### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC., Petitioner,

v.

EXACT SCIENCES CORPORATION, Patent Owner.

Case No.: IPR2024-01330 U.S. Patent 11,970,746

DECLARATION OF DUNCAN WHITNEY, Ph.D.



# **TABLE OF CONTENTS**

I.	Intro	Introduction				
II.	Qual	Qualifications and Experience 2				
III.	The Person of Ordinary Skill in the Art					
IV.	Technical Background					
	A.	Diag	gnostic Analysis of Biological Samples 8			
		1.	Diagnostic Tests Based on Detection of Biomarkers, such as Protein and DNA			
		2.	Sensitivity and Specificity as Measures of Diagnostic Performance			
		3.	Diagnostic Tests Commonly Measure Multiple Markers14			
		4.	Diagnostic Analyses Require Well-Preserved Samples 16			
	B.	Use	of Fecal Diagnostic Tests to Diagnose Colorectal Cancer 24			
		1.	Fecal Occult Blood Tests			
		2.	Fecal DNA-Based Tests			
		3.	RNA Expression was also used to Diagnose Colorectal Cancer			
	C.		narker Panels Empower Broader and Earlier Detection of orectal Cancer			
		1.	Panels of Different Fecal DNA biomarkers			
		2.	Panels Combining DNA Biomarkers and FOBT 35			
	D.	Hom	ne Collection of Fecal Samples			
		1.	Collecting and Partitioning Stool Samples 40			
		2.	Different Buffers were Used to Preserve Different Biomarkers in Fecal Samples			



		3.	Partitioning Samples into Multiple Vessels for Stabilization during Shipment	54	
V.	Legal	gal Standards			
VI.	The Challenged Patent				
	A.	The '	746 Patent	61	
	B.	Sumr	mary of the Claimed Subject Matter	65	
VII.	SUMMARY OF SELECTED PRIOR ART REFERENCES 71				
	A.	Lenh	ard (EX1004)	71	
	В.	Vilki	n (EX1005)	77	
	C.	Itzko	witz (EX1006)	82	
	D.	Kana	oka (EX1007)	86	
	E.	Shub	er (EX1008)	89	
	F.	Inbar	(EX1009)	92	
VIII.	OVE	RVIEV	W OF GROUNDS OF UNPATENTABILITY	97	
IX.			MS OF THE '746 PATENT ARE ANTICIPATED		
	A.		ard in view of Itzkowitz and Vilkin renders claims 1-4  obvious		
		1.	A POSA would be motivated to use the iFOBT of Viplace of the gFOBT of Lenhard		
		2.	A POSA would have been motivated to use the samp collection methodology of Itzkowitz in Lenhard's pr	ocess	
		3.	A POSA would have been motivated to use the DNA stabilizing buffer of Itzkowitz in Lenhard's process		
		4	Claim 1	. 110	



	5.	Claim 2: "The method of claim 1, further comprising delivering the sealable vessel containing the first portion of the fecal sample and the stabilizing buffer and the sealable container containing the second portion of the fecal sample and the solution to a medical diagnostics laboratory". 122			
	6.	Claim 3			
	7.	Claim 4: "The method of claim 3, wherein testing the nucleic acid comprises determining expression from a human gene."			
	8.	Claim 14: "The method of claim 3, wherein testing for an amount of a blood protein present in the second portion comprises testing for a concentration of hemoglobin in the second portion, wherein a concentration of hemoglobin is indicative of a presence of blood in the fecal sample." 131			
	9.	Claim 15: "The method of claim 14, wherein the testing for the concentration of hemoglobin comprises immunochemical detection of hemoglobin."			
	10.	Claims 16-19: "The method of claim 14, wherein the second portion of the fecal sample is considered positive for the presence of blood when the concentration of hemoglobin detected in the second portion is at least [5, 10, 20, or 50] ng/ml."			
Lenhard in view of Itzkowitz and Vilkin, in further view of Kanaoka renders obvious claims 12 and 13					
	1.	Claim 12: "The method of claim 4, wherein determining expression from the human gene comprises measuring an amount of RNA expressed from the human gene." 135			
	2.	Claim 13: "The method of claim 12, wherein measuring an amount of RNA expressed from the human gene comprises reverse transcriptase polymerase chain reaction (RT-PCR)"			
Shuber and Vilkin render obvious claims 1-4, and 14-19 139					
	1.	Claim 1			



B.

C.

	2.	Claim 2: "The method of claim 1, further comprising delivering the sealable vessel containing the first portion of the fecal sample and the stabilizing buffer and the sealable container containing the second portion of the fecal sample and the solution to a medical diagnostics laboratory". 151			
	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 14: "The method of claim 3, wherein testing for an amount of a blood protein present in the second portion comprises testing for a concentration of hemoglobin in the second portion, wherein a concentration of hemoglobin is indicative of a presence of blood in the fecal sample." 156			
	6.	Claim 15: "The method of claim 14, wherein the testing for the concentration of hemoglobin comprises immunochemical detection of hemoglobin."			
	7.	Claims 16-19: "The method of claim 14, wherein the second portion of the fecal sample is considered positive for the presence of blood when the concentration of hemoglobin detected in the second portion is at least [5, 10, 20, or 50] ng/ml."			
Shuber and Vilkin, in view of Kanaoka render obvious claims 12 and 13					
	1.	Claim 12 "The method of claim 4, wherein determining expression from the human gene comprises measuring an amount of RNA expressed from the human gene." 160			
	2.	Claim 13: "The method of claim 12, wherein measuring an amount of RNA expressed from the human gene comprises reverse transcriptase polymerase chain reaction (RT-PCR)			
Inbar anticipates claims 1 and 2					
	1.	Claim 1			



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