

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION AND)
MOUNT SINAI SCHOOL OF MEDICINE)
OF NEW YORK UNIVERSITY)
)
Plaintiffs,)
)
v.)
)
TRANSKARYOTIC THERAPIES, INC,)
)
Defendant.)

C.A. No. 00-677-GMS

ORDER

After considering the submission of the parties and hearing oral argument on the matter, IT IS
HEREBY ORDERED, ADJUDGED, AND DECREED that as used in the asserted claims of the patents
in suit:

1. The term “comprising” means “any method for producing human β -galactosidase A that includes (but need not be limited to) the following recited steps;”
2. The term “culturing” means “maintaining and proliferating the cells *in vitro* in a suitable medium;”
3. The term “mammalian cell” means “a cell derived from a warm-blooded animal, including humans, whose young are fed by milk secreted from mammary glands;”
4. The term “chromosomally integrated” means “the combining or bringing together or merging separate elements. In this case, the separate elements that are combined are the chromosome of the host cell and an exogenous nucleotide sequence encoding human β -galactosidase A with a promoter

and selectable marker;”

5. The term “nucleotide sequence encoding human β -galactosidase A” means “a coding sequence that is either a genomic sequence or cDNA. The nucleotide sequence must be chromosomally intergrated;”

6. The term “human β -galactosidase A” means “an enzyme that includes mannose-6-phosphate groups and has two amino acid chains (i.e. is dimeric) each with a sequence that corresponds to, or is substantially the same as, amino acid numbers 32-429 in Figures 1A-1C (and Seq ID No:1) of the ‘804 patent;”

7. The term “regulatory sequence” means “any and all sequences required for gene expression of the human β -galactosidase A gene, consisting of at least one sequence which promotes gene expression;”

8. The term “selectable marker” means “an exogenous DNA sequence which is introduced into a cell or organism along with a sequence of interest in order to provide that cell or organism with an easily identifiable trait that it does not naturally have and show that the cell or organism has been successfully transformed with the sequence of interest;”

9. The term “regulatory sequence” in the phrase “selectable marker controlled by the same or different regulatory sequence” means “a DNA sequence that causes the cell to express the selectable marker;”

10. The term “stably” in “stably overexpressed” means that “the nucleotide sequence encoding human β -galactosidase A stays in place once integrated into the chromosome, i.e. the chromosomal change is not transient;”

11. The term “overexpressed” in “stably overexpressed” means “the cell produces higher levels of β -galactosidase A than the unmodified parental cell from which it was derived;”

12. The term “enzymatically active β -galactosidase A enzyme” means “human β -galactosidase A enzyme that exhibits the ability to cut an β -galactosidic linkage in an activity assay, including, but not limited to assays (or variations thereof) described at col. 16, lines 38-55 of the ‘804 patent;”

13. The term “secreted” means “the mammalian cell exports the enzymatically active human β -galactosidase A enzyme from the cell to the surrounding culture medium;”

14. The term “isolating” means “separating enzymatically active human β -galactosidase A enzyme from the culture medium. Isolation does not mean purification;”

15. The term “selection” means “culturing the cells under conditions that permit preferential growth or survival of cells having the selectable marker;”

16. The term “amplified” means “the presence of multiple copies of the chromosomally integrated nucleotide sequences that encode human β -galactosidase A;”

17. The term “The method according to claim 1,[C] in which the nucleotide sequence encoding human β -galactosidase A encodes the amino acid sequence depicted in FIGS. 1A-1C [SEQ ID No.2] from amino acid residue number 1 to 430” includes all of the limitations of claim 1 and means “a nucleotide sequence encoding the amino acid sequence depicted in FIGS. 1A-1C [SEQ ID No.2] of the ‘804 patent, from amino acid residue number 1 to the end of the depicted amino acid sequence;”

18. The term “The method according to claim 1, [C] in which the nucleotide sequence encoding human β -galactosidase A encodes the amino acid sequence depicted in FIGS. 1A-1C [SEQ ID No.1] from amino acid residue number 31 to 430” includes all of the limitations of claim 1 and means “a nucleotide sequence encoding the amino acid sequence depicted in FIGS. 1A-1C [SEQ ID No.1] of the ‘804 patent, from amino acid residue number 31 to the end of the depicted amino acid sequence;”

19. The term “viral promoter” means “a regulatory sequence that is derived from a virus;”

20. The term “dihydrofolate reductase” means “the enzyme dihydrofolate reductase;”

21. The term “selection is methotrexate” means “growing the cells in culture media containing methotrexate.”

Date: November 28, 2001

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE