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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TODD M. KINSELLA¹

Appeal 2015-000579
Application 12/985,232
Technology Center 1600

Before JEFFERY N. FREDMAN, JOHN E. SCHNEIDER, and
RYAN H. FLAX, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for detecting muscle atrophy which have been rejected as failing to satisfy the written description requirement. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ Appellants identify the Real Party in Interest as Rigel Pharmaceuticals, Inc. Appeal Br. 3.

STATEMENT OF THE CASE

The present invention is directed method for detecting muscle atrophy by contacting a cell with a glucocorticoid receptor ligand and a myostatin receptor ligand. Spec. 1–2.

Claims 1, 2, 4, 6–8, 10, 11, 25, and 26 are on appeal. Claim 1 is illustrative and reads as follows:

1. A method comprising:
contacting a mammalian cell comprising a glucocorticoid receptor, a myostatin receptor and a recombinant nucleic acid comprising an atrogen promoter operably linked to a coding sequence encoding a reporter protein with a ligand that activates the glucocorticoid receptor and a ligand that is at least 80% identical to a wild-type mammalian GDF8 and activates the myostatin receptor, thereby activating said atrogen promoter and inducing expression of said reporter protein.

The claims stand rejected for failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph².

DISCUSSION

The Examiner finds that the Specification “does not provide adequate written description for: 1) the genus of ligands that are at least 80% identical to a wildtype mammalian GDF8 and activate the myostatin receptor; and 2) the genus of atrogen promoters.” Ans. 3. We shall address each of these positions in turn.

² Claims 1, 2, 4, 6–8 and 10 were rejected under 35 U.S.C. § 103(a), however, that rejection was withdrawn. Ans. 8.

The Myostatin Ligand

The Examiner finds that while the Specification discloses 9 different mammalian GDF8 proteins, all of them are wild-type proteins. Ans. 3. The Examiner finds that the claims encompass variants of GDF8 that are at least 80% identical to a wild-type mammalian GDF8 and have the activity of activation the myostatin receptor. *Id.* The Examiner finds that the Specification does not describe any such variants. *Id.* The Examiner also finds that the Specification does not contain a sufficient recitation of distinguishing identifying characteristics for the GDF8 variants.

Appellant argues that GDF8 is well known in the art and that a number of sequence variants have been identified. Appeal Br. 4–5. Appellant argues that at least a dozen examples of GDF8 from different species are known and that one skilled in the art would be able to envision numerous variants. Appeal Br. 5. Appellant also points to the fact that assays for identifying myostatin receptors are known in the art. *Id.* Appellant concludes that “one of ordinary skill in the art would have been able to design a large number of variants of GDF8 with the expectation that they would be active, even in the absence of the guidance discussed in the Applicants’ prior response.” Appeal Br. 6.

We are unpersuaded by Appellant’s argument. The issue is not one of enablement, but one of adequate written description. “Although there is often significant overlap” between the enablement and written description requirements, “they are nonetheless independent of each other.” *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 921 (Fed. Cir. 2004). An “invention may be enabled even though it has not been described.” *Id.*

To satisfy the written description requirement an applicant must describe the invention in such a way as to convey to one skilled in the art that applicant had the invention in his possession when the application was filed. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). In cases such as the instant application where a genus is claimed, the specification must contain “either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Id.* at 1350.

We agree with the Examiner that the instant Specification fails to satisfy either requirement. The Specification only describes several wild-type GDF8 proteins and does not describe a single variant, let alone one with at least (or only) 80% identity to a mammalian wild-type. Spec. 12. In addition, Appellant has pointed to nothing in the Specification which identifies any common structural features of the genus that would allow one skilled in the art to what proteins fall within the recited genus.

Appellant argues that it has disclosed at least one protein that has at least 80% identity to a mammalian wild-type GDF8 protein. Reply Br. 3. Appellant points to the disclosure of the *Danio rerio* GDF8 ortholog which has 68% identity with human GDF8 protein. *Id.* We are unpersuaded. The reference to the *Danio rerio* ortholog does not show that Appellant had in its possession a GDF8 variant that was at least 80% identical to a mammalian GDF8 protein as the *Danio rerio* ortholog is less than 80% identical to a mammalian protein. Appellant has not pointed to any variant that meets the 80% identity limitation.

Turning to claim 25, Appellant argues that the current Written Training Materials issued by the USPTO teach that a polypeptide having at least 85% identity to a disclosed polypeptide can meet the written description requirement. Appeal Br. 7. Appellant argues that since claim 25 calls for at least 90% identity to a mammalian GDF8 protein, the written description requirement is satisfied. The Examiner appears to accept Appellant's argument by stating that "[w]ith regard to claim 25, as indicated above, the Examiner acknowledges that one of ordinary skill in the art would be able to envision myostatin receptor ligands that comprise an amino acid sequence that is at least 90% identical to a wild-type mammalian GDF8 and exhibit the recited activity." Ans. 12. In addition, the Examiner also concedes that since mammalian GDF8 sequences are highly homologous having at least 90% identity, one skilled in the art could identify variable amino acids residues (<10% from the sequences and expect substitution of the variable residues will retain activity).

In view of the above, we conclude that there is not adequate written description for the myostatin limitation in claims 1, 2, 4, 6–8, 10, 11, and 26, but there is an adequate written description for the myostatin limitation in claim 25.

The Atrogen Promoter Limitation

The Examiner finds that the Specification does not contain an adequate written description of the genus of atrogen promoters recited in the instant claims. Ans. 3. The Examiner finds that atrogen promoter is broadly defined to include any gene promoter that is up-regulated in muscle cells in

response to an atrophy-inducing stimulus with only one possible stimulus (fasting) being identified. Ans. 6. The Examiner finds that only two examples of Atrogen promoters are described in the Specification, MuRF-1 gene and MAFbx gene. *Id.* The Examiner goes on to find that

Since the gene structures and the promoter sequences of MuRF-1 and MAFbx were known at the time of invention, one of ordinary skill in the art would be able to identify synthetic promoters that are at least 95% identical to a wild-type MuRF-1 or MAFbx promoter. However, the person skilled in the art cannot envision the genus of atrogen promoters as broadly claimed; and the disclosed MuRF-1 and MAFbx genes are not sufficient to represent the broad genus of atrogen genes and atrogen promoters. The specification does not provide adequate written description and evidence of possession of the claimed genus of atrogen promoters.

Id.

Appellant contends that the written description requirement has been met since the MuRF-1 and MAFbx genes have been analyzed in great detail and a variety of conserved sequences and transcription binding sites have been identified. Appeal Br. 8. Appellant argues that given this information, one skilled in the art would be able to envision synthetic promoters that have the same basic activities as the MuRF1 and MAFbx promoters. *Id.*

We have considered Appellant's argument and find it unpersuasive. As the Examiner points out,

the recitation of "atrogen promoter" encompasses a large genus of nucleic acid sequences. The specification defines the term "atrogen promoter" as "a promoter that is induced in muscle cells exposed to an atrophy-inducing stimulus (e.g., fasting, etc) prior to a detectable muscle atrophy phenotype, i.e., a detectable loss of muscle mass, shriveling of cells, etc., is observable." Based on the definition, the atrogen promoters

include all gene promoters that are up-regulated in muscle cells in response to “an atrophy-inducing stimulus”, and fasting is only one of those undefined atrophy-inducing stimuli. The specification only describes two genes, MuRF-1 and MAFbx. Clearly, these two examples are not sufficient to represent the broad genus. Without teachings from the specification, one of ordinary skill in the art would not be able to envision these atrogen promoters as claimed.

Ans. 13.

Moreover, the Specification does not recite any “structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Ariad Pharms., Inc.*, 598 F.3d at 1350.

With respect to claim 26, the Examiner again appears to concede that the limitation calling for 95% identity with a wild-type MuRF-1 or MAFbx promoter meets the written description requirement.

In view of the above, we conclude that there is not an adequate written description for the atrogen limitation in claims 1, 2, 4, 6–8, 10, 11, and 25, but there is adequate written description for the atrogen limitation in claim 26.

SUMMARY

We affirm the rejection of claims 1, 2, 4, 6–8, 10, 11, 25, and 26 for failing to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

Appeal 2015-000579
Application 12/985,232

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