UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC., Petitioner,

v.

EXACT SCIENCES CORPORATION, Patent Owner.

> Case No.: IPR2024-00459 U.S. Patent 11,634,781

PETITION FOR *INTER PARTIES* REVIEW OF U.S. PATENT 11,634,781

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| | | 1. | Claim 1 |
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| | | 3. | Claim 3 |
| | | 4. | Claim 4: "The method of claim 3, wherein testing the nucleic acid comprises determining expression from a human gene." |
| | | 5. | Claim 5: "The method of claim 4, wherein determining expression from the human gene comprises testing the nucleic acid for the presence of human DNA having an epigenetic modification." 37 |
| | | 6. | Claim 6: "The method of claim 5, wherein testing the nucleic acid for the presence of human DNA having an epigenetic modification comprises measuring an amount of a methylated human DNA." |
| | | 7. | Claim 7: "The method of claim 5, wherein the epigenetic modification comprises aberrant methylation." |
| | | 8. | Claim 8: "The method of claim 7, wherein the aberrant methylation comprises hypermethylation." 38 |
| | | 9. | Claim 9: "The method of claim 7, wherein the human DNA having an epigenetic modification comprises a gene and/or a promoter region of a gene." |

| | 10. | Claim 11: "The method of claim 5, wherein testing the nucleic acid for presence of human DNA having an epigenetic modification comprises modifying the nucleic acid with bisulfate ions under conditions wherein unmethylated cytosine is converted to uracil." | |
|----|------------------------------|--|--|
| | 11. | Claim 14: "The method of claim 3, wherein testing for an amount of blood protein in the removed portion comprises testing for a concentration of hemoglobin in the removed portion." | |
| | 12. | Claim 15: "The method of claim 14, wherein the testing for the concentration of hemoglobin comprises immunochemical detection of hemoglobin." | |
| | 13. | Claims 16-20: "The method of claim 14, wherein the removed portion of the fecal sample is considered positive for the presence of blood when the concentration of hemoglobin detected in the removed portion is at least [5, 10, 20, 50, or 200] ng/ml." | |
| B. | | und II: Lenhard in view of Itzkowitz and Vilkin, in er view of Kanaoka | |
| | 1. | Claim 12: "The method of claim 4, wherein determining expression from the human gene comprises measuring an amount of RNA expressed from the gene." | |
| | 2. | Claim 13: "The method of claim 12, wherein measuring an amount of RNA expressed from the gene comprises reverse transcriptase polymerase chain reaction (RT-PCR) | |
| C. | | Ground III: Lenhard in view of Itzkowitz and Vilkin, in further view of Derks | |
| D. | Ground IV: Shuber and Vilkin | | |
| | 1. | Claim 1 | |

| 2. | Claim 2: "The method of claim 1, further comprising delivering the sealable container containing the removed portion of the fecal sample and said buffer and the sealable collection vessel containing the remaining portion of the fecal sample and said stablizing buffer to a medical diagnostics laboratory" 55 |
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| 3. | Claim 3 55 |
| 4. | Claim 4: "The method of claim 3, wherein testing the nucleic acid comprises determining expression from a human gene." |
| 5. | Claim 5: "The method of claim 4, wherein determining expression from the human gene comprises testing the nucleic acid for the presence of human DNA having an epigenetic modification." 58 |
| 6. | Claim 6: "The method of claim 5, wherein testing the nucleic acid for the presence of human DNA having an epigenetic modification comprises measuring an amount of a methylated human DNA." |
| 7. | Claim 7: "The method of claim 5, wherein the epigenetic modification comprises aberrant methylation." |
| 8. | Claim 8: "The method of claim 7, wherein the aberrant methylation comprises hypermethylation." 59 |
| 9. | Claim 9: "The method of claim 7, wherein the human DNA having an epigenetic modification comprises a gene and/or a promoter region of a gene." |
| 10. | Claim 11: "The method of claim 5, wherein testing the nucleic acid for presence of human DNA having an epigenetic modification comprises modifying the nucleic acid with bisulfate ions under conditions wherein unmethylated cytosine is converted to uracil 60 |
| 11. | Claim 14: "The method of claim 3, wherein testing for an amount of blood protein in the removed |

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