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FICPI AI Patent Drafting Masterclass

16 September 2026

Corinthia Hotel, Budapest, Hungary

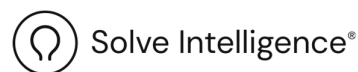
Exercise Materials: Biotechnology



120
YEARS

SINCE 1906

COURSE SPONSORS



AFTERNOON DRAFTING EXERCISE

Mutation detection in a cancer-susceptibility gene

DELEGATE NOTES

DELEGATE NOTES

This section contains instructions for delegates.

Circulate with the draft application, sequence listing, client letter and new figure.

Purpose

This exercise is about learning to use your AI drafting tool. It is not about biotechnology, and it is not about what you ought to claim.

You will be given a completed draft application, and a letter from the client supplying one new piece of subject matter. The task is to work that new material into the draft using your tool, and then check what the tool has produced.

There is no right answer.

What you get, and when

Before the workshop: the draft application (specification, claims, drawing and sequence listing). Please read it, and please don't try to identify the source patent.

At the start of the exercise: a letter from the client and new FIG. 2. The letter and figure contain everything you need.

You will have 50 minutes, working with your own AI drafting tool.

What to do

Using your tool, work the client's new information into the draft. That is likely to mean:

- adding a new example describing the variant and how it is detected;
- deciding how to handle the sequence — a new SEQ ID NO, or a definition tied to SEQ ID NO: 1;
- adding the new figure (FIG. 2) to the drawings and writing its legend;
- amending the claims to cover the new variant;
- updating the summary and anything else in the description that has to match.

Then review the result. Does it all still line up — positions, claim numbering, terminology? Has the tool added anything the client did not actually say?

Then discuss

Compare notes with the others: where the tool helped, where it went wrong, and what you had to correct yourself.

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Draft Patent Application — Advance Reading

Biotechnology / Life Sciences

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ADVANCE READING

Prepared for workshop use. Follow the circulation instructions in this document.

CANCER-SUSCEPTIBILITY GENE AND MUTATION DETECTION

Field and Background

The invention relates to a human cancer-susceptibility gene and to the detection of mutations in that gene.

A proportion of breast and ovarian cancer cases cluster within families in a pattern consistent with inheritance of a susceptibility allele. Linkage studies localised a susceptibility locus to chromosome 17q, but the gene had not been isolated. Risk assessment therefore depended on linkage analysis within large kindreds, which is uninformative for small families and individuals with few affected relatives. There remains a need for the isolated gene and its mutant alleles, so that predisposing mutations may be detected directly.

Alterations may include deletions, insertions and point mutations in coding or non-coding regions, which may introduce premature stop codons, alter the reading frame, disrupt RNA processing or reduce expression, and may thereby impair the function of the encoded tumour-suppressor protein.

Summary of the Invention

In one aspect, the invention provides an isolated DNA encoding a cancer-susceptibility polypeptide. In another aspect, it provides isolated DNA fragments. In a further aspect, the invention provides isolated mutant alleles of the gene that are associated with susceptibility to breast or ovarian cancer.

The invention also provides methods and kits for detecting a mutation in the gene. Detection may use amplification primers, direct sequencing, restriction analysis, allele-specific oligonucleotide hybridisation, single-strand conformation analysis or another suitable method. A mutation-specific reagent may distinguish a mutant allele from the corresponding wild-type allele.

Brief Description of Drawings

FIG. 1 shows a mutation and cosegregation analysis for a kindred carrying a single-nucleotide insertion that produces a frameshift.

Detailed Description

Gene and encoded product

SEQ ID NO: 1 is a 5,914-nucleotide cDNA whose coding sequence begins at nucleotide 120, with the sense codons extending to nucleotide 5708 and the termination codon occupying nucleotides 5709 to 5711. SEQ ID NO: 2 is the encoded polypeptide of 1,863 amino acids. All nucleotide positions in this specification and in the claims are numbered from nucleotide 1 of SEQ ID NO: 1; amino-acid positions are numbered from residue 1 of SEQ ID NO: 2. The gene is referred to herein as the FICP11 gene and its encoded product as the FICP11 polypeptide. The protein includes an N-terminal C3HC4 zinc-finger motif and a substantial acidic region toward the C-terminus. Multiple transcript forms may arise through alternative splicing.

Mutant alleles

Certain mutant alleles of the gene are associated with susceptibility to breast or ovarian cancer. In one embodiment, a mutant allele comprises SEQ ID NO: 1 having an additional cytosine at nucleotide position 5385. The insertion alters the reading frame and is predicted to produce an abnormal amino-acid sequence beginning 108 residues before the C-terminus of the wild-type protein. In another embodiment, a mutant allele comprises SEQ ID NO: 1 having guanine at nucleotide position 5443. The substitution changes a methionine residue to arginine. In a further embodiment, a mutant allele comprises SEQ ID NO: 1 having nucleotides 189-199 deleted. The deletion alters the reading frame and is predicted to produce an abnormal amino-acid sequence beginning at the 24th residue from the N-terminus. Other mutant alleles may be identified by the methods described herein.

Mutation detection

A tissue sample may be tested for an alteration of the wild-type gene. Germline testing may be carried out using DNA from blood or another tissue. Tumour tissue may be tested for somatic alterations. Suitable techniques include direct sequencing, restriction-fragment analysis, allele-specific oligonucleotide hybridisation, single-strand conformation analysis and amplification-based methods. In one approach, a portion of the gene may be amplified from nucleic acid in a sample and the amplified portion compared with the corresponding sequence of SEQ ID NO: 1 to determine whether a mutant allele is present.

Once a mutation is known, a mutation-specific primer or probe may be used to screen additional samples. The reagent should be sufficiently specific to distinguish the mutant allele from the corresponding wild-type allele under the selected assay conditions.

Kits

A kit for detecting a mutation in the gene may comprise one or more amplification primers, one or more allele-specific oligonucleotide probes, or both. The kit may further comprise a restriction enzyme whose recognition site is created or abolished by the mutation, one or more control nucleic acids, buffers and reagents for amplification or hybridisation, and instructions for detecting the mutation.

Example 1 - screening of candidate mutant alleles

Coding exons and associated splice junctions were amplified from genomic DNA or from cDNA prepared from lymphocyte RNA. Amplified sequences from affected kindreds were compared with the wild-type sequence. Candidate mutations were evaluated for likely disruption of the encoded protein, cosegregation with the disease-associated haplotype, and rarity in control populations.

Example 2 - single-nucleotide insertion

A single-nucleotide insertion was identified at nucleotide position 5385 in a coding exon of one kindred. The insertion of an additional cytosine alters the reading frame and is predicted to produce an abnormal C-terminal amino-acid sequence beginning 108 residues before the C-terminus. Sequencing of additional family members showed the insertion in carriers of the disease-associated haplotype and not in a non-carrier. This embodiment is illustrated in FIG. 1.

Example 3 - missense substitution

A further kindred contained a single-base substitution at nucleotide position 5443 that changes a methionine residue to arginine. An allele-specific oligonucleotide was used to test family members and control samples for the sequence variant. The variant cosegregated with the disease-associated haplotype and was not detected in the control population examined.

Brief Description of the Sequences

Identifier	Description
SEQ ID NO: 1	Wild-type cDNA of the cancer-susceptibility gene, with the coding sequence at nucleotides 120 to 5708.

Identifier	Description
SEQ ID NO: 2	Wild-type encoded polypeptide sequence of 1,863 amino acids.

Claims

1. An isolated DNA encoding a cancer-susceptibility polypeptide having the amino-acid sequence of SEQ ID NO: 2.
2. The isolated DNA of claim 1, wherein the DNA has the nucleotide sequence of SEQ ID NO: 1.
3. An isolated DNA comprising at least 15 consecutive nucleotides of the DNA of claim 2.
4. An isolated mutant DNA selected from the group consisting of: (a) SEQ ID NO: 1 having an additional cytosine at nucleotide position 5385; (b) SEQ ID NO: 1 having guanine at nucleotide position 5443; and (c) SEQ ID NO: 1 having nucleotides 189-199 deleted.
5. A pair of single-stranded DNA primers for determining whether a sample contains the FICPI1 gene, the sequences of said primers being derived from human chromosome 17q, wherein use of said primers in a polymerase chain reaction results in synthesis of DNA having all or part of the sequence of the gene.
6. A kit for detecting mutations associated with susceptibility to breast or ovarian cancer, comprising at least one oligonucleotide primer or allele-specific oligonucleotide probe specific for a mutation in the FICPI1 gene and instructions for detecting the mutation.
7. A method for detecting a mutant allele of the FICPI1 gene in a sample, comprising amplifying a portion of the gene from nucleic acid in the sample and determining whether the amplified portion differs from the corresponding sequence of SEQ ID NO: 1.
8. The method of claim 7, wherein the determining step comprises direct sequencing, digestion with a restriction enzyme, hybridisation with an allele-specific oligonucleotide, or single-strand conformation analysis.

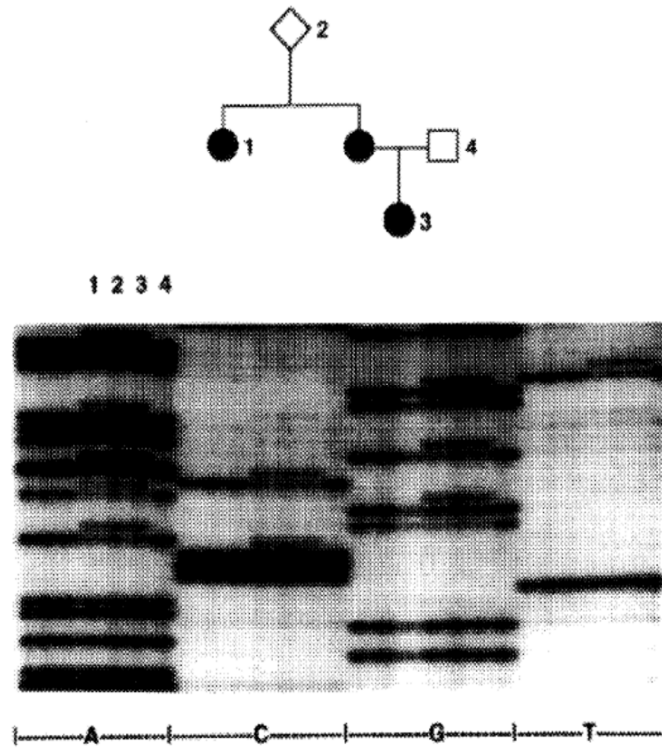


FIG. 1

Abstract

The disclosure concerns an isolated human cancer-susceptibility gene, its encoded polypeptide, mutant alleles associated with susceptibility to breast and ovarian cancer, and methods and kits for detecting mutations in the gene.

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Sequence Listing — Advance Reading

Biotechnology / Life Sciences

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ADVANCE READING

Prepared for workshop use. Follow the circulation instructions in this document.

Sequence Listing Information:

DTD Version: V1_3
File Name: FICPI AI Drafting Masterclass (Biotech).xml
Software Name: WIPO Sequence
Software Version: 2.3.0
Production Date: 2026-07-29

General Information:

Current application / Applicant file reference: CET-G5/BIO/2026-001
Applicant name: CET Biosciences AG
Applicant name / Language: en
Inventor name: Ronelle Goldhouse
Inventor name / Language: en
Invention title: CANCER-SUSCEPTIBILITY GENE AND MUTATION DETECTION (en)
Sequence Total Quantity: 2

Sequences:

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Sequence Number (ID): 2

Length: 1863

Molecule Type: AA

Features Location/Qualifiers:

- source, 1..1863
 > mol_type, protein
 > organism, Homo sapiens

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180	ELGSDSSEDT	VNKATYCSVG	DQELLQITPQ	GTRDEISLDS	AKKAACEFSE	TDVTNTEHHQ	
240	PSNNDLNTTE	KRAAERHPEK	YQGSSVSNLH	VEPCGTNTHA	SSLQHENSSL	LLTKDRMNVE	
300	KAFCNKSQK	PGLARSQHNR	WAGSKETCND	RRTPSTEEKV	DLNADPLCER	KEWNKQKLPC	
360	SENPRDTEDEV	PWITLNSSIQ	KVNEWFSRSD	ELLGSDSDSHD	GESESNAKVA	DVLDVLNEVD	
420	EYSGSSEKID	LLASDPHEAL	ICKSERVHSK	SVESNIEDKI	FGKTYRKKAS	LPNLSHVTEN	
480	LIIGAFVTEP	QIIQERPLTN	KLKRKRRTS	GLHPEDFIKK	ADLAVQKTPE	MINQGTNQTE	
540	QNGQVMNITN	SGHENKTKGD	SIQNEKNPNP	IESLEKESAF	KTKAEPISSS	ISNMELELNI	
600	HNSKAPKKNR	LRRKSSTRHI	HALELVSRN	LSPPNCTELQ	IDSCSSSEEI	KKKKYNQMPV	
660	RHSRNLQLME	GKEPATGAKK	SNKPNEQTSK	RHSDTFPEL	KLTNAPGSFT	KCSNTSELKE	
720	FVNPSLPREE	KEEKLETVKV	SNNAEDPKDL	MLSGERVLQT	ERSVESSSIS	LVPGTDYGTQ	
780	ESISLLEVST	LGKAKTEPNK	CVSQCAAFEN	PKGLIHGCSK	DNRNDTEGFK	YPLGHEVNHS	
840	RETSIEMEES	ELDAQYLQNT	FKVSKRQSFA	PFSNPGNAEE	ECATFSAHSG	SLKKQSPKVT	
900	FECEQKEENQ	GKNESNIKPV	QTVNITAGFP	VVGQKDKPVD	NAKCSIKGGS	RFCLSSQFRG	
960	NETGLITPNK	HGLLQNRYRI	PPLFPIKSFV	KTKCKKNLLE	ENFEEHSMSP	EREMGNENIP	
1020	STVSTISRNN	IRENVFKEAS	SSNINEVGSS	TNEVGSSINE	IGSSDENIQA	ELGRNRGPKL	
1080	NAMLRGLVLQ	PEVYQSLPG	SNCKHPEIKK	QEYEEVVQTV	NTDFSPYLIS	DNLEQPMGSS	
1140	HASQVCSETP	DDLDDGEIK	EDTSFAENDI	KESSAVFSKS	VQKGELSRSP	SPFTHTHLAQ	
1200	GYRRGAKKLE	SSEENLSSD	EELPCFQHLL	FGKVNNIPSQ	STRHSTVATE	CLSKNTEENL	
1260	LSLKNSLNDC	SNQVILAKAS	QEHHLSEETK	CSASLFSSQC	SELEDLTANT	NTQDPFLIGS	
1320	SKQMRHQSES	QGVGLSDKEL	VSDDEERGTG	LEENNQEEQS	MDSNLGEAAS	GCESETSVSE	
1380							

1440	DCSGLSSQSD	ILTTQQRDTM	QHNLIKLQQE	MAELEAVLEQ	HGSQPSNSYP	SIISDSSALE
1500	DLRNPEQSTS	EKAVLTSQKS	SEYPISQNPE	GLSADKFEVS	ADSSTSKNKE	PGVERSSPSK
1560	CPSLDDRWYM	HSCSGSLQNR	NYPSQEELIK	VVDVEEQQLE	ESGPHDLTET	SYLPRQDLEG
1620	TPYLESGISL	FSDDPESDPS	EDRAPESARV	GNIPSSTSAL	KVPQLKVAES	AQSPAAAHTT
1680	DTAGYNAMEE	SVSREKPELT	ASTERVNKRM	SMVVSGLTPE	EFMLVYKFAR	KHHITLTNLI
1740	TEETTHVVMK	TDAEFVCERT	LKYFLGIAGG	KWVVSFWVT	QSIKERKMLN	EHD FEVRGDV
1800	VNGRHHQGPK	RARESQRKI	FRGLEICCYG	PFTNMPTDQL	EWMVQLCGAS	VVKELSSFTL
1860	GTGVHPIVVV	QPDAWTEDNG	FHAIGQMCEA	PVVTREWVLD	SVALYQCQEL	DTYLIPQIPH
1863	SHY					
END						

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Client Letter — Workshop Day

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16 September 2026

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29 July 2026

Dr. Newton Ventive, Esq.

Docket Fielding LLP

Re: *draft patent application — “Cancer-Susceptibility Gene and Mutation Detection”*

Dear Newton,

Thank you for sending through the draft application. I have now read it carefully, and I think it captures our work very well — the description of the gene and of the variants we have found so far reads exactly as I would have hoped. There is, however, one further variant my team has just discovered that I would like added before we file.

The variant is a single base change, C to T, at nucleotide position 4056 of SEQ ID NO: 1, the wild-type sequence in the draft. This change converts a glutamine codon into a stop codon. We therefore predict that the mutant protein product is truncated and lacks the final 551 amino acids from the C-terminus.

Helpfully, the substitution also creates a new restriction-enzyme recognition site. This means that the variant can be detected by a straightforward PCR-then-digest test, rather than by sequencing the whole region. I have not included the enzyme name or any primer sequences here, but the principle is that carriers give both cut and uncut products, while non-carriers remain uncut.

In the family we have studied, the variant was present in relatives carrying the disease-associated haplotype and absent in the family members tested who did not carry it. I enclose a gel figure illustrating the restriction analysis, in which each lane contains the amplification product from a different family member.

Could you please incorporate this variant and the supporting assay into the draft, finalise the application, and file it as soon as possible ahead of the disclosure? We are sorry to trouble you with this now, as we know you are in Budapest at a very important conference this week, but since we need to disclose this remarkable discovery to our external partners by the end of the week, we would be most grateful if you would skip a couple of the wonderful dinners you will be attending and work on this for us instead, as you always do. We know you have access to some wonderful AI drafting tools, so perhaps they will help you be quick enough that you only miss the starter.

Kind regards,

Dr Ronelle Goldhouse

Chief Scientific Officer

CET Biosciences AG

Enclosure: Figure showing restriction analysis of amplification products from family members

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New Figure 2 — Workshop Day

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