO:74) to possess at least the same utility as a tissue marker identifier." (Appeal Br. 7.) We decline to render our conclusion on utility in this case solely on the basis of the split decision in the 2119 appeal. It is well-settled that each case is decided on its own facts and necessarily involves the exercise of reasoned discretion. *See In re Gyurik,* 596 F.2d 1012, 1018, n15 (CCPA 1979) ("In reviewing specific rejections of specific claims, this court does not consider allowed claims in other applications or patents.") The disposition of the 2119 appeal involves different claims than the ones on appeal here and it is not a precedential decision. Furthermore, that decision was not unanimous in its holding that the asserted utility of being a tissue marker is a substantial and specific utility for the polypeptide comprising an amino acid sequence of SEQ ID NO: 74. Additionally,

Appeal No. 2011-005611, decided after the 2119 Appeal and involving a similar polypeptide claim and a specification having a similar disclosure as in the 2119 appeal, unanimously affirmed the Examiner's rejection of lack of utility under 35 U.S.C. § 101 for the same reasons provided in the dissent in the 2119 appeal, and by the same panel of judges as the 2119 panel. We provide an independent review of the utility issue based on the facts presented in this case and the legal framework explained below.

Legal Framework

Section 101 provides: "Whoever invents . . . any new and *useful* ... composition of matter ... may obtain a patent therefor . . . ." (Emphasis added). In other words, a patent cannot be granted where utility has not been disclosed or is not readily apparent.

The Supreme Court announced in *Brenner v. Manson*, 383 U.S. 519 (1966) what is required to establish usefulness under section 101, stating:

> 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.* 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.

Brenner, 383 U.S. at 534–35 (emphases added). Thus, the utility requirement under § 101 must be substantial and specific. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

"Courts have used the labels 'practical utility' and 'real world' utility interchangeably in determining whether an invention offers a 'substantial' utility." *Id.* "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some

future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *Id.*

"Turning to the 'specific' utility requirement, an application must disclose a use which is not so vague as to be meaningless." *Id.*

ANALYSIS

Appellants asserted utility in the Specification for the seventy-nine "new human transmembrane proteins" discovered is a prophetic recitation of potential uses "for the diagnosis, treatment, or prevention of immune, reproductive, smooth muscle, neurological, gastrointestinal, developmental and cell proliferative disorders." (Spec. 23:27–30.) There is no category of disorder, much less specific condition, particularly identified for any of the transmembrane proteins discovered, much less for amino acid SEQ ID NO: 74. Indeed, the Specification does not disclose any biological function or activity for any of the novel seventy-nine proteins discovered. The Specification does not even disclose the physical or structural properties of the predicted protein with the amino acid sequence set forth in SEQ ID NO: 74, though it is identified as a transmembrane protein. (*See* Spec. 85 (Table 2.) That this amino acid sequence is a transmembrane provides no information that is specific or substantial as to the utility of the polypeptide comprising amino acid SEQ ID NO: 74, as the Specification discloses that transmembrane proteins include

- G-protein coupled receptors, which "include receptors for biogenic amines, lipid mediators of inflammation, peptide hormones, and sensory signal mediators";

- scavenger receptors that "may participate in the binding of low density lipoproteins (LDL) and foreign antigens";
- the transmembrane 4 or tetraspan family, which includes "platelet and endothelial cell membrane proteins, melanoma-associated antigens, leukocyte surface glycoproteins, colonal carcinoma antigens, tumor-associated antigens, and surface proteins of the schistosome parasites";
- tumor antigens;
- ion channels;
- proton pumps, "a large class of membrane proteins that . . . generate an electrochemical proton gradient across a membrane";
- ATP-binding cassette transporters, "a superfamily of membrane proteins that mediate transport and channel functions in prokaryotes and eukaryotes";
- proteins involved with exocytosis and endocytosis, and those associated with lysosomes and peroxisomes;
- endoplasmic reticulum membrane proteins;
- mitochondrial membrane proteins;
- lymphocyte and leukocyte membrane proteins; and
- membrane proteins associated with apoptosis and tumorigenesis.

(Spec. 3–10.) And, the Specification does not even identify a specific family of transmembrane protein to which the polypeptide comprising amino acid SEQ ID NO: 74 belongs. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the amino acid SEQ

ID NO: 74 was, as of the filing date, useful in any one of the prophetic uses set forth in the Specification. We agree with the Examiner that the scientific publications of Attwood and Skolnick support that conclusion. Thus, as the Examiner explained, any antibody that specifically binds to the polypeptide that has amino acid SEQ ID NO: 74 also cannot be linked to a disease state or treating diseases.

Much like was the case in *Fisher*, in the face of the utility rejection, here, Appellants have not presented any evidence showing that the amino acid sequence of SEQ ID NO:74 has been used in any of the application asserted utilities, much less an antibody that specifically binds to that sequence. Indeed, there does not appear to be any dispute that there is no substantial and specific utility set forth in the Specification, as Appellants instead argue that the claimed antibody has utility as a tissue marker identifier, (Appeal Br. 7–8), which is mentioned nowhere in the Specification.

It is true that the utility of an invention need not be set forth in the Specification; however, any such asserted utility must be, like one stated in the Specification, well-established, and not conjectural. *See In re Folkers*, 344 F.2d 970, 975 (CCPA 1965) ("Since appellants' newly discovered compounds belong to a class of compounds, the members of which have become well recognized as useful for a particular purpose because of a particular property, the only reasonable conclusion is that the new compounds, also possessing that property, are similarly useful.") *see also In re Kirk*, 376 F.2d 936, 945 (CCPA 1967) (noting that neither a product of only conjectural use nor a process to make such a product are "useful" within § 101). As the Federal Circuit explained in *Fisher*, asserted uses

which "represent merely hypothetical possibilities, objectives which the claimed [compound]. . . *could* possibly achieve, but none for which they have been used in the real world," where such uses are not well-established, is insufficient to meet the 101 standard absent evidence. *Fisher*, 421 F.3d at 1373.

Appellants contend that the Supreme Court asserted "'to violate Section 101 the claimed [invention] must be totally incapable of achieving a useful result.' *Brenner v. Manson*, 383 U.S. 519, 534 (1966)" and that as long as Appellants have provided an identifiable benefit of the claimed invention that is sufficient. (Reply Br. 4.) However, the Supreme Court did not articulate so broad a standard. The quoted statement by Appellants was made by the Federal Circuit in a case addressing a different issue of utility—whether claimed subject matter was inoperable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571–73 (Fed. Cir. 1992) (finding that there was sufficient evidence at trial to support the jury's finding that the claimed invention was not "totally incapable of" operability). Thus, not even the Federal Circuit has embraced the broad standard asserted by Appellants, *i.e.*, any identification of an identifiable benefit of the claimed invention is sufficient to meet the utility requirement of § 101. As discussed above, the standard for the test of usefulness under § 101 is a specific and substantial utility, *Brenner,* 383 U.S. at 534–35, and not one that is merely conjectural. *Fisher*, 421 F.3d at 1374.

The Examiner has explained why Appellants asserted use of the claimed antibody is conjectural. "[T]he specification provid[es] no guidance on how assessment of an unknown tissue sample as being one of reproductive, nervous, or gastrointestinal tissue would provide immediate

benefit to one of ordinary skill in the art at the time the invention was made." (Advisory Action 2; Ans. 11). "The expression data presented in the instant application does not even permit the skilled artisan to make a determination that a particular tissue type was in hand." (Ans. 11–12.) What may be determinable is that the tissue belongs to one of "reproductive, gastrointestinal or nerve" tissue genera. However, "this does not support an assertion that the claimed polynucleotides can be used to as markers for reproductive, nervous or gastrointestinal tissues because it cannot distinguish between the 3 generic types of tissue as it is found in all three types." (*Id.* at 9.) The antibodies to the polynucleotide encoding SEQ ID NO: 74 "cannot be used to confirm a particular tissue because the encoded polypeptide is expressed in reproductive, nervous, and gastrointestinal tissues." (*Id.* at 10.) Thus, the Examiner finds: "It is not clear how one can assert that the claimed invention is useful as *a tissue marker* when it cannot be used to determine *a tissue type*." (*Id.* at 10–11 (emphasis added).) "For example, β-actin is a protein that is expressed in many different tissues and would not be considered an appropriate tissue marker for this reason." (*Id.* at 11.)

According to Appellants, "[t]he fact that the polypeptide of SEQ ID NO: 74 is selectively expressed in reproductive, nervous and gastrointestinal tissues . . . is more than sufficient for applications such as forensic work, stem cell differentiation testing, or to confirm the identity of biopsy tissue." (Appeal Br. 7–8.) For example, Appellants assert that one of skill in the art "*may simply wish* to narrow down the scope of differentiated tissue types based on the expression of a tissue marker." (Appeal Br. 8 (emphasis added); Reply Br. 3.) Appellants further note that in "testing of early stage stem cell differentiation," "the skilled artisan *may simply wish* to narrow

down the scope of differentiated tissue types based on the expression of a tissue marker." (*Id.* (emphasis added).)

However, as the Examiner notes, "Appellant[s have] provided no evidence to support" that the fact that a protein could be narrowed to be one of possibly three different classes of tissue "would have provided any substantial or real world utility to the person of ordinary skill." (Ans. 12). In other words, what evidence is there that the "narrow[ing] down" to three classes of tissue is a real-world utility?

Appellants' tissue marker utility in forensics, stem cell differentiation testing, or identification of biopsy tissues, is simply attorney argument. "Attorney's argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974). Moreover, the attorney argument is conjectural as to the utilities asserted. For example the argument is that "a skilled artisan *may simply wish* to distinguish a gastrointestinal tissue sample from a cardiovascular tissue sample" (Reply Br. 3). Moreover, as the Examiner explained (Ans. 11–12), the antibody itself would not be able to establish the tissue sample was gastrointestinal, as the polypeptide to which the antibody binds is also noted to be expressed in reproductive and nerve tissue.

The attorney argument is not supported by inventor testimony, nor evidence, such as by articles or other industry testimony. If the attorney asserted utility were well-established and not simply conjectural one would expect that inventor testimony, articles, or other industry testimony would have been readily available and submitted in light of the fact that the question of utility as to the disclosed novel polypeptides identified in the present Specification has been ubiquitous throughout the prosecution of this

family of applications and for at least a decade. *See e.g.*, 2006 Appeal discussed above (in which Declaration evidence was provided by Appellants during prosecution to respond to the Examiner's lack of utility rejection in Application 09/700,590, the great-grandparent application of the application presently on appeal, as to claims directed to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:22).

For the reasons discussed, we find that the Examiner has provided scientific reasoning to challenge Appellants' asserted utility. We find that Appellants have not established with evidence that any of the asserted "uses" are well-established and not conjectural. Just as with the asserted utilities set forth in the Specification, Appellants have not presented any evidence showing that the amino acid sequence of SEQ ID NO:74, which cannot differentiate a specific tissue, has been used as a tissue marker or that such use is, nevertheless, well-established. In light of the foregoing, we, therefore, find a preponderance of the evidence on this record supports the Examiner's position that the claimed invention does not have a substantial and specific utility.

Appellants argue that the inventors have provided more information in the Specification regarding the disclosed HTMNPs than the inventors in *Fisher* provided regarding the ESTs involved in that appeal, including things the Federal Circuit criticized the inventors in *Fisher* for failing to do in its reasoning affirming the Board's conclusion that the Examiner had established that there was a lack of utility, and that such disclosure supports a finding that the claimed antibody has a specific, substantial and credible utility. (Appeal Br. 9–10.) We do not find this argument persuasive. Appellants concede that there is insufficient information regarding function

of the polypeptide that has amino acid SEQ ID NO: 74 to establish a utility based on such a function. (*See* Appeal Br. 7–8 (arguing only that the claimed antibody has utility as a tissue marker identifier).) Moreover, for the reasons discussed by the Examiner, the gene expression information is insufficient to establish that the claimed invention has a well-defined and particular benefit to the public. Furthermore Appellants have not established with evidence that the fact that a tissue sample could be identified as being reproductive tissue, gastrointestinal tissue, or nervous tissue, although not being able to identify by that sequence alone that the tissue belongs to only one of those categories, would be of any real world benefit, rather than conjectural benefit, in forensic work, stem cell differentiation or confirming identity of biopsy tissue.

For the reasons discussed, Appellants do not persuade us that the Examiner erred in maintaining the rejection of claim 21 as not being supported by a specific and substantial utility as required under 35 U.S.C. § 101.

Claims 23–33 have not been argued separately and therefore fall with claim 21. 37 C.F.R. § 41.37(c)(1)(iv).

Moreover, in light of our conclusion regarding the lack of utility, we also find that the preponderance of evidence supports the Examiner's conclusion that claims 21 and 23–33 are not enabled as to how to use the claimed antibody as required under 35 U.S.C. § 112, first paragraph.

II

Anticipation

The Examiner finds claims 21 and 24–33 are anticipated by U.S. Patent 7,833,733. The Examiner's rejection is premised on the fact that the

claimed invention is not entitled to the benefit of any of the earlier filed applications under 35 U.S.C.§ 120 because these earlier applications fail to meet the how to use requirement under 35 U.S.C. § 112, first paragraph for the reasons discussed above regarding lack of utility. (Final Action 14.) Appellants' do not contest any other aspect of the Examiner's anticipation rejection. (Appeal Br. 11.)

We agree with the Examiner's conclusion regarding lack of benefit. The Specification of the earlier filed applications is the same as that supporting the present application. (*Id.*) As discussed above, we agree with the Examiner that the Specification fails to enable how to use the claimed invention. Thus, we agree with the Examiner that the claims cannot claim benefit under 35 U.S.C. § 120 of the effective filing date of any of the earlier effective filed applications. Consequently, we also agree with the Examiner that U.S. Patent 7,833,733 qualifies as prior art.

SUMMARY

We affirm the rejection of claims 21 and 23–33 under 35 U.S.C. § 101 as not being supported by a specific and substantial or credible real world asserted utility.

We affirm the rejection of claims 21 and 23–33 under 35 U.S.C. § 112, 1st paragraph as the specification fails to adequately teach how to use the claimed invention.

We affirm the rejection of claims 21 and 23–33 under 35 U.S.C. § 102(b) as anticipated by McNagny.

TIME PERIOD FOR RESPONSE

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

AFFIRMED