WTS

WTS RZECZNICY PATENTOWI | WTS PATENT ATTORNEYS

Anna Grzelak and Rafał Witek

Patenting of molecular markers in Poland and Europe – comparative case study and indications for Polish applicants

Diagnostic assays based on moleculars markers
10-11 May 2016, Warsaw, Poland

Topics:

- Comparison of Polish Industrial Patent Law and European Patent Convention- regulations relating to bio-med inventions.

- Comparative case study of the outcome of the procedures in different jurisdictions PL, EPO and US.

- Patent eligibility for bio-med inventions in US vs. EPO/PL – in brief view.

- Why not to follow the US way? Why should we hope for changes in US patent law in bio-med?

- How one can effectively protect inventions in bio-med?

Comparison of the Polish Industrial Patent Law and the European Patent Convention

PL (Industrial Property Law):	EP (European Patent Convnention):
Patentable inventions- Art. 24 IPL	Patentable inventions- Art. 52 (1) EPC
NOT an invention – Art. 28 IPL (*not be regarded as inventions:* *(i) discoveries*)	NOT an invention – Art. 52(2) & (3) EPC (*not be regarded as inventions:* *(2a) discoveries;* *(3) excludes subject matter or activities* ***as such***
Exceptions to patentability- Art. 29 IPL Patents shall not be granted for: (iii) methods for treatment of the human or animal body by surgery or **therapy or diagnostic methods applied on human or animal bodies**; this provision s**hall not apply to products, and in particular to substances or compositions applied in diagnostics or treatment.**	Exceptions to patentability- Art. 53 EPC European patents **shall not be granted** in respect of: (c) methods for treatment of the human or animal body by surgery or **therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.**

Comparison of the Polish Patent Law and the European Patent Convention

PL (Industrial Property Law):	EP (European Patent Convnention):
Novelty - Art. 25 IPL	Novelty - Art. 54 EPC
Inventive step - Art. 26 IPL	Inventive step - Art. EPC
Industrial applications- Art. 27 IPL	Industrial applications – Art. 57 EPC
Special Provisions Governing Biotechnological Inventions Chapter 9 IPL: Biotechnological Inventions – **Art. 93 $^{1-7}$ IPL** General definitions - Art. 93^{1} IPL**:** -Biotechnological inventions; -Biological material -Microbiological process	**Biotechnological Inventions** Chapter V of IR: Biotechnological Inventions – **Rules 26-34 of IR** General definitions - Rule 26 of IR: -Biotechnological inventions; -Biological material; -Microbiological process -as **a supplementary means of interpretation** **Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used**

Comparison of the Polish Patent Law and the European Patent Convention

PL (Industrial Property Law):	EP (European Patent Convnention and Implementing Regulations to EPC):
The human body and its elements and **exceptions to patentability – Art. 93³ IPL:** • The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, **including the sequence or partial sequence of a gene, cannot constitute patentable inventions**; • exceptions for cloning human beings, modifying germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, modifying the genetic identity of animals (suffering, no benefits)	The human body and its elements and **exceptions to patentability** – **Rule 28 and Rule 29 (1) IR** • The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, **including the sequence or partial sequence of a gene, cannot constitute patentable inventions**; • exceptions for cloning human beings, modifying germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, modifying the genetic identity of animals (suffering, no benefits)

Comparison of the Polish Patent Law and the European Patent Convention

PL (Industrial Property Law):	EP (European Patent Convnention and Implementing Regulations to EPC):
Patentable biotechnological inventions – Art. 93^2 IPL: • **isolated biological material** even if it previously occurred in nature; • element isolated from the human body including **the sequence or partial sequence of a gene even if identical to natural element;** • **industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application**, and in the independent patent claim the function of the sequence must be indicated	Patentable biotechnological inventions – Rule 27 IR and Rule 29 (2) & (3): • **isolated biological material** even if it previously occurred in nature; • element isolated from the human body **including the sequence or partial sequence of a gene even if identical to natural element** • **industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application**

Comparison of the Polish Patent Law and the European Patent Convention

PL (Industrial Property Law):	EP (European Patent Convnention and Implementing Regulations to EPC):
Requirements of patent applications relating to nucleotide and amino acid sequences:	
Art. 93³ (4) IPL: **-** if the invention relates **to industrial application of a sequence or a partial sequence of a gene,** the applicant must provide nucleotide or amino acid sequences in electronic form	**Rule 30 IR of EPC** -the description shall contain a sequence listing conforming to the rules laid down by the President of the EPO for the standardised representation of nucleotide and amino acid sequences (electronic form, WIPO St25)
If biological material which is not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art may be **disclosed by a deposit**	
Deposit of biological material – **Art. 93⁶ IPL:** the disclosure thereof may be made by reference to the material deposited in a recognised depositary institution on **the application filing date at the latest**	Deposit of biological material – **Rule 31, 33, 34 IR** - **a sample of the biological material has been deposited with a recognised depositary institution** (terms as in the Budapest Treaty) **not later than on the application filing date**

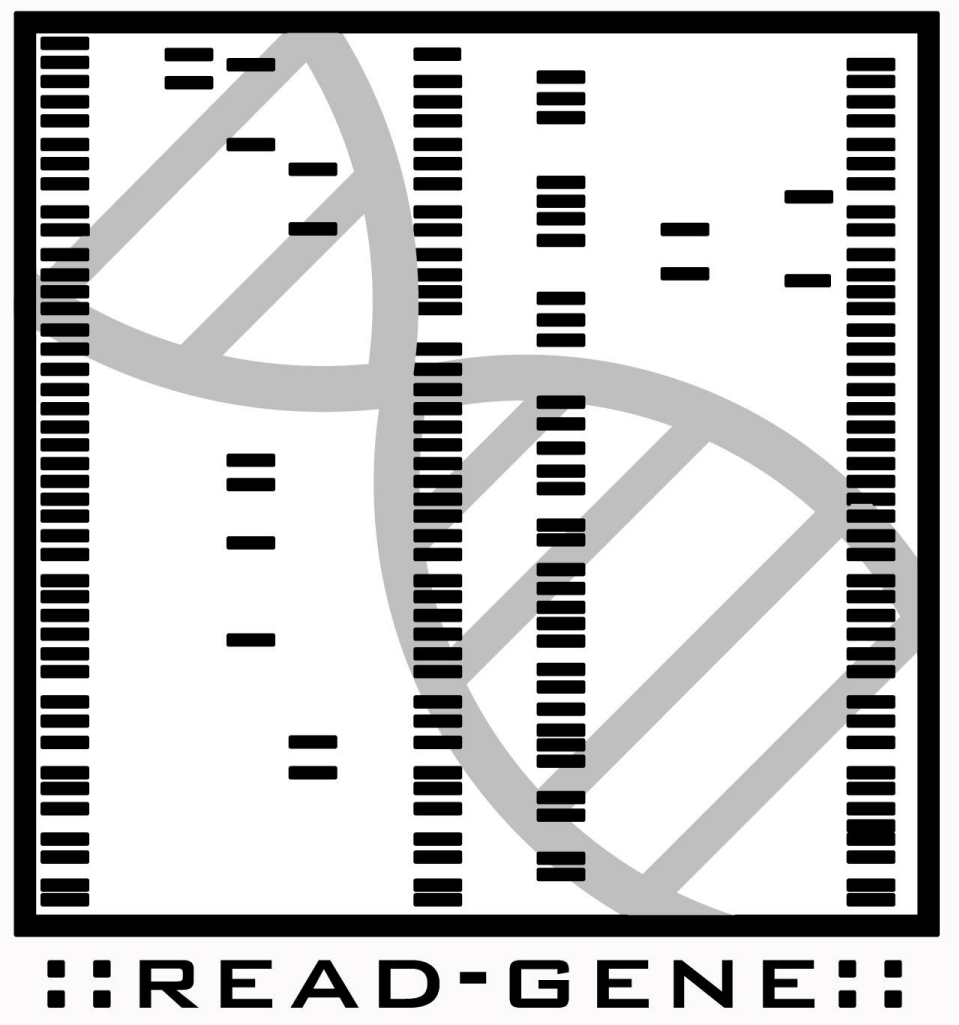
The regulations relating to the biotechnological inventions including patenting molecular markers are almost identical under IPL and EPC.

Is the outcome of the same procedures in PL and EPO identical?

Pomeranian Medical University
Read-Gene S.A.

„The company's special fields are chemoprevention, clinical trials **and genetic testing**.

Read-Gene **philosophy in genetics is to improve cancer prevention, early detection, and treatment** and in effect to decrease the cost of oncologic management."



Patent strategy:

- Creation of the company's value through a systematic construction of the company's patent portfolio.

- Adjustment of the territorial range of a patent protection to the current and potential market.

The company focuses on genetic examination of patients of Slavic origin. The aim of patenting is the protection of markets where the company sells its products and services and where there may exist a demand for such services.

Therefore, the scope of protection since the company's establishment is focusing on Poland, Europe, and the USA.

The current portfolio of the company comprises **over 40 patent families** including **more than 20 Polish patents**, **several European patents and patent applications**, and **4 US patents**.

What kind of inventions are protected by the company?

Searching for a correlation between the selected genotype features, such as the presence of specific mutations of the selected genes, and the existing or predicted phenotype features.

In particular, the phenotype features include: a predisposition to a specific type of tumour, susceptibility to a chemotherapy with a specific anti-cancer drug, an expected course of a cancer, especially cancer malignancy.

The genetic studies conducted by the company led to the determination of specific genetic profiles correlated with particular phenotypes.

The diagnostic tests developed by the company are based on the examination of a patient's genotype in order to determine whether s/he has a genetic profile correlated with a specific phenotype.

Categories of the claimed inventions:

In order to obtain possibly broad scope of protection, we have claimed:

1. **A method** of diagnosing a particular phenotype comprising identification of genotype features correlated with said phenotype.

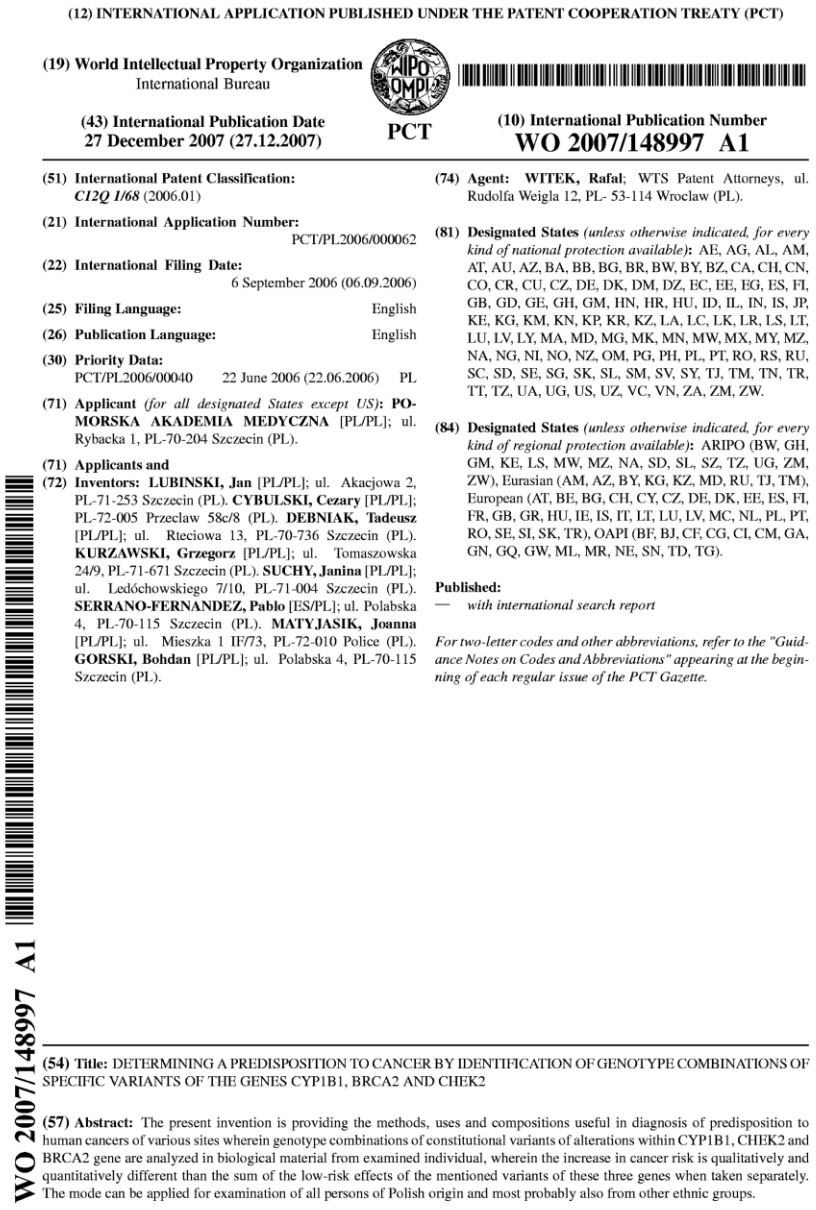
2. **The use** of defined genotype features to identify a particular phenotype.

3. **A kit** for diagnosing a specific phenotype comprising tools for the identification of defined genotype features;

Examples of the claims from patent application

PCT/PL2006/000062

DETERMINING A PREDISPOSITION TO CANCER BY IDENTIFICATION OF GENOTYPE COMBINATIONS OF SPECIFIC VARIANTS OF THE GENES CYP1B1, BRCA2 AND CHEK2



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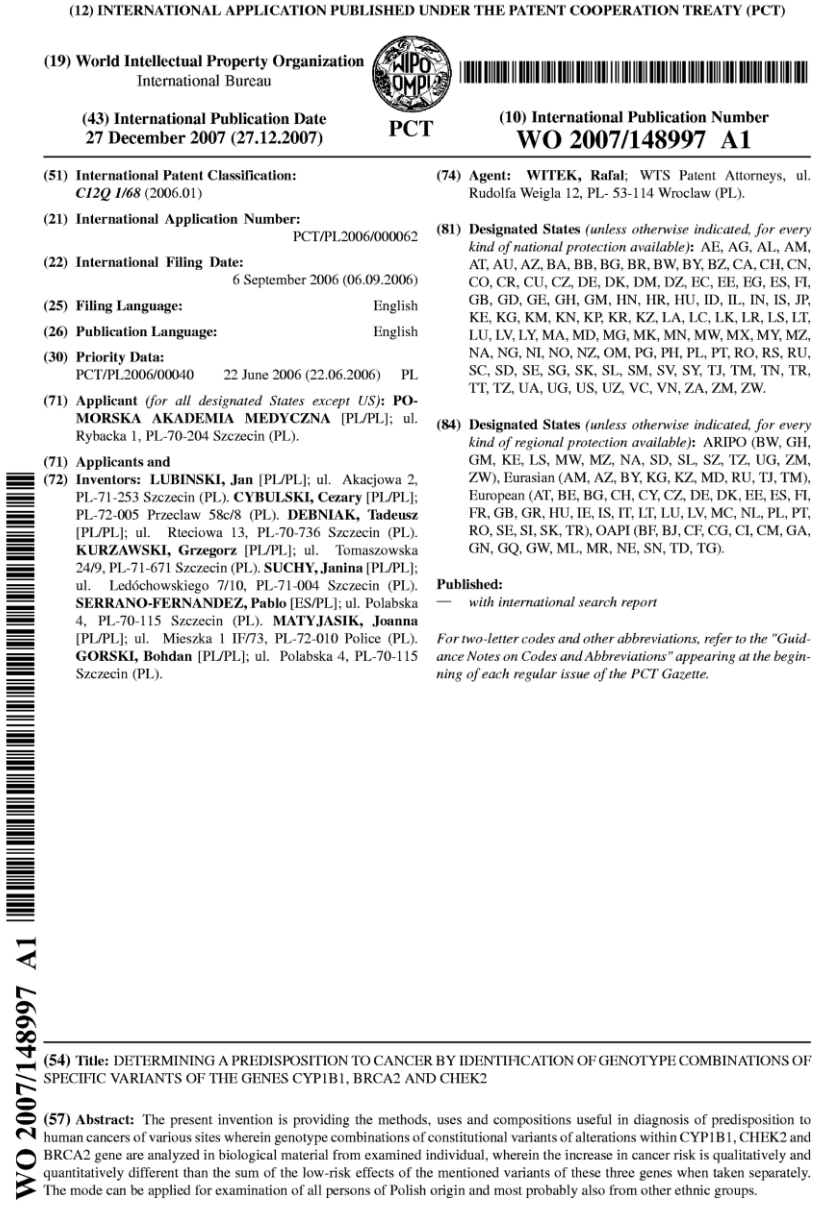
PCT/PL2006/000062

1. A method for detecting a predisposition to cancer in human subject characterized in, that comprises

detecting in a biological sample from the subject the combined genotype based on identified variants of genotypes of CYPIBI gene, CHEK2 gene and BRC A2 gene,

wherein the presence of the combined genotype is indicating a high-risk predisposition to at least one of the following cancers: cancers of the breast, colon, kidney, larynx, lung, pancreas, prostate, thyroid, female genital tract and ovaries,

which is qualitatively and quantitatively different than the sum of the low-risk effects of the variants of these three genes when taken separately.



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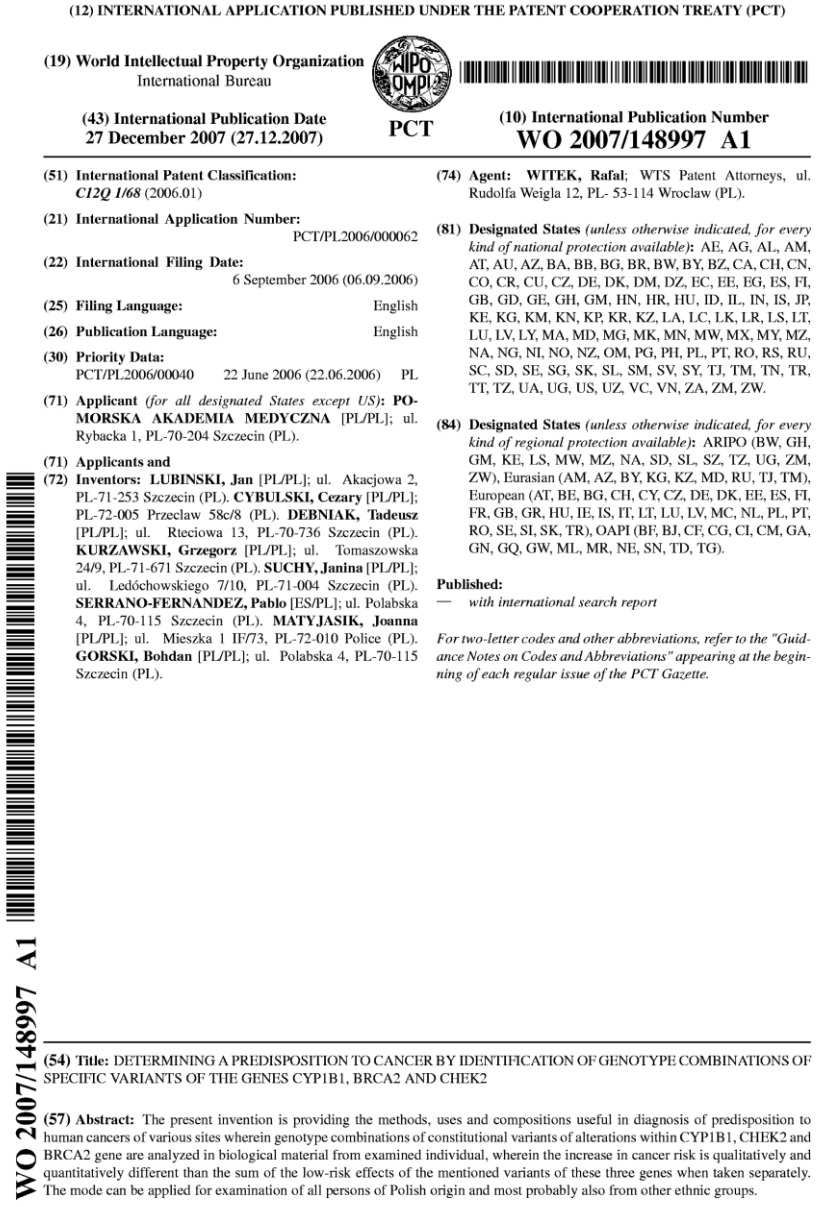
PCT/PL2006/000062

14. Use of combined genotype based on identified variants of genotypes of CYPlBl gene, CHEK2 gene and BRCA2 gene or polynucleotides specific for this combined genotypes or polypeptides encoded by these polynucleotides
for diagnosing in human subject a high-risk predisposition to at least one of the following cancers: cancers of the breast, colon, kidney, larynx, lung, pancreas, prostate, thyroid, female genital tract and ovaries,
which is qualitatively and quantitatively different than the sum of the low-risk effects of the variants of these three genes when taken separately,
wherein
the identified variant of genotype of CYPlBl gene comprises at least one of the genotypes based on C142G, G355T and C4326G SNPs within CYPlBl gene
and
the identified variant of genotype of CHEK2 gene comprises at least one of the genotypes based on llOOdelC, del5395, and IVS2+1G>A truncating variants and I157T missense variant of CHEK2 gene
and
the identified variant of genotype of BRCA2 gene comprises C5972T variant of BRCA2 gene.

PCT/PL2006/000062

18. Diagnostic composition for detection of predisposition to cancer in human subject, comprising oligonucleotides allowing amplification of regions of genome of said human specific for CYPlBl genotypes defined in claim 5 and CHEK2 genotypes defined in claim 6 and BRCA2 genotype defined in claim 7,
wherein the presence of the combined genotype of these three genes is indicating a high-risk predisposition to at least one of the following cancers: cancers of the breast, colon, kidney, larynx, lung, pancreas, prostate, thyroid, female genital tract and ovaries, which is qualitatively and quantitatively different than the sum of the low-risk effects of the variants of these three genes when taken separately.



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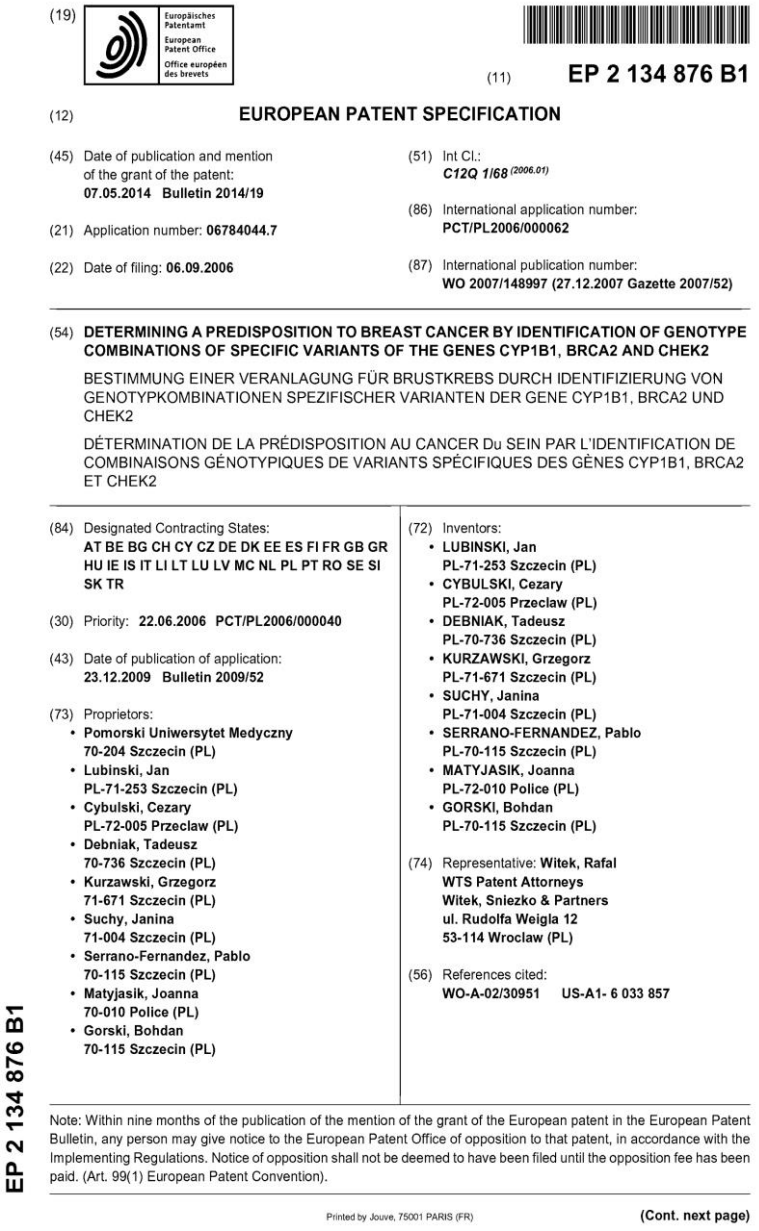
Claims accepted in various jurisdictions

EP2134876B1

DETERMINING A PREDISPOSITION TO BREAST CANCER BY IDENTIFICATION OF GENOTYPE COMBINATIONS OF SPECIFIC VARIANTS OF THE GENES CYP1B1, BRCA2 AND CHEK2



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(54) **DETERMINING A PREDISPOSITION TO BREAST CANCER BY IDENTIFICATION OF GENOTYPE COMBINATIONS OF SPECIFIC VARIANTS OF THE GENES CYP1B1, BRCA2 AND CHEK2**

BESTIMMUNG EINER VERANLAGUNG FÜR BRUSTKREBS DURCH IDENTIFIZIERUNG VON GENOTYPKOMBINATIONEN SPEZIFISCHER VARIANTEN DER GENE CYP1B1, BRCA2 UND CHEK2

DÉTERMINATION DE LA PRÉDISPOSITION AU CANCER Du SEIN PAR L'IDENTIFICATION DE COMBINAISONS GÉNOTYPIQUES DE VARIANTS SPÉCIFIQUES DES GÈNES CYP1B1, BRCA2 ET CHEK2

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(56) References cited:
WO-A-02/30951 US-A1- 6 033 857

EP 2 134 876 B1

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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EP2134876B1

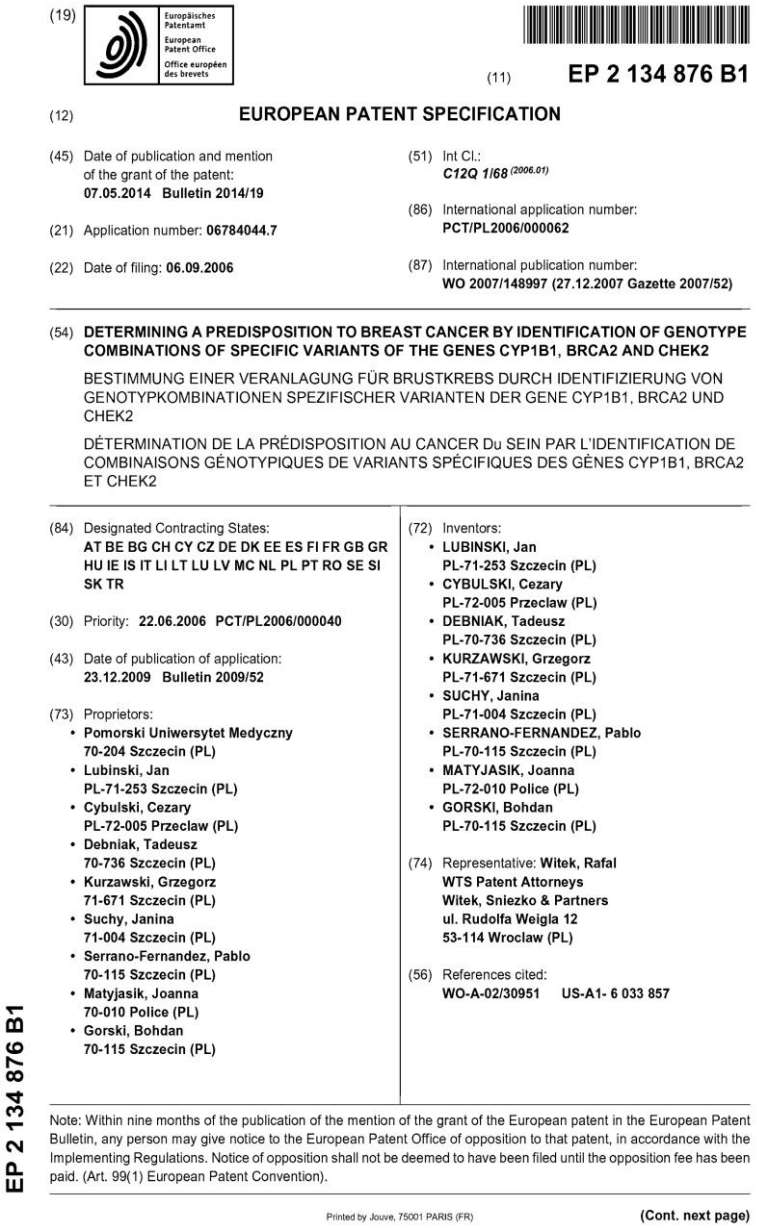
1. A method for detecting a disproportionate increase in breast cancer risk in human subject characterized in that it comprises:

a) identifying in a biological sample from the subject the genotypes of:
i) CYP1B1 gene variants at positions 142 (codon 48), 355 (codon 119) and 4326 (codon 432), wherein the CYP1B1 gene genotype variants comprise the following combinations:
- 142 not G/G, 355 not G/G, 4326 C/C, or
- 142C/C, 355G/G, 4326 not G/G, or
- 142G/G, 355T/T, 4326C/C;
ii) 1100delC, del5395, IVS2+1G>A truncating variants and I157T missense variant within CHEK2 gene;
iii) C5972T variant within BRCA2 gene;

b) establishing a presence of a genotype leading to a disproportionate increase in breast cancer risk in case of identification at least one of the following combined genotype:
- at least one of the CYP1B1 gene genotype variant as indicated in point i) combined with at least one of the CHEK2 gene genotype variant as indicated in point ii), or
- at least one of the CHEK2 gene genotype variant as indicated in point ii) combined with BRCA2 gene genotype variant as indicated in point iii), or
- at least one of the CYP1B1 gene genotype variant as indicated in point i) and at least one of the CHEK2 gene genotype variant as indicated in point ii) and BRCA2 gene genotype variant as indicated in point iii).

EP2134876B1

7. Use of the combined genotype of CYP1B1 gene, CHEK2 gene and BRCA2 gene as defined in claim 1 for in vitro diagnosing a disproportionate increase in breast cancer risk in human subject.



(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11) EP 2 134 876 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: **07.05.2014 Bulletin 2014/19**

(21) Application number: **06784044.7**

(22) Date of filing: **06.09.2006**

(51) Int Cl.: ***C12Q 1/68*** *(2006.01)*

(86) International application number: **PCT/PL2006/000062**

(87) International publication number: **WO 2007/148997 (27.12.2007 Gazette 2007/52)**

(54) **DETERMINING A PREDISPOSITION TO BREAST CANCER BY IDENTIFICATION OF GENOTYPE COMBINATIONS OF SPECIFIC VARIANTS OF THE GENES CYP1B1, BRCA2 AND CHEK2**

BESTIMMUNG EINER VERANLAGUNG FÜR BRUSTKREBS DURCH IDENTIFIZIERUNG VON GENOTYPKOMBINATIONEN SPEZIFISCHER VARIANTEN DER GENE CYP1B1, BRCA2 UND CHEK2

DÉTERMINATION DE LA PRÉDISPOSITION AU CANCER Du SEIN PAR L'IDENTIFICATION DE COMBINAISONS GÉNOTYPIQUES DE VARIANTS SPÉCIFIQUES DES GÈNES CYP1B1, BRCA2 ET CHEK2

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

(30) Priority: **22.06.2006 PCT/PL2006/000040**

(43) Date of publication of application:
23.12.2009 Bulletin 2009/52

(73) Proprietors:
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- **Suchy, Janina**
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- **Serrano-Fernandez, Pablo**
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(56) References cited:
WO-A-02/30951 US-A1- 6 033 857

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EP 2 134 876 B1

Case study – Read-Gene S.A.

RZECZPOSPOLITA POLSKA

Urząd Patentowy Rzeczypospolitej Polskiej

(12) **TŁUMACZENIE PATENTU EUROPEJSKIEGO**

(19) **PL** (11) **PL/EP 2134876**

(13) **T3**

(51) Int.Cl.
C12Q 1/68 (2006.01)

(96) Data i numer zgłoszenia patentu europejskiego:
06.09.2006 06784044.7

(97) O udzieleniu patentu europejskiego ogłoszono:
07.05.2014 Europejski Biuletyn Patentowy 2014/19
EP 2134876 B1

(54) Tytuł wynalazku:

Określanie predyspozycji do raka piersi poprzez identyfikację kombinacji genotypu specyficznych wariantów genów CYP1B1, BRCA2 oraz CHEK2

(30) Pierwszeństwo:
22.06.2006 WO PCT/PL2006/000040

(43) Zgłoszenie ogłoszono:

23.12.2009 w Europejskim Biuletynie Patentowym nr 2009/52

(45) O złożeniu tłumaczenia patentu ogłoszono:

31.10.2014 Wiadomości Urzędu Patentowego 2014/10

(73) Uprawniony z patentu:

Pomorski Uniwersytet Medyczny, Szczecin, PL
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Dębniak, Tadeusz, Szczecin, PL
Kurzawski, Grzegorz, Szczecin, PL
Suchy, Janina, Szczecin, PL
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PL/EP 2134876 T3

(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11) **EP 2 134 876 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
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(21) Application number: **06784044.7**

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(30) Priority: **22.06.2006 PCT/PL2006/000040**

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(74) Representative: **Witek, Rafal**
WTS Patent Attorneys
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(56) References cited:
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EP 2 134 876 B1

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PL214855B1

Patent granted by Polish Patent Office

RZECZPOSPOLITA POLSKA

Urząd Patentowy Rzeczypospolitej Polskiej

(12) **OPIS PATENTOWY** (19) **PL** (11) **214855** (13) **B1**

(21) Numer zgłoszenia: **375857**

(22) Data zgłoszenia: **23.06.2005**

(51) Int.Cl.
C12Q 1/68 (2006.01)
A61P 35/00 (2006.01)

(54) **Sposób wykrywania genetycznie uwarunkowanej predyspozycji do nowotworów różnych narządów poprzez identyfikację wariantu genu *CYP1B1* oraz zastosowania obejmujące taką zmianę**

(43) Zgłoszenie ogłoszono:
27.12.2006 BUP 26/06

(45) O udzieleniu patentu ogłoszono:
30.09.2013 WUP 09/13

(73) Uprawniony z patentu:
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(74) Pełnomocnik:
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PL 214855 B1

PL214855B1

Accepted method claim:

1. Sposób wykrywania genetycznie uwarunkowanej predyspozycji do nowotworów, **znamienny tym**, że w próbce materiału genetycznego pobranej od pacjenta bada się obecność zmiany germinalnej w obrębie genu CYP1B1, którą to jest obecność mutacji A119S wariant 355T/T, a obecność rzeczonej zmiany wskazuje na predyspozycję o niskiej penetracji do raków wybranych spośród następujących narządów: piersi, krtani oraz płuc, przy czym pacjent jest osobą pochodzenia polskiego.

machine translation:

A method of detecting genetic predisposition to cancer, characterized in that in a sample of genetic material extracted from the patient is tested showed presence germ within the CYP1B1 gene, which is a mutation A119S variant of 355T / T and the presence of said changes indicate a predisposition of low penetrance cancer selected from the following organs: breast, larynx and lung, wherein the patient is a person of Polish origin.

PL214855B1

Accepted use claims concerning:

„use of germline alteration”

4. Zastosowanie zmiany germinalnej w obrębie genu CYP1B1 lub polinukleotydu zawierającego tę zmianę do wykrywania *in vitro* zwiększonej, genetycznie uwarunkowanej predyspozycji o niskiej penetracji do przynajmniej jednego spośród następujących raków: piersi, krtani oraz płuc, przy czym zmianą germinalną w obrębie genu CYP1B1 jest mutacja A119S wariant 355T/T, a pacjent jest osobą pochodzenia polskiego.

„use of detection of mutiation”

7. Zastosowanie wykrywania mutacji konstytucyjnej A119S wariant 355T/T w genie CYP1B1 do diagnozowania *in vitro* genetycznie uwarunkowanej predyspozycji o niskiej penetracji do przynajmniej jednego spośród następujących raków: piersi, krtani oraz płuc u pacjenta pochodzenia polskiego.

„use of polypeptide”

10. Zastosowanie polipeptydu kodowanego przez allel genu CYP1B1 zawierający zmianę germinalną do wykrywania *in vitro* genetycznie uwarunkowanej predyspozycji o niskiej penetracji do przynajmniej jednego spośród następujących raków: piersi, krtani oraz płuc, w którym zmianą germinalną w obrębie genu CYP1B1 jest mutacja A119S wariant 355T/T, przy czym zmiana wykrywana jest u pacjenta pochodzenia polskiego.

PL214855B1

Accepted use claims concerning:

„use of polynucleotide”

12. Zastosowanie polinukleotydu zawierającego polinukleotyd posiadający w pozycji odpowiadającej pozycji 355 eksonu 2 ludzkiego genu CYP1B1 mutację Nt355G>T albo inny polinukleotyd kodujący wariant białka CYP1B1 zawierający w pozycji 119 substytucję A119S wariant 355T/T albo polipeptydu kodowanego przez rzeczony polinukleotyd do wytwarzania kompozycji diagnostycznej do wykrywania *in vitro* zwiększonej genetycznie uwarunkowanej predyspozycji o niskiej penetracji do nowotworu u osoby posiadającej genom zawierający wariant allelu genu CYP1B1 kodujący wariant białka CYP1B1 zawierający w pozycji 119 substytucję A119S wariant 355T/T, przy czym wykrywana jest predyspozycja, o niskiej penetracji do przynajmniej jednego spośród następujących raków: piersi, krtani oraz płuc u pacjenta pochodzenia polskiego.

„use of antibody”

13. Zastosowanie przeciwciała specyficznego wobec polipeptydu kodowanego przez polinukleotyd zawierający polinukleotyd posiadający w pozycji odpowiadającej pozycji 355 eksonu 2 ludzkiego genu CYP1B1 mutację Nt355G>T albo inny polinukleotyd kodujący wariant białka CYP1B1 zawierający w pozycji 119 substytucję A119S wariant 355T/T do wytwarzania kompozycji diagnostycznej do wykrywania *in vitro* zwiększonej genetycznie uwarunkowanej predyspozycji o niskiej penetracji do nowotworu u osoby posiadającej genom zawierający wariant allelu genu CYP1B1 kodujący wariant białka CYP1B1 zawierający w pozycji 119 substytucję A119S wariant 355T/T, przy czym wykrywana jest predyspozycja, o niskiej penetracji do przynajmniej jednego spośród następujących raków: piersi, krtani oraz płuc u pacjenta pochodzenia polskiego.

Problems observed during an attempt to obtain a broad protection in the Polish and European Patent Office:

1. A necessity to narrow the claimed kit to a structural definition (i.e. sequence of primers)

2. The doubts connected with the technical character of a claimed use

In my opinion, the recognition of the technical character of the second medical use shall confirm also the technical character of the diagnostics use.

The problems relating to the inventive step recognition (Polish Patent Office, European Patent Office)

The claimed inventions related to solutions for which there was a different prior art level.

In effect, the essence of the invention can be connected with the following:

- a new phenotypic feature (mutation) associated with cancer;
- a new composition of the known phenotypic features (the set of mutations) as correlated with a specific phenotype, e.g. an increased risk of breast cancer in the group of patients from Polish population;
- determining that the course of the same cancer, e.g. a breast cancer, in the same group of patients is extremely severe,
- determining that the same group of patients is sensitive to chemotherapy with a particular anti-cancer drug.

Patents granted by the USPTO before the practice change

US 7,407,755 B2

Patent granted by USPTO

(12) **United States Patent**
Lubiński et al.

(10) **Patent No.: US 7,407,755 B2**
(45) **Date of Patent: Aug. 5, 2008**

(54) **DETERMINING A PREDISPOSITION TO CANCER**

(76) Inventors: **Jan Lubiński**, Ul. Akacjowa 2, Szczecin (PL) 71-253; **Janina Suchy**, ul. Ledochoskiego 7/10, Szczecin (PL) 71-004; **Grzegorz Kurzawski**, ul. Tomaszowska 24/9, Szczecin (PL) 71-671; **Tadeusz Dêbniak**, ul. Rteclowa 13, Szczecin (PL) 70-736; **Cezary Cybulski**, 72-005 Przeclaw 58c/8, Przeclaw (PL) 72-005

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **11/037,657**

(22) Filed: **Jan. 18, 2005**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 60/565,724, filed on Apr. 27, 2004, provisional application No. 60/563,089, filed on Apr. 16, 2004, provisional application No. 60/536,746, filed on Jan. 15, 2004.

(51) **Int. Cl.**

C12Q 1/68	(2006.01)
C07H 21/04	(2006.01)
C12P 19/34	(2006.01)

(52) **U.S. Cl.** **435/6**; 536/23.1; 435/91.2

(58) **Field of Classification Search** ..... None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2002/0004206 A1 * 1/2002 Berger et al. 435/6

OTHER PUBLICATIONS

Dong et al. Mutations in CHEK2 Associated with Prostate Cancer Risk. 2003. American Journal of Human Genetics. vol. 72 pp. 270-280.*

Bell et al. Heterozygous Germ Line hCHK2 Mutations in Li-Fraumeni Syndrome. 1999. Science. vol. 286 pp. 2528-2531.*

Dufault et al. Limited Relevance of the CHEK2 gene in hereditaty breast cancer. International Journal of Cancer. vol. 110 pp. 320-325.*

Ingvarsson et al. Mutation analysis of the CHK2 gene in breast carcinoma and other cancers. 2002. Breast Cancer Research. vol. 4 pp. 1-6.*

Verhagen, Arianne. Is the ρ value really so significant. 2004. Australian Journal of Physiotherapy vol. 50 pp. 261-262.*

Dufault, Michael et al. Limited Relevance of the CHEK2 gene in hereditary breast cancer. 2004. International Journal of Cancer. vol. 110 pp. 320-325.*

* cited by examiner

Primary Examiner—Sarae Bausch
Assistant Examiner—Amanda Shaw
(74) *Attorney, Agent, or Firm*—Gary J. Gershik; Cooper & Dunham LLP

(57) **ABSTRACT**

The present invention relates to methods and kits for determining a predisposition and surveillance protocols for developing cancer of various sites due to specific mutation in at least one allele of CHEK2 gene and/or at least one allele of NOD2 gene and/or at least one allele of CDKN2A gene.

14 Claims, 3 Drawing Sheets

US 7,407,755 B2

Accepted method claims:

1. A method for detecting in a human subject a predisposition to breast, stomach, or thyroid cancer comprising obtaining a DNA sample from the human subject, and determining whether an IVS2+1G>A alteration is present in the CHEK2 gene of the human subject, wherein presence of the IVS2+1G>A alteration in the CHEK2 gene is indicative of a predisposition to breast, stomach, or thyroid cancer.

8. A method for detecting in a human subject a predisposition to colon or kidney cancer comprising obtaining a DNA sample from the human subject, and determining the presence of a I157T alteration in the CHEK2 gene in said DNA sample, wherein presence of the I157T alteration in the CHEK2 gene is indicative of a predisposition to colon or kidney cancer.

Currently, these types of inventions are not patentable in the USA.

Patent eligibility for bio-med inventions in US vs. EPO – in brief view

US:	EP:
§101 of 35 USC - machines, composition of matter, articles of manufacture, and processes are patentable inventions; Judical exceptions: -Abstract ideas -**Natural phenomena** -**Laws of nature** To determine subject matter eligibility: TEST: Do the claims as the whole recite **significantly more** that the abstract idea?	Art. 52 EPC - patentable invention - any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. Exclusions in Art. 52 and 53 EPC - discoveries „as such" and exceptions to patentability (plant or animal varieties, essentially biological processes for the production of plants or animals, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body) Difference between invention and discovery provided by **technical effect / given function.** In EPO there is no problem with the abstract idea but there may be a problem with the inventive step.

Difference: two analytical approaches designated for the same purpose to exclude „mere discoveries" from being patented but in US there are „significantly more" requirements added.

Patent eligibility for bio-med inventions in US vs. EPO – in brief view

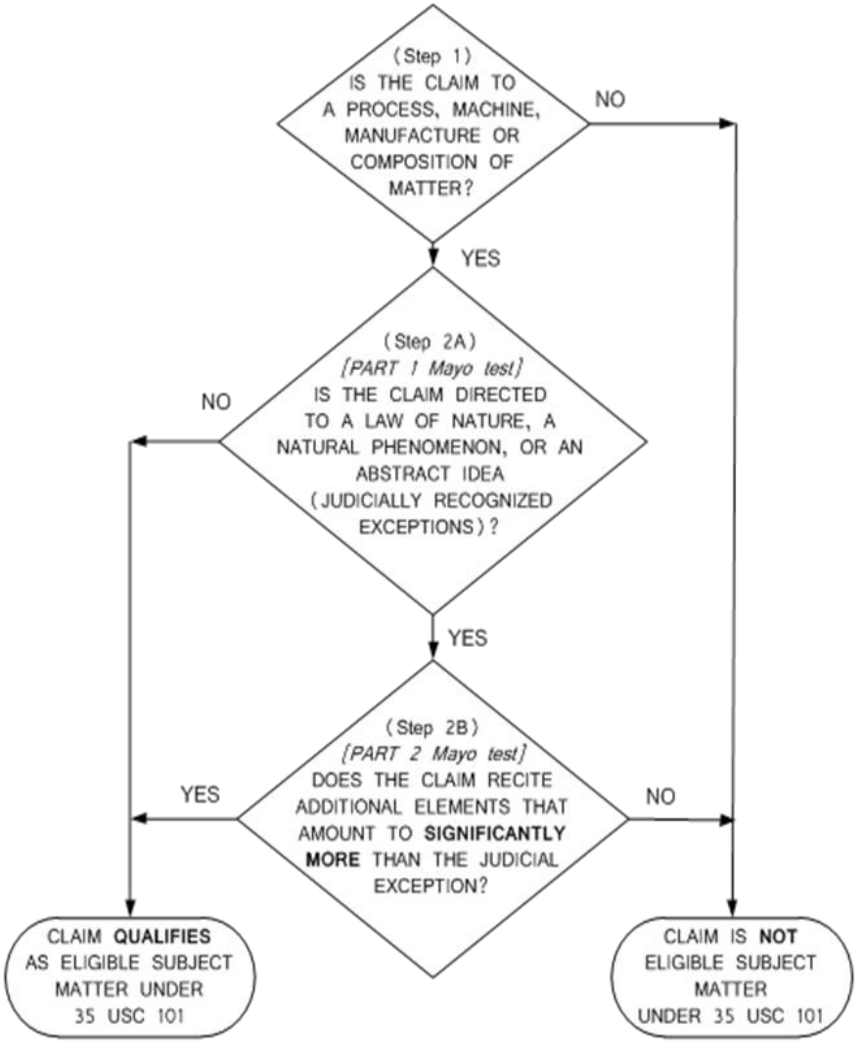
Examiners in the US shall:

- Review the disclosure to identify what applicant considers as the invention.

- Determine if the claim falls into a statutory category.

- Identify the judicial exception recited in the claim (if any).

- Determine if the claim as a whole recites significantly more than the judicial exception itself.



Patent eligibility for bio-med inventions in US vs. EPO – in brief view

US:

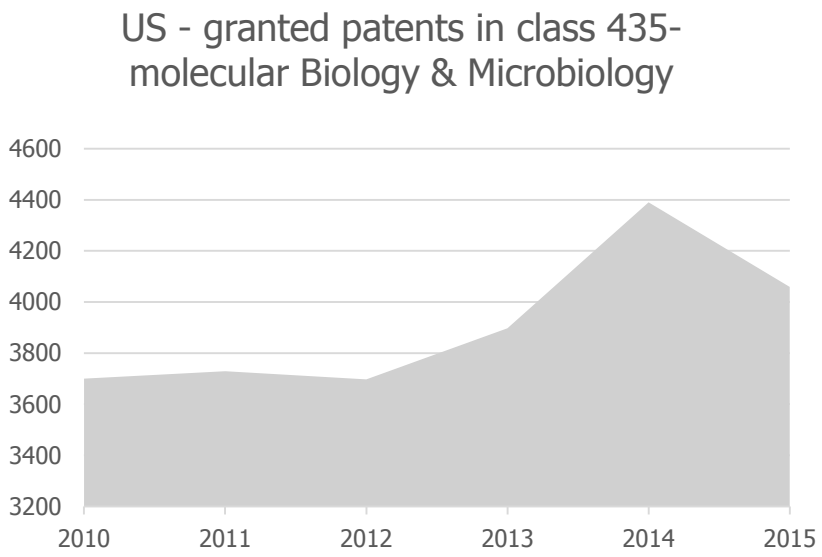
Cases influencing Judical Exceptions- Supreme Court Decision:

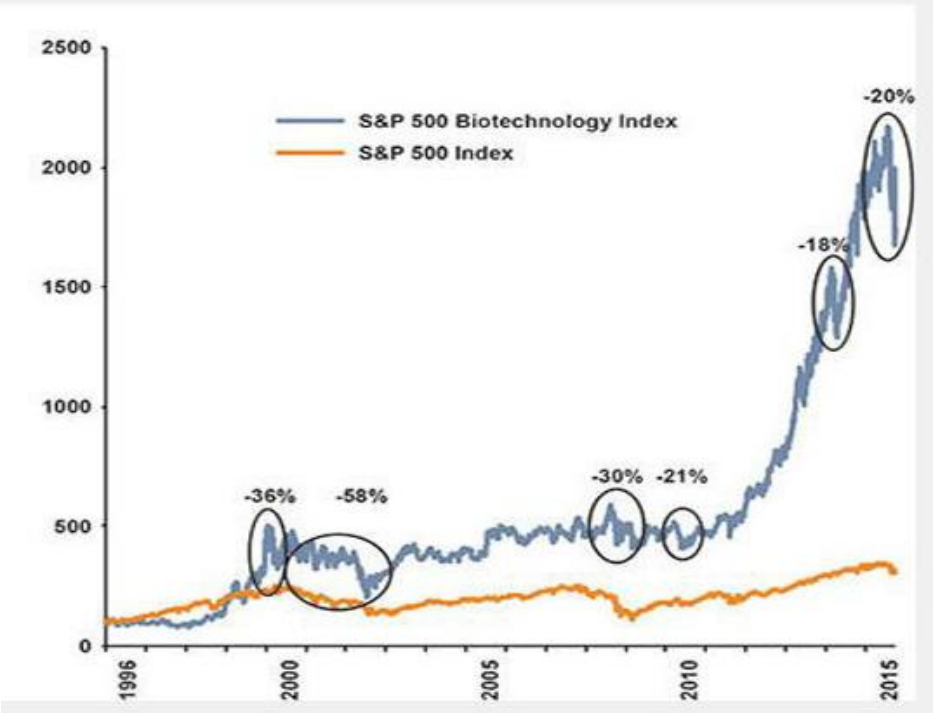
Mayo vs. Prometheus (2012)- US 6,355,623: optimizing therapeutic efficiancy by measurment of 6-thioguanine level in subject with gastrointensinal disorder- process reciting a law of nature – personalized medicine dosing not patentable (granted EP1115403)

Myriad Genetics vs. Association for Molecular Pathology (2013) – product of nature - genetic test based on BRCA1 and BRCA2, naturally occuring isolated DNA is not patent eligible, even when its function is indicated in application, cDNA patentable

Federal Circuit – decision appealed
Ariosa vs. Sequenom (2015)- method of detection paternally inherited nucleic acid of fetal origin in pregnant female serum or plasma - natural phenomenon even if PCR was used to detect cffDNA, MaterniT21 test- alternative for prenatal diagnosis of fetal DNA from female blood

Nature exceptions (Myriad Guidelines):
- **correlation between biomarker and disease;**
- **diagnostic methods**;
- chemicals derived from natural sources, isolated DNA, RNA;
- organisms (isolated bacteria, plants).





Price return of S&P 500 Biotechnology Index and the S&P 500 indexed to 100 from January 1, 1996 – September 30, 2015; circles represent drops in index value and values show peak-to-trough returns during the period. Source: FactSet

Patent eligibility for bio-med inventions in US – the influence of IP in bio-med in US on industry and development

The effect of changes in US practice :

- Risk in biotech ventures;
- Uncertainty of claims that may be allowed in US, challenge of patenting bio-med worldwide;
- Changes in stock markets/values of shares and in numbers of patents filing / granting.

Suggestions for patent drafting for Polish applicants:

- Prepare the strategy, ask for advice;
- Provide description and claims beyond mere comparing, provide as many examples as possible;
- Clearly indicate the feature(s) and effect(s) /improvement(s) obtained due to the use of these feature(s);
- Provide additional elements beyond the law of nature, natural product, abstract idea like adding non-conventional steps - novel testing techniques or testing reagents or devices;
- Provide information that you solved a specific technical problem in a specific technology;
- Fulfill all formal requirements (sequence listing, deposits).

Importance of IP protection for bio-med industry and development

„The incentives to innovate provided by the patent system **depend above all on predictability**.

Only with the knowledge that patents will provide some period of exclusivity will innovators continue to make the massive investment of time and resources needed to develop innovative diagnostic tests and deliver these life-changing products to patients in need."

(from BRIEF OF *AMICUS CURIAE* COALITION FOR 21ST CENTURY MEDICINE IN SUPPORT OF SEQUENOM)

We strongly recommend to keep the EPO and PPO open to the possibility of patenting the bio-med inventions as broad as possible as this is the only way to reward the innovators and investors and allows the future development of innovative products and methods.

Thank you for your attention!

Questions?

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