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The Supreme Court and DNA Patents: A Myriad of Ramifications

July 1, 2013

7 patents; 179 claims; 15 contested claims; 9 claims before the Supreme Court

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
5747282	1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2. [1863aa]	Yes	Yes	?	5/5/15
282	2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1. [5914 bp]	Yes	Yes	Yes?	5/5/15
282	3. The isolated DNA of claim 1 which contains BRCA1 regulatory sequences.	No	No		5/5/15
282	4. The isolated DNA of claim 2 which contains BRCA1 regulatory sequences.	No	No		5/5/15
282	5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.	Yes	Yes	No?	5/5/15
282	6. An isolated DNA having at least 15 nucleotides of the DNA of claim 2.	Yes	Yes	No?	5/5/15
282	7. An isolated DNA selected from the group consisting of: (a) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having T at nucleotide position 4056; (b) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having an extra C at nucleotide position 5385; (c) a DNA having the nucleotide sequence set forth in SEQ ID NO: 1 having G at nucleotide position 5443; and, (d) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having 11	Yes	Yes	Yes?	5/5/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	base pairs at nucleotide positions 189-199 deleted.				
282	8. A replicative cloning vector which comprises the isolated DNA of claim 1 or parts thereof and a replicon operative in a host cell.	No	No		5/5/15
282	9. A replicative cloning vector which comprises the isolated DNA of claim 2 or parts thereof and a replicon operative in a host cell.	No	No		5/5/15
282	10. An expression system which comprises the isolated DNA of claim 1 or parts thereof operably linked to suitable control sequences.	No	No		5/5/15
282	11. An expression system which comprises the isolated DNA of claim 2 or parts thereof operably linked to suitable control sequences.	No	No		5/5/15
282	12. Host cells transformed with the expression system of claim 10.	No	No		5/5/15
282	13. Host cells transformed with the expression system of claim 11.	No	No		5/5/15
282	14. A method of producing BRCA1 polypeptide which comprises culturing the cells of claim 12 under conditions effective for the production of said BRCA1 polypeptide and harvesting the BRCA1 polypeptide.	No	No		5/5/15
282	15. A method of producing BRCA1 polypeptide which comprises culturing the cells of claim 13 under conditions effective for the production of said BRCA1 polypeptide and harvesting the BRCA1 polypeptide.	No	No		5/5/15
282	16. A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.	No	No		5/5/15
282	17. The pair of primers of claim 16 wherein said BRCA1 gene has the nucleotide		No		5/5/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	sequence set forth in SEQ ID NO:1.				
282	18. A kit for detecting mutations in the BRCA1 gene resulting in a susceptibility to breast and ovarian cancers comprising at least one oligonucleotide primers specific for a BRCA1 gene mutation and instructions relating to detecting mutations in the BRCA1 gene.	No	No		5/5/15
282	19. A kit for detecting mutations in the BRCA1 gene resulting in a susceptibility to breast and ovarian cancers comprising at least one allele-specific oligionucleotide probe for a BRCA1 gene mutation and instructions relating to detecting mutations in the BRCA1 gene.	No	No		5/5/15
282	20. A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.	No	Yes	Yes	5/5/15
5837492	1. An isolated DNA molecule coding for a BRCA2 polypeptide, said DNA molecule comprising a nucleic acid sequence encoding the amino acid sequence set forth in SEQ ID NO:2. [3418 aa]	Yes	Yes	?	12/18/15
492	2. The isolated DNA molecule of claim 1, wherein said DNA molecule comprises the nucleotide sequence set forth in SEQ ID NO:1.[11385 bp]	No	No		12/18/15
492	3. The isolated DNA molecule of claim 1, wherein said DNA molecule is an allelic variant of the nucleotide sequence set forth in SEQ ID NO:1. [11385 bp]	No	No		12/18/15
492	4. The isolated DNA molecule of claim 1, which contains BRCA2 regulatory	No	No		12/18/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	sequences [3418 aa]				
492	5. An isolated DNA molecule comprising at least 15 contiguous nucleotides of the DNA molecule of claim 1.	No	No		12/18/15
492	6. An isolated DNA molecule coding for a mutated form of the BRCA2 polypeptide set forth in SEQ ID NO:2 [3418 aa], wherein said mutated form of the BRCA2 polypeptide is associated with susceptibility to cancer.	Yes	Yes	?	12/18/15
492	7. The isolated DNA molecule of claim 6, wherein the DNA molecule comprises a mutated nucleotide sequence set forth in SEQ ID NO:1 [11385 bp].	Yes	Yes	Yes?	12/18/15
492	8. The isolated DNA molecule of claim 7, wherein the mutation is selected from the group consisting of a deletion mutation, a nonsense mutation, an insertion mutation and a missense mutation.	No	No		12/18/15
492	9. An isolated DNA molecule comprising at least 15 contiguous nucleotides of the DNA of claim 6.	No	No		12/18/15
492	10. The isolated DNA molecule of claim 6 selected from the group consisting of: (a) SEQ ID NO:1 having AC at nucleotide positions 277 and 278 deleted; (b) SEQ ID NO:1 having four nucleotides at positions 982-985 deleted; […] (mm) SEQ ID NO:1 having a C instead of a T at position 6921.	No	No		12/18/15
492	11. A replicative cloning vector which comprises the isolated DNA molecule of claim 1, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 1, and a replicon operative in a host cell.	No	No		12/18/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
492	12. A replicative cloning vector which comprises the isolated DNA molecule of claim 2, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 2, and a replicon operative in a host cell.	No	No		12/18/15
492	13. A replicative cloning vector which comprises the isolated DNA molecule of claim 3, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 3, and a replicon operative in a host cell.	No	No		12/18/15
492	14. A replicative cloning vector which comprises the isolated DNA molecule of claim 6, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 6, and a replicon operative in a host cell.	No	No		12/18/15
492	15. A replicative cloning vector which comprises the isolated DNA molecule of claim 7, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 7, and a replicon operative in a host cell.	No	No		12/18/15
492	16. An expression vector which comprises the isolated DNA of claim 1, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 1, operably linked to transcription regulatory regions.	No	No		12/18/15
492	17. An expression vector which comprises the isolated DNA of claim 2, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 2, operably linked to transcription regulatory regions.	No	No		12/18/15
492	18. An expression vector which comprises the isolated DNA of claim 3, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 3, operably linked to transcription regulatory regions.	No	No		12/18/15
492	19. An expression vector which comprises the isolated DNA of claim 6, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 6, operably linked to transcription regulatory regions.	No	No		12/18/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
492	20. An expression vector which comprises the isolated DNA of claim 7, or at least 15 contiguous nucleotides of the isolated DNA molecule of claim 7, operably linked to transcription regulatory regions.	No	No		12/18/15
492	21. An isolated host cell transformed with the expression vector of claim 16.	No	No		12/18/15
492	22. An isolated host cell transformed with the expression vector of claim 17.	No	No		12/18/15
492	23. An isolated host cell transformed with the expression vector of claim 18.	No	No		12/18/15
492	24. An isolated host cell transformed with the expression vector of claim 19.	No	No		12/18/15
492	25. An isolated host cell transformed with the expression vector of claim 20.	No	No		12/18/15
492	26. A method of producing recombinant BRCA2 polypeptide which comprises culturing the cells of claim 21 under conditions effective for the production of said BRCA2 polypeptide and harvesting the recombinant BRCA2 polypeptide.	No	No		12/18/15
492	27. A method of producing recombinant BRCA2 polypeptide which comprises culturing the cells of claim 22 under conditions effective for the production of said BRCA2 polypeptide and harvesting the recombinant BRCA2 polypeptide.	No	No		12/18/15
492	28. A method of producing recombinant BRCA2 polypeptide which comprises culturing the cells of claim 23 under conditions effective for the production of said BRCA2 polypeptide and harvesting the recombinant BRCA2 polypeptide.	No	No		12/18/15
492	29. A pair of single-stranded DNA primers of at least 15 nucleotides in length for determination of the nucleotide sequence of a BRCA2 gene by a polymerase chain reaction, the sequence of said primers being isolated from human chromosome 13, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA comprising all or at least 15 contiguous nucleotides of the BRCA2 gene.	No	No		12/18/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
492	30. The pair of primers of claim 29 wherein said BRCA2 gene has the nucleotide sequence set forth in SEQ ID NO:1 [11,385 bp].	No	No		12/18/15
5693**473**	1. An isolated DNA comprising an altered BRCA1 DNA having at least one of the alterations set forth in Tables 12A [missense/premature stop/frameshift], 14 [frameshift/nonsense/missense/splice site], 18 [missense] or 19 [SNP or frameshift in intron] with the proviso that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.	Yes	Yes	Yes?	12/2/14
473	2. An isolated DNA comprising an altered BRCA1 DNA having one of the alterations set forth in Tables 12A or 14 with the provision that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.	No	No		12/2/14
473	3. An isolated DNA comprising an altered BRCA1 DNA having one of the alterations set forth in Tables 18 or 19.	No	No		12/2/14
473	4. A nucleic acid probe specifically hybridizable to a human altered BRCA1 DNA and not to wild-type BRCA1 DNA, said altered BRCA1 DNA having one of the alterations set forth in Tables, 12A, 14, 18 or 19 [missense, frameshift, nonsense, splice site].	No	No		12/2/14
473	5. A nucleic acid probe specifically hybridizable to human altered BRCA1 DNA and not to wild-type BRCA1 DNA, said altered BRCA1 DNA having one of the alterations set forth in Tables 12A or 14 with the proviso that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.	No	No		12/2/14
473	6. A nucleic acid probe specifically hybridizable to human altered BRCA1 DNA and not to wild-type BRCA1 DNA, said altered BRCA1 DNA having one of the alterations set forth in Tables 18 or 19.	No	No		12/2/14

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
473	7. The nucleic acid probe of claim 6 wherein said altered BRCA1 DNA has the alteration comprising a deletion of AG in codon 23.	No	No		12/2/14
473	8. The nucleic acid probe of claim 6 wherein said altered BRCA1 DNA has the alteration comprising an insertion of a nucleotide C corresponding to a base number 5382 in SEQ ID NO:1.	No	No		12/2/14
473	9. The nucleic acid probe of claim 6 wherein said altered BRCA1 DNA has the alteration comprising a deletion of 40 nucleotides corresponding to base numbers 1294-1333 of SEQ ID NO:1.	No	No		12/2/14
473	10. The nucleic acid probe of claim 6 wherein said altered BRCA1 DNA has the ablation comprising a substitution of a G for the T corresponding to a base number 391 in SEQ ID NO:17.	No	No		12/2/14
473	11. The isolated DNA of claim 2 wherein said altered BRCA1 DNA has the alteration comprising a deletion of AG in codon 23.	No	No		12/2/14
473	12. The isolated DNA of claim 2 wherein said altered BRCA1 DNA has the alteration comprising an insertion of a nucleotide C corresponding to a base number 5382 in SEQ ID NO:1.	No	No		12/2/14
473	13. The isolated DNA of claim 2 wherein said altered BRCA1 DNA has the alteration comprising a deletion of 40 nucleotides corresponding to base numbers 1294-1333 in SEQ ID NO:1.	No	No		12/2/14
473	14. The isolated DNA of claim 2 wherein said altered BRCA1 DNA has the alteration comprising a substitution of a G for the T corresponding to a base number 391 in SEQ ID NO:17.	No	No		12/2/14
5709**999**	1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A	No	Yes	Not eligible	1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	[SNP/frameshift], 14 [SNP/frameshift], 18 [SNP] or 19 [SNP] in a human which comprises **analyzing** a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or **analyzing** a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.				
999	2. The method of claim 1 which comprises analyzing BRCA1 RNA from the subject.	No	No		1/20/15
999	3. The method of claim 2 wherein a germline alteration is detected by hybridizing a BRCA1 gene probe which specifically hybridizes to nucleic acids containing at least one of said alterations and not to wild-type BRCA1 sequences to RNA isolated from said human sample and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said alteration in said RNA and thereby the presence of said germline alteration in said sample.	No	No		1/20/15
999	4. The method of claim 1 wherein a germline alteration is detected by obtaining a first BRCA1 gene fragment from a BRCA1 gene isolated from said human sample and a second BRCA1 gene fragment from a wild-type BRCA1 gene, said second fragment corresponding to said first fragment, forming single-stranded DNA from said first BRCA1 gene fragment and from said second BRCA1 gene fragment, electrophoresing said single-stranded DNAs on a non-denaturing polyacrylamide gel, comparing the mobility of said single-stranded DNAs on said gel to determine if said single-stranded DNA from said first BRCA1 gene fragment is shifted relative to said second BRCA1 gene fragment and sequencing said single-stranded DNA from said first BRCA1 gene fragment having a shift in mobility.	No	No		1/20/15
999	5. The method of claim 1 wherein a germline alteration is detected by hybridizing a BRCA1 probe which specifically hybridizes to nucleic acids containing at least one of said alterations and not to wild-type BRCA1 sequences to genomic DNA isolated from said sample and detecting the presence of a hybridization product, wherein a presence of said product indicates the presence of said germline	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	alteration in the sample.				
999	6. The method of claim 1 wherein a germline alteration is detected by amplifying all or part of a BRCA1 gene in said sample using a set of primers specific for a wild-type BRCA1 gene to produce amplified BRCA1 nucleic acids and sequencing the amplified BRCA1 nucleic acids.	No	No		1/20/15
999	7. The method of claim 1 wherein a germline alteration is detected by amplifying all or part of a BRCA1 gene in said sample using a primer specific for an allele having for one of said alterations and detecting the presence of an amplified product, wherein the presence of said product indicates the presence of said allele in the sample.	No	No		1/20/15
999	8. The method of claim 1 wherein a germline alteration is detected by molecularly cloning all or part of a BRCA1 gene in said sample to produce a cloned nucleic acid and sequencing the cloned nucleic acid.	No	No		1/20/15
999	9. The method of claim 1 wherein a germline alteration is detected by forming a heteroduplex consisting of a first strand of nucleic acid selected from the group consisting of BRCA1 gene genomic DNA fragment isolated from said sample, BRCA1 RNA fragment isolated from said sample and BRCA1 cDNA fragment made from mRNA from said sample and a second strand of a nucleic acid consisting of a corresponding human wild-type BRCA1 gene fragment, analyzing for the presence of a mismatch in said heteroduplex, heteroduplex and sequencing said first strand of nucleic acid having a mismatch.	No	No		1/20/15
999	10. The method of claim 1 wherein a germline alteration is detected by amplifying BRCA1 gene nucleic acids in said sample, hybridizing the amplified nucleic acids to a BRCA1 DNA probe which specifically hybridizes to nucleic acids containing at least one of said alterations and not to wild-type BRCA1 sequences and detecting the presence of a hybridization product, wherein a presence of said product indicates the presence of said germline alteration.	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
999	11. The method of claim 1 wherein a germline alteration is detected by analyzing the sequence of a BRCA1 gene in said sample for one of the deletion mutations set forth in Tables 12A or 14.	No	No		1/20/15
999	12. The method of claim 1 wherein a germline alteration is detected by analyzing the sequence of a BRCA1 gene in said sample for one of the point mutations set forth in Tables 12A or 14 with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.	No	No		1/20/15
999	13. The method of claim 1 wherein a germline alteration is detected by analyzing the sequence of a BRCA1 gene in said sample for one of the insertion mutations set forth in Tables 12A or 14 with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.	No	No		1/20/15
999	14. The method of claim 1 wherein a germline alteration is detected by obtaining a first BRCA1 gene fragment from a BRCA1 gene isolated from said human sample and a second BRCA1 gene fragment from a BRCA1 allele specific for one of said alterations, said second fragment corresponding to said first fragment, forming single-stranded DNA from said first BRCA1 gene fragment and from said second BRCA1 gene fragment, electrophoresing said single-stranded DNAs on a non-denaturing polyacrylamide gel and comparing the mobility of said single-stranded DNAs on said gel to determine if said single-stranded DNA from said first BRCA1 gene fragment is shifted relative to said second BRCA1 gene fragment, wherein no shift in electrophoretic mobility indicates the presence of said alteration in said sample.	No	No		1/20/15
999	15. The method of claim 1 wherein a germline alteration is detected by obtaining a first BRCA1 gene fragment from (a) BRCA1 gene genomic DNA isolated from said sample, (b) BRCA1 RNA isolated from said sample or (c) BRCA1 cDNA made from mRNA isolated from said sample and a second BRCA1 gene fragment from a	No	No		1/20/15

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	BRCA1 allele specific for one of said alterations, said second fragment corresponding to said first fragment, forming single-stranded DNA from said first BRCA1 gene fragment and from said second BRCA1 gene fragment, forming a heteroduplex consisting of single-stranded DNA from said first BRCA1 gene fragment and single-stranded DNA from said second BRCA1 gene fragment and analyzing for the presence of a mismatch in said heteroduplex, wherein no mismatch indicates the presence of said alteration.				
999	16. The method of claim 1 wherein said germline alteration consists of the deletion of AG in codon 23 of a BRCA1 gene.	No	No		1/20/15
999	17. The method of claim 1 wherein said germline alteration comprises an insertion of a nucleotide C at a position corresponding to a base number 5382 in SEQ ID NO1.	No	No		1/20/15
999	18. The method of claim 1 wherein said germline alteration consists of a deletion of 40 nucleotides corresponding to base numbers 1294-1333 in SEQ ID NO:1.	No	No		1/20/15
999	19. The method of claim 1 wherein said germline alteration comprises a substitution of a G for the T corresponding to a base number 391 in SEQ ID NO:17.	No	No		1/20/15
999	20. The method of claim 3 wherein said germline alteration consists of a deletion of AG in codon 23.	No	No		1/20/15
999	21. The method of claim 3 wherein said germline alteration comprises an insertion of a nucleotide C at a position corresponding to a base number 5382 in SEQ ID NO1.	No	No		1/20/15
999	22. The method of claim 3 wherein said germline alteration consists of a deletion of 40 nucleotides corresponding to base numbers 1294-1333 in SEQ ID NO:1.	No	No		1/20/15
999	23. The method of claim 3 wherein said germline alteration comprises a	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	substitution of a G for the T corresponding to a base number 391 in SEQ ID NO:17.				
999	24. The method of claim 5 wherein said germline alteration consists of a deletion of AG in codon 23.	No	No		1/20/15
999	25. The method of claim 5 wherein said germline alteration comprises an insertion of a nucleotide C at a position corresponding to a base number 5382 in SEQ ID NO1.	No	No		1/20/15
999	26. The method of claim 5 wherein said germline alteration consists of a deletion of 40 nucleotides corresponding to base numbers 1294-1333 in SEQ ID NO:1.	No	No		1/20/15
999	27. The method of claim 5 wherein said germline alteration comprises a substitution of a G for the T corresponding to a base number 391 in SEQ ID NO:17.	No	No		1/20/15
999	28. The method of claim 7 wherein said germline alteration consists of a deletion of AG in codon 23.	No	No		1/20/15
999	29. The method of claim 7 wherein said germline alteration comprises an insertion of a nucleotide C at a position corresponding to a base number 5382 in SEQ ID NO1.	No	No		1/20/15
999	30. The method of claim 10 wherein said germline alteration comprises a substitution of a G for the T corresponding to a base number 391 in SEQ ID NO:17.	No	No		1/20/15
999	31. The method of claim 7 wherein said germline alteration consists of a deletion of 40 nucleotides corresponding to base numbers 1294-1333 in SEQ ID NO:1.	No	No		1/20/15
999	32. The method of claim 7 wherein said germline alteration comprises a substitution of a G for the T corresponding to a base number 391 in SEQ ID	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	NO:17.				
999	33. The method of claim 10 wherein said germline alteration consists of a deletion of AG in codon 23.	No	No		1/20/15
999	34. The method of claim 10 wherein said germline alteration comprises an insertion of a nucleotide C at a position corresponding to a base number 5382 in SEQ ID NO1.	No	No		1/20/15
999	35. The method of claim 10 wherein said germline alteration consists of a deletion of 40 nucleotides corresponding to base numbers 1294-1333 in SEQ ID NO:1.	No	No		1/20/15
5710001	1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises gene comparing a first sequence selected form [sic] the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.	No	Yes	Not eligible	1/20/15
001	2. The method of claim 1 wherein the wild-type BRCA1 gene has the sequence set forth in SEQ ID NO:1.	No	No		1/20/15
001	3. The method of claim 1 wherein a nucleic acid sequence of BRCA1 RNA from the tumor sample is compared to a nucleic acid sequence of BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from the nontumor sample.	No	No		1/20/15
001	4. The method of claim 3 wherein the nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which is specifically hybridizes to either a wild-	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	type or an altered BRCA1 allele to RNA isolated from said tumor sample and to RNA isolated from said nontumor sample and analyzing for the presence of a hybridization product in each sample, wherein a presence of said product in only one of said tumor and said nontumor samples indicates the presence of a somatic alteration.				
001	5. The method of claim 1 wherein a nucleotide sequence of a regulatory region of the BRCA1 gene from said tumor sample is compared with a nucleotide sequence of a regulatory region of the BRCA1 gene from said nontumor sample, said regulatory region corresponding to nucleotides 1-1531 of SEQ ID NO:13.	No	No		1/20/15
001	6. The method of claim 1 wherein the nucleic acid sequence is compared by obtaining a first BRCA1 gene fragment from a BRCA1 gene from said tumor sample and a second BRCA1 gene fragment from a BRCA1 gene from a nontumor sample, said second fragment corresponding to said first fragment, forming single-stranded DNA from said first BRCA1 gene fragment and from said second BRCA1 gene fragment, electrophoresing said single-stranded DNAs on a non-denaturing polyacrylamide gel, comparing the mobility of said single-stranded DNAs on said gel to determine if said single-stranded DNA from said first BRCA1 gene fragment is shifted relative to said single-stranded DNA from said second BRCA1 gene fragment and sequencing said single-stranded DNA from said first BRCA1 gene fragment having a shift in mobility.	No	No		1/20/15
001	7. The method of claim 1 wherein the nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to either a wild-type or an altered BRCA1 allele to genomic DNA isolated from said tumor sample and to genomic DNA isolated from said nontumor sample and analyzing for the presence of a hybridization product in each sample, wherein a presence of said product in only one of said tumor and said nontumor samples indicates the presence of a somatic alteration.	No	No		1/20/15
001	8. The method of claim 1 wherein the nucleic acid sequence is compared by amplifying all or part of the BRCA1 gene from said tumor sample and from said	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	nontumor sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.				
001	9. The method of claim 1 wherein the nucleic acid sequence is compared by amplifying part of the BRCA1 gene using a primer specific for a specific BRCA1 altered allele and analyzing for the presence of a hybridization product in each sample, wherein a presence of said product in only one of said tumor and said nontumor samples indicates the presence of a somatic alteration.	No	No		1/20/15
001	10. The method of claim 1 wherein the nucleic acid sequence is compared by molecularly cloning all or part of the BRCA1 gene from said tumor sample and from said nontumor sample to produce cloned nucleic acids and sequencing the cloned nucleic acids.	No	No		1/20/15
001	11. The method of claim 1 wherein a nucleic acid sequence is compared by obtaining a first BRCA1 gene fragment from (a) BRCA1 genomic DNA isolated from said tumor sample, (b) BRCA1 RNA isolated from said tumor sample or (c) BRCA1 cDNA made from mRNA isolated from said tumor sample, obtaining a second BRCA1 gene fragment from (a) BRCA1 genomic DNA isolated from said nontumor sample, (b) BRCA1 RNA isolated from said nontumor sample or (c) BRCA1 cDNA made from mRNA isolated from said nontumor sample, said second BRCA1 gene fragment corresponding to said first BRCA1 gene fragment, forming single-stranded DNA from said first BRCA1 gene fragment and from said second BRCA1 gene fragment, forming a heteroduplex consisting of single-stranded DNA from said first BRCA1 gene fragment and single-stranded DNA from said second BRCA1 gene fragment analyzing the heteroduplex to determine if said single-stranded DNA from said first BRCA1 gene fragment has a mismatch relative to said single-stranded DNA from said second BRCA1 gene fragment and sequencing said single-stranded DNA from said first BRCA1 gene fragment having a mismatch.	No	No		1/20/15
001	12. The method of claim 1 wherein the nucleic acid sequence is compared by amplifying BRCA1 gene sequences from said tumor sample and from said	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	nontumor sample to produce amplified nucleic acids, hybridizing the amplified nucleic acids to a BRCA1 DNA probe which specifically hybridized to either a wild-type or an altered BRCA1 allele and analyzing for the presence of a hybridization product in each sample, wherein a presence of said product in only one of said tumor and said nontumor samples indicates the presence of a somatic alteration.				
001	13. The method of claim 1 wherein the nucleic acid sequence is compared by analyzing BRCA1 gene sequences in said tumor sample and said nontumor sample for a deletion mutation.	No	No		1/20/15
001	14. The method of claim 1 wherein the nucleic acid sequence is compared by analyzing BRCA1 gene sequences in said tumor sample and said nontumor sample for a point mutation.	No	No		1/20/15
001	15. The method of claim 1 wherein the nucleic acid sequence is compared by analyzing BRCA1 gene sequences in said tumor sample and said nontumor sample for an insertion mutation.	No	No		1/20/15
001	16. The method of claim 1 wherein the nucleic acid sequence is compared by hybridizing a tumor sample and a nontumor sample in situ with a nucleic acid probe which specifically hybridizes to either a wild-type or an altered BRCA1 allele and detecting the presence of a hybridization product in each sample, wherein the presence of said product in only one of said tumor and said nontumor samples indicates the presence of a somatic alteration.	No	No		1/20/15
001	17. The method of claim 1 wherein a nucleic acid sequence of BRCA1 cDNA made from mRNA from the tumor sample is compared to a nucleic acid sequence of BRCA1 RNA or BRCA1 cDNA from said nontumor sample.	No	No		1/20/15
001	18. The method of claim 1 wherein a nucleic acid sequence of BRCA1 gene from the tumor sample is compared to a nucleic acid sequence of BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample.	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
001	19. A method for detecting an alteration in a BRCA1 gene from a tumor sample from a human subject, said alteration selected from the group consisting of the alterations set forth in Tables 11 [frameshift, missense, loss of transcript] and 12 [frameshift, missense], which comprises analyzing a BRCA1 gene or BRCA1 RNA isolated from said tumor sample or analyzing a BRCA1 cDNA made from mRNA isolated from said tumor sample for the presence of said alteration.	No	No		1/20/15
001	20. the method of claim 19 wherein an alteration is detected by hybridizing a BRCA1 gene probe which specifically hybridizes to nucleic acids containing said alteration and not to wild-type BRCA1 sequences to RNA isolated from said tumor sample and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said alteration in the tumor.	No	No		1/20/15
001	21. The method of claim 19 wherein an alteration is detected by hybridizing a BRCA1 gene probe which specifically hybridizes to nucleic acids containing said denaturation and not to wild-type BRCA1 sequences to genomic DNA isolated from said sample and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said alteration in the tumor.	No	No		1/20/15
001	22. The method of claim 19 wherein an alteration is detected by amplifying all or part of a BRCA1 gene in said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.	No	No		1/20/15
001	23. The method of claim 19 wherein an alteration is detected by amplifying part of a BRCA1 gene in said sample using a primer specific for said alteration and detecting the presence of an amplified product, wherein the presence of said product indicates the presence of said alteration in the tumor.	No	No		1/20/15
001	24. The method of claim 19 wherein an alteration is detected by molecularly cloning all or part of a BRCA1 gene in said sample to produce a cloned nucleic acid and sequencing the cloned nucleic acid.	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
001	25. the method of claim 19 wherein an alteration is detected by amplifying BRCA1 gene nucleic acids in said sample, hybridizing the amplified nucleic acids to a BRCA1 DNA probe which specifically hybridizes to nucleic acids containing said alteration and not to wild-type BRCA1 sequences and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said alteration.	No	No		1/20/15
001	26. A method for screening a tumor sample from a human subject for the presence of a somatic alteration in a BRCA1 gene in said tumor which comprises comparing BRCA1 polypeptide from said tumor sample from said subject to BRCA1 polypeptide from a nontumor sample from said subject to analyze for a difference between the polypeptides, wherein said comparing is performed by (i) detecting either a full length polypeptide or a truncated polypeptide in each sample or (ii) contacting an antibody which specifically binds to either an epitope of an altered BRCA1 polypeptide or an epitope of a wild-type BRCA1 polypeptide to the BRCA1 polypeptide from each sample and detecting antibody binding, wherein a difference between the BRCA1 polypeptide from said tumor sample from the BRCA1 polypeptide from said nontumor sample indicates the presence of a somatic alteration in the BRCA1 gene in said tumor sample.	No	No		1/20/15
001	27. The method of claim 26 wherein said comparing is by detecting a truncated BRCA1 polypeptide.	No	No		1/20/15
001	28. The method of claim 26 wherein said comparing is by contacting an antibody which specifically binds to an epitope of an altered BRCA1 polypeptide from each sample and detecting antibody binding.	No	No		1/20/15
001	29. The method of claim 19 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		1/20/15
001	30. The method of claim 20 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		1/20/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
001	31. The method of claim 21 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		1/20/15
001	32. The method of claim 22 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		1/20/15
001	33. The method of claim 23 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		1/20/15
001	34. The method of claim 24 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		1/20/15
001	35. The method of claim 25 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		1/20/15
5753441	1. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.	No	Yes	Not eligible	8/12/14
441	2. The method of claim 1 wherein the wild-type BRCA1 gene has the sequence set forth in SEQ ID NO:1.	No	No		8/12/14
441	3. The method of claim 1 wherein the nucleic acid sequence of BRCA1 RNA from the subject is compared to nucleic acid sequences of wild-type BRCA1 gene, BRCA1 RNA orBRCA1 [sic] cDNA.	No	No		8/12/14
441	4. The method of claim 3 wherein the nucleic acid sequence is compared by	No	No		8/12/14

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to RNA isolated from said subject and detecting of the presence of a hybridization product, wherein a presence of said product indicates the presence of said allele in the subject.				
441	5. The method of claim 1 wherein a regulatory region of the BRCA1 gene from said subject is compared with a regulatory region of wild-type BRCA1 gene sequences, said regulatory region corresponding to nucleotides 1-1531 of SEQ ID NO:13.	No	No		8/12/14
441	6. The method of claim 1 wherein a germline nucleic acid sequence is compared by obtaining a first BRCA1 gene fragment from a BRCA1 gene from a human sample and a second BRCA1 gene fragment from a wild-1ype BRCA1 gene, said second fragment corresponding to said first fragment forming single-stranded DNA from said first BRCA1 gene fragment and from said second BRCA1 gene fragment, electrophoresing said single-stranded DNAs on a non-denaturing polyacrylamide gel, comparing the mobility of said single-stranded DNAs on said gel to determine if said single-stranded DNA from said first BRCA1 gene fragment is shifted relative to said second BRCA1 gene fragment and sequencing said single-stranded DNA from said first BRCA1 gene fragment having a shift in electrophoretic mobility.	No	No		8/12/14
441	7. The method of claim 1 wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.	No	No		8/12/14
441	8. The method of claim 1 wherein a germline nucleic acid sequence is compared by amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.	No	No		8/12/14
441	9. The method of claim 1 wherein a germline nucleic acid sequence is compared	No	No		8/12/14

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	by amplifying all or part of a BRCA1 gene using a primer specific for a specific BRCA1 mutant allele and detecting the presence of an amplified product, wherein the presence of said product indicates the presence of said specific allele.				
441	10. The method of claim 1 wherein a germline nucleic acid sequence is compared by molecularly cloning all or part of a BRCA1 gene from said sample to produce a cloned nucleic acid and sequencing the cloned nucleic acid.	No	No		8/12/14
441	11. The method of claim 1 wherein a germline nucleic acid sequence is compared by obtaining a first BRCA1 gene fragment from (a) BRCA1 gene genomic DNA isolated from said sample, (b) BRCA1 RNA isolated from said sample or (c) BRCA1 CDNA [sic] made from mRNA isolated from said sample, obtaining a second BRCA1 gene fragment from (a) wild-type BRCA1 genomic DNA, (b) wild-type BRCA1 RNA or (c) wild-type cDNA made from wild-type mRNA, said second BRCA1 gene fragment corresponding to said first BRCA1 gene fragment, forming single-stranded DNA from said first BRCA1 gene fragment and from said second BRCA1 gene fragment, forming a heteroduplex consisting of single-stranded DNA from said BRCA1 gene fragment and single-stranded DNA from said second BRCA1 gene fragment, analyzing the heteroduplex to determine if said single-stranded DNA from said first BRCA1 gene fragment has a mismatch relative to said single-stranded DNA from said second BRCA1 gene fragment and sequencing said first single-stranded DNA from said first BRCA1 gene fragment having a mismatch.	No	No		8/12/14
441	12. The method of claim 1 wherein a germline nucleic acid sequence is compared by amplifying BRCA1 nucleic acids from said sample to produce amplified nucleic acids, hybridizing the amplified nucleic acids to a BRCA1 DNA probe specific for a BRCA1 allele and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said allele in the subject.	No	No		8/12/14
441	13. The method of claim 1 wherein a germline nucleic acid sequence is compared by analyzing BRCA1 nucleic acids in said sample for a deletion mutation.	No	No		8/12/14

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
441	14. The method of claim 1 wherein a germline nucleic acid sequence is compared by analyzing BRCA1 nucleic acids in said sample for a point mutation.	No	No		8/12/14
441	15. The method of claim 1 wherein a germline nucleic acid sequence is compared by analyzing BRCA1 nucleic acids in said sample for an insertion mutation.	No	No		8/12/14
441	16. The method of claim 1 wherein a germline nucleic acid sequence is compared by hybridizing the tissue sample in situ with a nucleic acid probe specific for a BRCA1 allele and detecting the presence of a hybridization product, wherein a presence of said product indicates the presence of said allele in the subject.	No	No		8/12/14
441	17. The method of claim 1 wherein a nucleic acid of a germline BRCA1 cDNA made from mRNA from said sample is compared to nucleic acid sequences of wild-type BRCA1 gene, BRCA1 RNA or BRCA1 cDNA.	No	No		8/12/14
441	18. The method of claim 1 wherein a nucleic acid sequence of a germline BRCA1 gene from the subject is compared to nucleic acid sequences of wild-type BRCA1 gene, BRCA1 RNA or BRCA1 CDNA [sic].	No	No		8/12/14
441	19. The method of claim 1 wherein said difference is selected from the group consisting of missense mutations within the zinc finger motif, deletions, insertions, frameshift mutations, nonsense mutations and splice site mutations.	No	No		8/12/14
441	20. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 11 [frameshift, missense, and deletion of transcript] and 12 [frameshift and missense] which comprises analyzing a sequence of the BRCA1 gene or BRCA1 RNA from a human sample or analyzing the sequence of BRCA1 CDNA [sic] made from mRNA from said sample.	No	No		8/12/14
441	21. The method of claim 20 wherein a germline alteration is detected by hybridizing a BRCA1 gene probe which specifically hybridizes to an allele of one of	No	No		8/12/14

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	said alterations to RNA isolated from said human sample and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said allele in the sample.				
441	22. The method of claim 20 wherein a germline alteration is detected by hybridizing a BRCA1 gene probe which specifically hybridizes to one of said alterations to genomic DNA isolated from said sample and detecting of the presence of a hybridization product, wherein the presence of said product indicates the presence of said alteration in the sample.	No	No		8/12/14
441	23. The method of claim 20 wherein a germline alteration is detected by amplifying all or part of a BRCA1 gene in said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.	No	No		8/12/14
441	24. The method of claim 20 wherein a germline alteration is detected by amplifying part of a BRCA1 gene in said sample using a primer specific for an allele having one of said alterations and detecting the presence of an amplified product, wherein the presence of said product indicates the presence of said allele in the sample.	No	No		8/12/14
441	25. The method of claim 20 wherein a germline alteration is detected by molecularly cloning all or part of a BRCA1 gene in said sample to produce a cloned nucleic acid and sequencing the cloned nucleic acid.	No	No		8/12/14
441	26. The method of claim 20 wherein a germline alteration is detected by amplifying BRCA1 gene nucleic acids in said sample, hybridizing the amplified nucleic acids to a BRCA1 DNA probe specific for one of said alterations and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said alteration.	No	No		8/12/14
441	27. A method for screening for a germline alteration in a BRCA1 gene in a human subject which comprises analyzing a BRCA1 polypeptide from a tissue sample from said subject for an altered BRCA1 polypeptide by (i) detecting either a full length BRCA1 polypeptide or a truncated BRCA1 polypeptide or (ii) contacting an	No	No		8/12/14

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	antibody which specifically binds to an epitope of an altered BRCA1 polypeptide to the BRCA1 polypeptide from said sample and detecting bound antibody, wherein the presence of a truncated protein or bound antibody indicates the presence of a germline alteration in the BRCA1 gene.				
441	28. The method of claim 27 wherein a BRCA1 polypeptide is analyzed by detecting a truncated BRCA1 polypeptide.	No	No		8/12/14
441	29. The method of claim 27 wherein a BRCA1 polypeptide is analyzed by contacting an antibody which specifically binds to an epitope of an altered BRCA1 polypeptide to the BRCA1 polypeptide from said sample.	No	No		8/12/14
441	30. The method of claim 20 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		8/12/14
441	31. The method of claim 21 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		8/12/14
441	32. The method of claim 22 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		8/12/14
441	33. The method of claim 23 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		8/12/14
441	34. The method of claim 24 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:l.	No	No		8/12/14
441	35. The method of claim 25 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		8/12/14
441	36. The method of claim 26 wherein said alteration consists of a deletion of 11 nucleotides corresponding to base numbers 189-199 in SEQ ID NO:1.	No	No		8/12/14

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
441	37. A kit for screening for an alteration in a BRCA1 gene in a human subject which comprises at least one antibody (i) which specifically binds to wild-type BRCA1 polypeptide but not a truncated BRCA1 polypeptide or (ii) which specifically binds to an epitope of an altered BRCA1 polypeptide.	No	No		8/12/14
6033857	1. A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence.	No	Yes	Not eligible	12/18/15
857	2. A method for diagnosing a predisposition for breast cancer in a human subject which comprises comparing the germline sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from said subject with the germline sequence of the wild-type BRCA2 gene or the sequence of its mRNA, wherein an alteration in the germline sequence of the BRCA2 gene or the sequence of its mRNA of the subject indicates a predisposition to said cancer.	No	Yes	Not eligible	12/18/15
857	3. The method of claim 2 wherein an alteration is detected in a regulatory region of the BRCA2 gene.	No	No		12/18/15
857	4. The method of claim 2 wherein the detection in the alteration in the germline sequence is determined by an assay selected from the group consisting of (a) observing shifts in electrophoretic mobility of single-stranded DNA on non-denaturing polyacrylamide gels, (b) hybridizing a BRCA2 gene probe to genomic DNA isolated from said tissue sample, (c) hybridizing an allele-specific probe to genomic DNA of the tissue sample, (d) amplifying all or part of the BRCA2 gene from said tissue sample to produce an amplified sequence and sequencing the amplified sequence, (e) amplifying all or part of the BRCA2 gene from said tissue sample using primers for a specific BRCA2 mutant allele, (f) molecularly cloning all or part of the BRCA2 gene from said tissue sample to produce a cloned sequence and sequencing the cloned sequence, (g) identifying a mismatch between (1) a	No	No		12/18/15

Patent	Claim	Reviewed by SCOTUS?	ACLU contested?	Patent Eligible under §101?	Exp.
	BRCA2 gene or a BRCA2 mRNA isolated from said tissue sample, and (2) a nucleic acid probe complementary to the human wild-type BRCA2 gene sequence, when molecules (1) and (2) are hybridized to each other to form a duplex, (h) amplification of BRCA2 gene sequences in said tissue sample and hybridization of the amplified sequences to nucleic acid probes which comprise wild-type BRCA2 gene sequences, (i) amplification of BRCA2 gene sequences in said tissue sample and hybridization of the amplified sequences to nucleic acid probes which comprise mutant BRCA2 gene sequences, (j) screening for a deletion mutation in said tissue sample, (k) screening for a point mutation in said tissue sample, (l) screening for an insertion mutation in said tissue sample, (m) in situ hybridization of the BRCA2 gene of said tissue sample with nucleic acid probes which comprise the BRCA2 gene.				
857	5. A method for detecting a mutation in a neoplastic lesion at the BRCA2 gene in a human subject which comprises comparing the sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from a lesion of said subject with the sequence of the wild-type BRCA2 gene or the sequence of its mRNA, wherein an alteration in the sequence of the BRCA2 gene or the sequence of its mRNA of the subject indicates a mutation at the BRCA2 gene of the neoplastic lesion.	No	No		12/18/15
857	6. The method of claim 5 wherein an alteration is detected in the a [sic] regulatory regions of the BRCA2 gene.	No	No		12/18/15
857	7. The method of claim 5 wherein the detection in the alteration in the BRCA2 sequence is determined by an assay selected from the group consisting of (a) observing shifts in electrophoretic mobility of single-stranded DNA on non-denaturing polyacrylamide gels, (b) hybridizing a BRCA2 gene probe to DNA isolated from said tissue sample, (c) hybridizing an allele-specific probe to DNA of the tissue sample, (d) amplifying all or part of the BRCA2 gene from said tissue sample to produce an amplified sequence and sequencing the amplified sequence, (e) amplifying all or part of the BRCA2 gene from said tissue sample using primers for a specific BRCA2 mutant allele, (f) molecularly cloning all or part of the BRCA2 gene from said tissue sample to produce a cloned sequence and	No	No		12/18/15

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	sequencing the cloned sequence, (g) identifying a mismatch between (1) a BRCA2 gene or a BRCA2 mRNA isolated from said tissue sample, and (2) a nucleic acid probe complementary to the human wild-type BRCA2 gene sequence, when molecules (1) and (2) are hybridized to each other to form a duplex, (h) amplification of BRCA2 gene sequences in said tissue sample and hybridization of the amplified sequences to nucleic acid probes which comprise wild-type BRCA2 gene sequences, (i) amplification of BRCA2 gene sequences in said tissue sample and hybridization of the amplified sequences to nucleic acid probes which comprise mutant BRCA2 gene sequences., (0) screening for a deletion mutation in said tissue sample, (k) screening for a point mutation in said tissue sample, (1) screening for an insertion mutation in said tissue sample, (m) in situ hybridization of the BRCA2 gene of said tissue sample with nucleic acid probes which comprise the BRCA2 gene.				
857	8. A method for confirming the lack of a BRCA2 mutation in a neoplastic lesion from a human subject which comprises comparing the sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from a lesion of said subject with the sequence of the wild-type BRCA2 gene or the sequence of its RNA, wherein the presence of the wild-type sequence in the tissue sample indicates the lack of a mutation at the BRCA2 gene.	No	No		12/18/15