

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD BELANGER, CAROLINE LABBE,
and YALI CHENG

Appeal 2007-3898
Application 10/443,976
Technology Center 1600

Decided: April 25, 2008

Before DEMETRA J. MILLS, LORA M. GREEN,
and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GREEN, *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 9, 11-15, and 17-19. We have jurisdiction under 35 U.S.C. § 6(b). Claim 9 is representative of the claims on appeal, and reads as follows:

9. A fungus of the genus *Pseudozyma* genetically transformed with an expression vector capable of directing the production of a recombinant polypeptide, wherein said expression vector comprises a promoter originating from a species of fungi and said promoter is active in the genus *Pseudozyma*.

We affirm.

BACKGROUND

The Specification notes that the “invention relates to the use of fungi as a host in a host-vector system and method for the production of recombinant proteins.” (Spec. 1.) According to the Specification:

Over the past few years, genetic transformation systems have been successfully developed for many organisms, including fungi. However, *Pseudozyma* spp. appeared neglected since neither methods to perform genetic transformation nor production of recombinant products within these organisms are known at this time.

(*Id.* at 2.)

As to the *Pseudozyma* species used, the Specification teaches that “the strain of *Pseudozyma* utilized to produce such proteins may be *Pseudozyma antarctica*, *Pseudozyma aphidis*, *Pseudozyma flocculosa*, *Pseudozyma fusiformata*, *Pseudozyma prolifica*, *Pseudozyma rugulosa*, *Pseudozyma tsukubaensis* or any fungal strain which can be identified as a member of the *Pseudozyma* genus based on conventional and/or molecular identification techniques.” (*Id.* at 3.) As to the promoters that may be used to drive the expression of recombinant proteins, the Specification teaches that any promoter that is functional in *Pseudozyma* spp. may be used, which include

“a promoter originating from other species of fungi or other organisms . . . , as well as endogenous, synthetic, or chimeric promoters.” (*Id.* at 10.)

The Specification provides examples of driving protein expression in the *Pseudozyma* species *Pseudozyma flocculosa* and *Pseudozyma antarctica*, using the *Ustilago maydis hsp70* promoter (*see, e.g.*, at 15-22, Examples III and IV).

DISCUSSION

Claims 9, 11-15, and 17-19 stand rejected under 35 U.S.C. § 112, first paragraph, “as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” (Answer¹ 4.) As Appellants do not argue the claims separately, claims 11-15 and 17-19 stand or fall with claim 9, and we focus our analysis on claim 9. 37 C.F.R. § 41.37(c)(1)(vii).

“A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (bracketed material in original). The claims in *Lilly* were directed generically to vertebrate or mammalian insulin cDNAs. *See id.* at 1567. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs.

¹ All references to the Answer are to the Examiner’s Answer mailed March 14, 2007.

The *Lilly* court explained that

a generic statement such as. . . ‘mammalian insulin cDNA,’ without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. at 1568. Finally, the *Lilly* court set out exemplary ways in which a genus of cDNAs could be described:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id. at 1569.

Our appellate reviewing court revisited the issue of describing DNA. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F. 3d 956 (Fed. Cir. 2002). The *Enzo* court held that a claimed DNA could be described without, necessarily, disclosing its structure. The court adopted the standard that “the written description requirement can be met by ‘show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.’” *See id.* at 964 (emphasis omitted, ellipsis and bracketed material in original).

Our appellate review court has also noted that “*Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003).

With respect to the use of an assay to support written description, in *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004), the patent claimed a method of selectively inhibiting the enzyme PGHS-2 (also known as COX-2) by “administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human.” *Id.* at 918. The patent “describe[d] in detail how to make cells that express either COX-1 or COX-2, but not both . . . , as well as ‘assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product.[’]” *Id.* at 927.

The court held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of *which* peptides, polynucleotides, or small organic molecules have the desired characteristic, the claims failed to meet the description requirement of § 112. *See id.* (“As pointed out by the district court, the ‘850 patent does not disclose just ‘which “peptides, polynucleotides, and small organic molecules” have the desired characteristic of selectively inhibiting PGHS-2.’ . . . Without such disclosure, the claimed methods cannot be said to have been described.”).

According to the Examiner, Appellants claim

any *Pseudozyma* strain comprising an expression vector comprising a promoter with the ability to express a gene in any *Pseudozyma* species by function only, without any disclosed or known correlation between the elements of such promoters and their function. The [S]pecification only provides teachings of a single promoter (the *Ustilago maydis hsp70* promoter) that has the ability to express a gene in two *Pseudozyma* species. The [S]pecification does not teach what other promoters will necessarily have the ability to express a gene of interest in any other *Pseudozyma* species. Thus, the skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant [S]pecification to see that applicant was in possession of the claimed invention.

(Answer 5.)

The Examiner notes further that the prior the art does not “overcome the deficiencies of the instant [S]pecification,” as there “is no description in the art that allows one to envision a representative number of promoters that are functional in a wide variety of *Pseudozyma* species by disclosing structural or functional features of such promoters.” (*Id.* at 5.) The Examiner cites Cheng², published prior to the priority date of the instant application, for its teaching of a method of transforming and expressing a gene in *P. flocculosa*, which is the *Pseudozyma* species exemplified in the instant Specification (*id.* at 5-6). Cheng, the Examiner asserts,³ transformed

² Cheng et al., “Establishment of a gene transfer system for *Pseudozyma flocculosa*, an antagonistic fungus of powdery mildew fungi,” *Mol. Genet. Genomics*, Vol. 266, pp. 96-102 (2001).

³ Cheng in fact looked at the ability of promoters from other fungal species to confer either Hyg B or benomyl resistance, and not all of the promoters were *hsp 70* promoters (Cheng, p. 97, Table 1). Cheng still demonstrates, however, that four fungal promoters failed to allow for protein expression in *P. flocculosa* (*see* App. Br. 17). Thus, the Examiner’s misstatement as to what Cheng teaches is harmless, and does not change the analysis.

the *Pseudozyma* species with five different plasmids comprising the HygB gene operably linked to *hsp70* promoters from different organisms, but only one of the five promoters allowed for expression of the marker gene (*id.* at 6). According to Cheng, the promoters that did not work had been reported to be functional in a “fairly wide range of hosts.” (*Id.*, quoting Cheng, p. 101, left column.) The Examiner argues that it is unclear from the disclosure of Cheng as to why one promoter worked, while the other four did not, and that Appellants have also not explained what structural properties of the one promoter allowed for expression in *P. flocculosa* (Answer 6).

The Examiner concludes:

Neither the instant [S]pecification nor the state of the art teaches a structure-function relationship for a representative number of promoters that are functional in a broad range of *Pseudozyma* species. The [S]pecification provides a description for a single example, wherein the *hsp70* promoter from *U. maydis* is used to express a gene in a single *Pseudozyma* species, *P. flocculosa*. Although the state of the art confirms this description, it also indicates that a number of functionally related (i.e., *hsp70* promoters derived from different organisms) promoters that are functional in a wide range of organisms are incapable of functioning as promoters in even this single species of *Pseudozyma*. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant [S]pecification.

(*Id.* at 6-7.)

Appellants argue that they were in possession of the claimed invention at the time of filing, as the instant application “describes reduction to practice of protein expression in *Pseudozyma* using an *hsp*⁷⁰ promoter derived from a related Basidiomycetes fungus (*Ustilago maydis*).” (App. Br.

8-9.) Appellants assert further that the Specification describes a broader genus, and thus “one of skill in the art would appreciate that any promoter that can drive expression in *Pseudozyma* could be used in the present invention.” (*Id.* at 9.)

Appellants’ arguments are not convincing, as they are not commensurate in scope with the claimed subject matter. The claims encompass the use of any promoter from any fungal source, and are not limited to promoters from *Pseudozyma* or closely related species such as Basidiomycetes fungus. There is no functional or structural guidance provided by the Specification of promoters from other species of fungus that will allow for protein expression in *Pseudozyma*, other than that the promoter need be functional in *Pseudozyma*.

Appellants assert that the instant Specification, in fact, describes reduction to practice in two *Pseudozyma* species (App. Br. 10). Moreover, Appellants argue citing *In re Rasmussen*, 650 F.2d 1212, 1215 (CCPA 1981), “a single species can adequately describe a genus where the disclosed species includes a functional element and the genus includes a broader limitation related to that function.” (App. Br. 10.) Appellants argue further that Example 18 of the *Revised Interim Written Description Guidelines* also supports their position, as the Example notes that “a broad claim directed to a method for expressing protein in *Neurospora crassa* mitochondria encompassing the use of any promoter is adequately supported by disclosure of a single functional promoter.” (App. Br. 12.) Appellants argue similarly, “function, rather than identity or structure, is critical to the invention.” (*Id.* at 13.)

Appellants' arguments are again not convincing. First, Example 18 of the Guidelines is drawn to a method, whereas instant claim 9 is drawn to a product. Thus, while the disclosure of a single functional promoter may be sufficient to a claim drawn to a method of expressing a protein, more written description is required to a claim to a product comprising a promoter. *See, e.g., Lilly*, 119 F.3d at 1568 (noting that “written description of an invention involving a chemical genus . . . ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.”) The only written descriptive support in the Specification for the genus of promoters active in *Pseudozyma* species is the *hsp*⁷⁰ promoter from a related Basidiomycetes fungus, *Ustilago maydis* (*See, e.g., Spec., Example III*), and deletion mutants thereof (*Spec. Example VI*). The only function provided is that the promoter be active in *Pseudozyma* species. The disclosure of a single species of promoter, with no guidance as to the structure of which other fungal promoters will be active in *Pseudozyma* species, is not sufficient to provide written descriptive support for the broad genus of any fungal promoter that is active in *Pseudozyma* species.

Appellants reliance on *Rasmussen* does not convince us to the otherwise, as that case was drawn to a new matter rejection, *id.* at 1214, and the court found that the newly added language was not new matter as an example in the found in *Rasmussen*'s specification supported the language being objected to as new matter, *id.* at 1215.

Appellants assert, citing *Capon v. Eshhar*, (Fed. Cir. 2005), that compliance with the written description requirement must be considered in the context of the invention and the state of the art (App. Br. 14). According

to Appellants, “the art provides extensive guidance regarding promoter choice.” (*Id.*) Appellants cite to the Declaration of Richard Bélanger filed under 37 C.F.R. § 1.132 (Bélanger Declaration) for the proposition that “one skilled in the art of fungal gene expression would know that using heterologous promoters from a closely related species generally results in successful expression, whereas heterologous promoters from distantly related species are typically unable to drive gene expression.” (*Id.*) Appellants further cite Schillberg⁴ as evidence demonstrating that “(1) heterologous Basidiomycetes promoters generally work in Basidiomycetes fungi and (2) that heterologous Ascomycetes promoters generally do *not* work in Basidiomycetes fungi.” (*Id.*)

We have carefully considered the Declaration, Shillberg, as well as Cheng, and find that they do not support Appellants’ position.

As to the Declaration, the Declaration notes how *Pseudozyma flocculosa* was formerly known as *Sporothrix flocculosa*, and when it was reclassified, the fungus “transited from one of the least evolved groups in the fungal kingdom) (Endomyecetales, Ascomycetes) to one of the most highly evolved (Ustilaginales, Basidiomycetes).” (Declaration, ¶ 4.) In addition, the Declaration notes that “initial attempts at gene expression us[ing] Ascomycetes promoter . . . resulted in little or no gene expression,” whereas promoters from Basidiomycetous fungus resulted in “excellent gene expression.” (Declaration, ¶ 5.) The Declaration notes further that “a substantial corpus of negative results has been published detailing the failure of Ascomycete[s] promoters to function in Basidiomycetes.” (Declaration, ¶

⁴ Schillberg et al., “Transient transformation of the rust fungus *Puccinia graminis* f. sp. *Tritici*,” *Mol. Gen. Genet.*, Vol. 262, pp. 911-915 (2000).

8.) According to the Declaration, “[o]ur work, as published in Cheng and described in the present application, is clearly consistent with the literature. Promoters from a species belonging to a lower class of fungi, such as Ascomycetes, are not functional in *Pseudozyma*, while a promoter from another Basidiomycetes species (*Ustilago maydis*) is functional.” (*Id.*) The Declaration states that “the present [S]pecification provides enablement for use of *Pseudozyma* species transformed with any vector comprising a Basidiomycetes promoter capable of directing the expression of a polypeptide of interest.” (Declaration, ¶ 9.)

Cheng, as the Declaration and the Examiner note, found that the only promoter that allowed for protein expression in *P. flocculosa* was a promoter from *U. maydis*, whereas “none of the vectors containing promoter sequences from ascomycetes allowed selection of transformants in *P. flocculosa*,” that is, none of the promoters from ascomycetes allowed for protein expression in *P. flocculosa* (Cheng, p. 101, second column). Schillberg also notes that “ascomycete promoters cannot drive gene expression in basidiomycetes . . . , indicating that regulatory sequences from ascomycetes are not recognized by the transcriptional machinery or are rapidly inactivated by methylation.” (Schillberg, p. 913, first column.) The reference notes further that for “heterologous gene expression in basidiomycetes, homologous promoter sequences or promoters from other basidiomycetes perform well, demonstrating the importance of promoter choice for the expression of heterologous genes.” (*Id.*, sentence bridging the columns.)

Thus, we do not disagree with the statements in the Declaration, or the references cited by Appellants to support their position. The issue is,

however, the claims are not limited to using a promoter from Basidiomycetes species, but are drawn to any fungal promoter, including those from Ascomycetes, which have been shown not to work. The Specification provides no written description of fungal promoters that allow for expression in *Pseudozyma*, other than promoters from Basidiomycetes species, such as the *hsp70* promoter from *U. maydis*. Thus, the Declaration and references cited by Appellants to support their position as to the written description rejection are not commensurate in scope with the claimed subject matter.

Therefore, for the reasons set forth by the Examiner in the rejection and the reasons set forth above, we affirm the rejection of claims 9, 11-15, and 17-19 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description.

Claims 9, 11-15, and 17-19 stand rejected under 35 U.S.C. § 112, first paragraph,

because the specification, while being enabling for *Pseudozyma* transformed with an expression vector comprising a *U. maydis* *hsp70* promoter operably linked to a protein of interest, does not reasonably provide enablement for any *Pseudozyma* species transformed with any vector comprising a promoter capable of directing the expression of a polypeptide of interest in said *Pseudozyma*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

(Answer 7.) As Appellants do not argue the claims separately, claims 11-15 and 17-19 stand or fall with claim 9, and we focus our analysis on claim 9. 37 C.F.R. § 41.37(c)(1)(vii).

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.” *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

“[T]o be enabling, the specification . . . must teach those skilled in the art how to make and use *the full scope of the claimed invention* without ‘undue experimentation.’” *Wright*, 999 F.2d at 1561 (emphasis added), *quoted in Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Thus, “there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed.” *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991), *quoted in Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999). Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

“Patent protection is granted in return for an enabling disclosure . . . , not for vague intimations of general ideas that may or may not be workable.” *Genentech*, 108 F.3d at 1366. “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 [skilled in the art] to understand and carry out the invention.” *Id.* at 1366 (emphasis added).

In the rejection of the claims, the Examiner specifically goes through the following *Wands* factors.

Nature of the Invention: The Examiner notes that the invention is drawn to a particular fungus, of the species *Pseudozyma*, comprising a vector having the ability to direct the expression of a polypeptide in the fungus (Answer 8). According to the Examiner, in order to make and use the invention, “the skilled artisan would require knowledge of a broad genus of promoters that necessarily have the ability to direct the expression of a polypeptide in a broad genus of *Pseudozyma* species.” (*Id.*)

Breadth of the claims: The Examiner finds that the claims are very broad, “encompassing a host cell, comprising an expression vector having any promoter that is functional in a broad genus of host cells.” (*Id.*)

Number of working examples and guidance provided: The Examiner notes that the Specification provides a single example of a promoter, *i.e.*, the *Ustilago maydis hsp70* promoter, that is shown to direct the expression of a polypeptide in the fungus. The Examiner asserts that “[i]n order to make and use the invention, the skilled artisan would require knowledge of a broad

genus of promoters that necessarily have the ability to direct the expression of *Pseudozyma* species.” (*Id.*)

State of the art: The Examiner again cites Cheng for its teaching of a method of transforming and expressing a gene in *P. flocculosa*, in which the *Pseudozyma* species was transformed with five different plasmids comprising the HygB gene operably linked to *hsp70* promoters from different organisms, but only one of the five promoters allowed for expression of the marker gene (Answer 8-9). According to the Examiner, “the state of the art demonstrates that, even among functionally related promoters, it is unpredictable which promoters are able to drive the expression of a polypeptide of interest in any *Pseudozyma* species.” (*Id.* at 9.)

Unpredictability of the art and the amount of experimentation required: The Examiner asserts that given the breadth of the claims, the lack of guidance and description in the instant Specification, and the unpredictability as demonstrated by the prior art, “the skilled artisan would be required to perform empirical undue and unpredictable trial and error experimentation in order to make and use the claimed invention.” (*Id.*)

Appellants argue that the claimed invention maybe practiced with only routine experimentation (App. Br. 17). According to Appellants, the only evidence relied upon in Cheng by the Examiner is the fact that four Ascomycetes promoters failed to express protein in *P. flocculosa* (App. Br. 17). Cheng, Appellants assert, “explains the failure of these four promoters and explicitly teaches what types of promoters would be most likely to function in *Pseudozyma*.” (App. Br. 17-18.) Appellants argue, based on Cheng, which teaches that the promoter from *U. maydis* was successful in

transforming *P. flocculosa* because it is related, and Schillberg, whose teachings are similar, “one of skill in the art would know to test promoters from species closely related to *Pseudozyma*, for example, those from other Basidiomycetes fungi. Thus, it would not be necessary to perform trial-and-error experimentation to practice the claimed invention.” (App. Br. 19.)

Appellants argue further that they have tested seven additional promoters from three species of Basidiomycetes (App. Br. 19, citing Exhibit V). According to Appellants:

These data demonstrate that Appellants were able to readily identify functional fungal promoters for use in *Pseudozyma* using methods known in the art at the time of filing (Exhibit V). In total, eight promoters derived from Basidiomycetes fungi have been identified as functional, whereas five promoters derived from Ascomycetes fungi did not function in *Pseudozyma*. Thus, as postulated by Cheng and noted in the art, these results unequivocally support the notion that promoters from closely related species (e.g., Basidiomycetes fungi) are functional in *P. flocculosa* and *P. antarctica*, whereas promoters from distantly related species (e.g., Ascomycetes fungi) are not. On this basis, Appellants have demonstrated that only routine experimentation is required to practice the invention over the scope of the claims.

(*Id.* at 22.)

Appellants’ arguments are not convincing, as the claims are not limited to promoters from species closely related to *Pseudozyma*, such as from other Basidiomycetes fungi, but encompass any fungal promoter. The Specification does not provide guidance as to the regulatory components or structural features that are necessary for the promoter to allow expression in *Pseudozyma*. And the only guidance provided by Cheng and Schillberg is to use transcriptional control sequences from the host organism itself or related

species (Cheng, p. 101, paragraph bridging columns 1 and 2 (quoted by the App. Br. At p. 18); Schillberg, p. 101). Thus, one skilled in the art would have to perform trial and error experimentation to determine which promoters from fungi that are not closely related to *Pseudozyma* that would allow for gene expression in *Pseudozyma*, such as Ascomycetes, promoters from which have been shown not to work.

Appellants also argue, relying on *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998), that “enablement in the present case is based on the disclosure [of] a species of the claimed genus and a disclosure sufficient to allow one of skill to identify new species within the claimed genus.” (App. Br. 23.) Again Appellants arguments are unavailing, as the court relied on the Kohler/Milstein technique, a technique that was well known in the art in the production of antibodies, to support the enablement of the patent. *Cellpro*, 152 F.3d at 1359-61. In addition, the court found that Cellpro had failed to raise a genuine factual dispute as to the enablement of the patent at issue. *Id.* at 1362. In the instant case, the only guidance the Specification provides for the genus of fungal promoters active in *Pseudozyma* species is the *hsp*⁷⁰ promoter from a related Basidiomycetes fungus, *Ustilago maydis* (See, e.g., Spec., Example III), and the Examiner has presented evidence that promoters from other fungal species, such as Ascomycetes, do not allow for expression in the *Pseudozyma* species *P. flocculosa* (see, e.g., Cheng). Thus, the preponderance of the evidence supports the Examiner’s conclusion that the Specification fails to enable the full scope of the claimed subject matter, which is a fungus of the genus *Pseudozyma* genetically transformed with an expression vector capable of directing the production of a recombinant polypeptide, wherein said

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expression vector comprises a promoter originating from any species of fungi that is active in the genus *Pseudozyma*.

For the reasons set forth above, we agree that the preponderance of the evidence supports the Examiner's conclusion that the Specification fails to enable the full scope of claim, and the rejection is affirmed.

CONCLUSION

In summary, we affirm the rejections of claims 9, 11-15, and 17-19 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description and lack of enablement.

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

AFFIRMED

Ssc:

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