



22 April 2016

Overview National Laws on Nucleic Acid Sequences

The table below contains answers to the following questions:

- 1) Is there purpose/function limited protection of nucleic acid sequences in the patent legislation of your jurisdiction? (YES/NO)
- 2) Could you please explain this and cite the relevant legal provision(s)?¹
- 3) Has the patent office in your jurisdiction published guidelines for examination of purpose/function limited protection of nucleic acid sequences? If yes, could you please cite the relevant part(s) of those guidelines?

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| AL | NO | The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability. | NO |

¹ Please note that the English translations provided are not necessarily official.

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| | <p>Excerpts from ALBANIAN LAW Nr. 9947 dated 07.07.2008 ON INDUSTRIAL PROPERTY:</p> <p>Article 5 Patentable Inventions [...] 5. Biotechnological inventions shall also be patentable if they concern: [...] ç) an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.</p> <p>Article 6 Exceptions to patentability Patents shall not be granted in respect of: [...] 3. 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. [...]</p> <p>Article 10 Applicability in Industry and Agriculture</p> | |
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| | | <p>[...] 2. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.</p> | |
| AT | NO | <p>A purpose/function has only to be indicated in the specification and not in the claims. It is needed to meet the requirement of industrial applicability and does not limit the scope of the claims (see Sec 1 and 89a of the Austrian Patents Act).</p> <p>Excerpts from the Austrian Patents Act:</p> <p>§ 1. Patentable inventions (1) On request, patents shall be granted for inventions in all fields of technology, provided that they are new (section 3), not obvious to the person skilled in the art from the state of the art, and susceptible of industrial application. (2) Inventions that fulfill the conditions of subsection 1 shall be patented, even if they concern a product consisting of or containing biological material or a method by means of which biological material is produced, processed or used, wherein biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. These patentable inventions shall also include 1. biological material which is isolated from its natural environment or produced by means of a technical method even if it previously occurred in nature;</p> | <p>No, but there exist examination guidelines in which the industrial applicability of sequences is discussed (the most relevant parts thereof are cited below).</p> <p>Excerpt from the Examination Guidelines of Biotechnological Inventions of the Austrian Patent Office:</p> <p>6 Industrial Applicability The Patent Act (§ 1 para. 1 of the Patent Law) stipulates that an invention must be industrially applicable. This is not the case if the product is unusable or useless. It is therefore necessary to consider whether the claimed invention fulfills a useful purpose. Directive 98/44 / EC (recital 22) and § 89a Patent Law stipulate that the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed. Therefore, the intended use of a sequence, i.e. its function, has to be derivable from the application as filed at the filing date. [...] The possible use of short DNA sequences or ESTs (= partially sequenced cDNA clones) as probes, is not considered to be sufficient. [...]</p> |

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| | | <p>2. an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element. [...]</p> <p>(3) The following in particular shall not be regarded as inventions: [...]</p> <p>2. the human body at the various stages of its formation and development; 3. the simple discovery of one of the elements of the human body, including the sequence or partial sequence of a gene; [...]</p> <p>§ 89a. The industrial application of a sequence or partial sequence of a gene must be disclosed in the application.</p> | |
| BE | NO | <p>The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability.</p> <p>Excerpts from the Belgian Code of Economic Law:</p> <p>Art. XI.5. [...]</p> <p>§ 6. The human body, at the various stages of its formation and development, and the simple discovery</p> | NO |

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| | | <p>of one of parts thereof, including the sequence or partial sequence of a gene, are not patentable. A portion of the human body which has been isolated, or otherwise produced by a technical method, including a sequence or a partial sequence of a gene, is susceptible to patenting, even if the structure of that part is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene which serves as a basis for the invention is to be concretely disclosed in the patent application. [...]</p> | |
| BG | NO | <p>According to Art. 37 (5) of the Bulgarian Patent Law (last amendment 18.05.2012), a purpose/function has only to be indicated in the specification and not in the claims. It is needed to meet the requirement of industrial applicability and does not limit the scope of the claims.</p> | <p>Art. 36(6) of the Guideline for examination (19.03.2008) indicates only the case when a deficiency of nucleic acid sequences have been noticed and the time given to the Applicant to correct them.</p> |
| CH | NO | <p>Excerpts from the Federal Act on Patents for Inventions (Patent Act)(text available under https://www.admin.ch/opc/en/classified-compilation/19540108/index.html):</p> <p>Art. 1b 1 A naturally occurring sequence or partial sequence of a gene is not patentable as such. 2 Sequences that are derived from a naturally occurring sequence or partial sequence of a gene may, however, be patented as an invention if they are produced by means of a technical process, their</p> | <p>Extract from CH - Examination Guidelines:</p> <p>11.2.2 Naturally occurring DNA sequences; sequences derived therefrom</p> <p>Claims on sequences or partial sequences of naturally occurring genes both in their natural environment as well as in isolated form (as genomic DNA) are not permissible. It should be noted that Art. 1b para. 1 of the Patent Law refers not only to sequences of human origin, but also to those of animal or plant origin.</p> |

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| | <p>function is specifically indicated, and the further requirements of Article 1 are fulfilled; Article 2 remains reserved.</p> | <p>In contrast, sequences which are derived from a naturally occurring sequence can be patentable (Art. 1b para. 2 of the Patent Law). By "derived sequence" is meant any sequence which is obtained from a sequence or partial sequence of a gene and which is functionally equivalent to that. Therefore it includes, in particular cDNA, RNA, polypeptides and proteins.</p> <p>In case of derived sequences a patentable invention is recognized only if the sequences have been isolated or obtained in some other way by a technical process. However, this alone does not justify the existence of an invention, there must also be a function disclosed in a credible way in the description. Since this function is part of the invention, it must be contained in the documents as filed (see. Art. 49 para. 2 lett. b PatG (Patent Law)). If there is no indication of a function at the filing date, the patent application must be dismissed (after appropriate threats)</p> <p>The term "function" describes any property of the sequence that causally contributes to a result usable in the art. If a derived sequence of a gene is used to produce a protein (or a portion of a protein), it is not only required to disclose this protein, but also its function. When a nucleotide sequence is not used for the production of a protein, the function to be indicated could for example be that the sequence has a specific transcriptional promoter activity. Providing mere general and speculative information on said function is not sufficient. They must be sufficiently specified, be substantial and credible. As part of the examination additional information or documents can be requested based on Art. 13 VwVG (Administrative Procedural Law) to enable the required assessment of the function.</p> |
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| | | | <p>The protection by a claim of a nucleotide sequence derived from a gene sequence is limited to the sequence sections which perform the function described in the patent. The wording of Art. 8c PatG (Patent Law) shows that this does not affect the amino acid sequences. In order to render the scope of protection clear in case of derived nucleotide sequences, the patent applicant must provide (if necessary as part of the examination), which sequence sections are functionally relevant. Not relevant sequence segments shall be deleted from the claims, either by the applicant or by the examiner.</p> |
| CY | NO | | NO |
| CZ | NO | <p>In the patent legislation, there are not any specific legal provisions related to this issue. However, in respect to the general patentability principle, the industrial applicability of DNA sequences must be fully disclosed in the patent application.</p> <p>Excerpts from ACT No. 206/2000 Coll. of 21 June 2000 on the Protection of Biotechnological Inventions and on the Amendment to Act No. 132/1989 Coll., on the Protection of Rights to New Plant and Animal Varieties, as amended by Act No. 93/1996 Coll.:</p> <p>Section 3 Exclusions of patentability Patents shall be not granted to [...] b) human body at various stages of its formation and development, and the simple discovery of one of its</p> | <p>NO. The Examination Guidelines do not mention purpose/function limited protection for sequences at all.</p> |

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| | | <p>elements, including the sequence or partial sequence of a gene; it does not apply to an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element, and [...]</p> <p>Section 5 Special provisions on the application of biotechnological invention [...] (8) If the application concerns an invention of the sequence or partial sequence of a gene, their industrial applicability must be made obvious in the patent application.</p> | |
| DE | YES | <p>The German patent law foresees the following (implementation of Article 5(3) of the Biotech Directive):</p> <p>Section 1a [...] (3) The industrial application of a sequence or partial sequence of a gene shall be disclosed in the application specifying the function performed by the sequence or partial sequence. (4) If the invention concerns a sequence or partial sequence of a gene whose structure corresponds to that of a natural sequence or partial sequence of a</p> | <p>The official guidelines for examination do not contain anything concerning the cited provisions since the last update is still from 2004 and the biotech directive was implemented into the German patent law only in 2005.</p> <p>There is an English leaflet “Information for Patent Applicants” (2014 edition) available from the internet set of the German Patent and Trademark Office containing the following statements:</p> <p>“1.5 (What is capable of being protected? / Industrial Application) [...] The industrial application of a sequence or a partial sequence of</p> |

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| | | <p>human gene, the patent claim shall include its use for which industrial application is disclosed pursuant to subsection (3).</p> | <p>a gene must be disclosed in the application specifying what function the sequence or partial sequence performs. If the structure of a sequence or a partial sequence of a gene is identical to the structure of a natural sequence or partial sequence of a human gene, its use shall be included in the patent claim (Sec. 1a (3) and (4) Patent Act)."</p> <p>"VI.2.1 (Documents to submit / Application documents / Claims) [...] If the sequence or partial sequence of a gene, having a structure identical to the structure of a natural sequence or partial sequence of a human gene, is the subject matter of the invention, the patent claim shall include its use, for which the industrial application has been disclosed under Section 1a (3) of the Patent Act."</p> <p>"VI.2.2 (Documents to submit / Application documents / Description) [...] The industrial application of a sequence or partial sequence of a gene shall be disclosed in the application specifying what function the sequence or partial sequence performs (Sec. 1a (3) Patent Act)."</p> |
| DK | NO | <p>There is no purpose/function limited protection in Denmark. Consequently, full product protection can be enjoyed.</p> <p>Excerpts from the Danish patent law: 1a.-(1) The human body, at the various stages of its</p> | <p>The patent office has also NOT issued any guidelines in respect of that.</p> |

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| | | <p>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.</p> <p>(2) Notwithstanding subsection 1 an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> | |
| EE | NO | <p>Excerpts from the Estonian Patent Act (Act No. RT I 1994, 25, 406, as last amended by Act No. RT I, 28.12.2011,1):</p> <p>§ 6. Subject of invention [...]</p> <p>(2) The following, inter alia, are not regarded as the subject of inventions:</p> <p>1) discoveries, including descriptions of the formation or development of the human body or sequence or partial sequence of human gene, scientific theories and mathematical methods; [...]</p> | NO |
| ES | NO | <p>According to art 5 of the Spanish patent law (ley de Patentes) genes are patentable, and claims directed to DNA sequences do not need to be limited to their function. The only requirement is that the function should be explicitly disclosed in the application (description is enough). There is also a new law coming into force on 1 April 2017, but the provisions</p> | <p>The guidelines of the Spanish Patent Office (part E) state that the function has to be described in the application. In that case the DNA sequence as such is patentable. The relevant part of these guidelines reads:</p> <p>The industrial application of a total or partial sequence must be explicitly disclosed in the patent application at the time of filing.</p> |

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| | | concerning this point are the same. | Hence, a DNA fragment without any indication of a particular function is not considered patentable. However, a DNA fragment for which a particular function is indicated, for example to be used as a probe for disease diagnostic, is considered patentable, unless there are other reasons for its rejection. |
| FI | NO | <p>There is no purpose/function limited protection for nucleic acid sequences in patent legislation in Finland. The patenting of DNA sequences, RNA sequences and amino acid sequences requires that their industrial use is disclosed in the application.</p> <p>Excerpts from the Patents Act:</p> <p>CHAPTER 1 , General Provisions</p> <p>Section 1a (30.6.2000/650) 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.</p> <p>An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may, without prejudice to the provisions of subsection (1), where the requirements for patentability are fulfilled, constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> | <p>NO. In the guidelines (Handbook, "Patenttikäsikirja", I.2.2. p. 137) it reads:</p> <p>The patenting of DNA sequences, RNA sequences and amino acid sequences requires that the sequence and the industrial use is disclosed in the application.</p> |
| FR | YES | The protection of an isolated DNA sequence is limited to its identified function. The purpose/function limited | The French patent office has not issued specific guidelines regarding the patentability of DNA sequences. However, the |

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| | <p>protection provided in the French law relates to human genes and sequences, i.e., is not said to apply to all types of organisms.</p> <p>Article L613-2-1 of the Intellectual Property Code provides that the scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description. Although this article does not specify that the sequence is human it has to be noticed that this provision has been introduced in the law on 6 August 2004 in the same amendment than the article L.611-18 which targets specifically human sequences.</p> <p>In practice, a claim directed to a gene sequence is considered as being limited to the technical application of a specific function associated with said sequence. In other words, the scope of a claim directed to a gene sequence will not be that of a product claim per se but rather the product for its specific disclosed function(s).</p> <p>To the best of our knowledge, there is no case law in France to illustrate this point.</p> <p>Excerpts from the Intellectual Property Code:</p> <p>Article L611-18 (inserted by Act No. 2004-800 of 6 August 2004, Article 17a II, Official Journal of 7</p> | <p>French Examination guidelines contain a small paragraph regarding this point (Paragraph 2.3 (4); Page 116):</p> <p><i>(4) les séquences totales ou partielles d'un gène prises en tant que telles. Les inventions portant sur des éléments (éléments intrinsèques, tels que les cellules, protéines, ADN, divers métabolites) ou des produits (excrétas, tels que a sueur et l'urine) d'origine humaine, sont également considérées comme non brevetables, lorsque ces éléments et produits sont considérés en tant que tels, c'est à dire :</i></p> <p><i>lorsque ces éléments ou produits sont présentés tels qu'ils se retrouvent dans la nature, en interaction avec leur environnement naturel. Par exemple un fragment d'ADN non isolé, tel qu'il se trouve intégré dans la totalité du génome humain. Breveter un tel AND non isolé, reviendrait à breveter le génome humain lui-même.</i></p> <p><i>lorsque ces éléments ou produits ont été simplement isolés et chimiquement caractérisés, alors qu'aucune fonction ou application industrielle n'a encore été identifiée. C'est le cas notamment d'un fragment d'ADN isolé dont on a déterminé la séquence, alors que l'on ne connaît pas le produit pour lequel cet ADN code ni, a fortiori, la fonction de ce dernier qui pourrait permettre d'en envisager une application pratique dans l'industrie (thérapeutique, agrochimique, etc.).</i></p> <p><i>En revanche une invention portant sur un élément isolé du corps humain ou autrement produit par un proceed technique, et qui est susceptible d'application industrielle, n'est pas exclue de la</i></p> |
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| | <p>August 2004):</p> <p>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.</p> <p>Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realization and the exploitation of this particular use. Such use must be disclosed in the patent application in a concrete and precise manner. The following, in particular, shall be considered unpatentable:</p> <p>[...]</p> <p>d) total or partial sequences of a gene as such.</p> <p>Article L613-2-1(inserted by Act No. 2004-800of 6 August 2004, Article 17 a III, Official Journal of 7 August 2004):</p> <p>The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description.</p> <p>The rights created by the grant of a patent including a gene sequence may not be called upon against a later claim on the same sequence if this claim satisfies the</p> | <p><i>brevetabilité, même si la structure de cet élément isolé est identique à celle d'un élément naturel. En effet, cet élément isolé est par exemple le résultat de procédés techniques l'ayant identifié, purifié, caractérisé et multiplié en dehors du corps humain, techniques que seul l'homme est capable de mettre en oeuvre et que la nature est incapable d'accomplir par elle-même (considérants 20 et 21 de la Directive 98/44/CE).</i></p> <p>These guidelines confirm the fact that the function and the technical application of a DNA sequence have to be clearly disclosed so as to render this sequence patentable. The first example concerns a non-isolated DNA fragment (i.e. such as integrated in the human genome). According to the guidelines such a DNA fragment is not patentable. The second example concerns the situation where a DNA fragment has been isolated and sequenced but the product of this sequence is not known and a fortiori its function is also not known. According to the guidelines such a DNA fragment is also not patentable.</p> |
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| | | requirements of Article L. 611-18 and if it discloses any other particular application of this sequence. | |
| GB | NO | <p>Isolated nucleic acid sequences may be patented, so long as the industrial application of the sequence is disclosed in the application as filed. However, for this protection to extend to propagated material, the genetic information must perform its function.</p> <p>Excerpt from Schedule A2, introduced by s76A UKPA:</p> <p>BIOTECHNOLOGICAL INVENTIONS [...] 3. The following are not patentable inventions – (a) 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; [...] 5. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. 6. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed. [...]</p> | <p>No, the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office issued in 2013 do not consider purpose or function limited protection for nucleic acid sequences. The Guidelines only confirm that the industrial application of nucleic acid sequences is required for patentability:</p> <p>55. Where the invention resides in a sequence or partial sequence of a gene, paragraph 6 of Schedule A2 to the Act additionally requires disclosure in the application as filed of the industrial application of that gene. The absence of this disclosure in an application when filed would seem to be fatal to that application.</p> <p>103. Paragraph 2 of Schedule A2 to the Patents Act 1977 permits biological material which is isolated from its natural environment or produced by means of a technical process to be the subject of an invention even if it previously occurred in nature. Paragraph 5 of Schedule A2 similarly states that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may also constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> <p>104. However, in line with section 1(2)(a) of the Patents Act and Paragraph 3(a) of Schedule A2, the simple discovery of biological material, eg a human gene, is not patentable. This is the situation that applies when a gene sequence is known</p> |

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| | | | simply as a sequence, possibly as part of the genome or in an isolated state. In that sense it is a discovery; nothing more is known about it other than that it exists as a piece of information. |
| GR | NO | <p>In Greece there is no other legislation regarding biotechnology and genetic engineering except the adaptation to Directive 98/44 of the European Parliament and of the Council on the legal protection of biotechnological inventions (Presidential Decree 321/2001).</p> <p>Excerpts from PRESIDENTIAL DECREE No. 321/24.09.2001:</p> <p>Article 4</p> <p>1. 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.</p> <p>2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence of partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> <p>3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.</p> | The Greek patent office has not published any kind of guidelines for examination of purpose/function limited protection for nucleic acid sequences. |
| HR | NO | Excerpts from the Croatian Patent Law: | According to the Section B-II 2.2. of the Guidelines for examination of the patent application: |

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| | | <p>EXCLUSION FROM PATENTABILITY Article 6 Excluded from patent protection shall be: [...] 2. 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. An invention relating to an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application as originally filed.</p> | <p>2.2 Sequences and partial sequences of genes In general it is required that the description of a Croatian patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. In relation to sequences and partial sequences of genes, this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention (EU Dir. 98/44/EC, rec. 23). In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could e.g. be that the sequence exhibits a certain transcription promoter activity.</p> |
| HU | NO | <p>The industrial applicability of a sequence or a partial sequence of a gene must only be disclosed in the patent application.</p> <p>Excerpts from ACT XXXIII OF 1995 on the protection of inventions by patents:</p> <p>Patentable biotechnological inventions</p> <p>Article 5/A [...] (3) The human body, at the various stages of its</p> | <p>NO. There is nothing in the Guidelines concerning the purpose/function of patentable sequences.</p> |

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| | | <p>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.</p> <p>(4) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> <p>Disclosure of the invention, the claims and the abstract</p> <p>Article 60 (1) A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings. The industrial applicability of a sequence or a partial sequence of a gene shall be disclosed in the patent application. [...]</p> | |
| IE | NO | <p>No, there is no limitation on protection. However, as per The European Communities (Legal Protection of Biotechnological Inventions) Regulations 2000 (which implements EU Directive 98/44/EC) Section 5(3) "If an invention concerns the sequence or partial sequence of a gene the industrial application thereof shall be disclosed in the patent application as filed".</p> | <p>No, there are no Irish Patent Office examination guidelines.</p> |

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| | | <p>Excerpt from S.I. No. 247/2000 - European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000:</p> <p>5. (1) 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, shall not be patentable. (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. (3) If an invention concerns the sequence or partial sequence of a gene the industrial application thereof shall be disclosed in the patent application as filed.</p> | |
| IS | NO | <p>There is no limitation on claims scope stipulated by the Icelandic Patent Act, but the Regulation on Patents No. 477/2012, with amendments (valid from 11 October 2013) stipulates that "If an invention concerns a gene, how the nucleotide sequence or part of the sequence can be utilised commercially must be specified."</p> <p>Excerpt from the Icelandic Patent Act No. 17/1991, including all amendments:</p> <p>Article 1 a (Act No. 22/2004, Art. 2 (a) (Valid from May 11 2004)):</p> | No, there are no such guidelines in Iceland. |

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| | | <p>The human body in its various stages of formation or development and the mere discovery of any of its elements, such as nucleotide sequences or partial nucleotide sequences of genes, cannot be considered patentable inventions.</p> <p>Notwithstanding Paragraph 1, an element of the human body, including a nucleotide sequence or partial nucleotide sequence of a gene, which is isolated from the body or produced in another way by a technical process may be considered a patentable invention even if the structure of such an element is identical to the structure of a natural element.</p> <p>Excerpt from the Regulation on Patents No. 477/2012, with amendments (valid from 11 October 2013):</p> <p>Art. 13 Description [...] If an invention concerns a gene, how the nucleotide sequence or part of the sequence can be utilised commercially must be specified. [...]</p> | |
| IT | YES | <p>Italian Industrial Property Code foresees the following (implementation of Articles 5 of EU Biotech Directive):</p> <p>Art. 81 quarter(1)(d) IPC states that function and industrial applicability must be concretely indicated and described for an element isolated from the human body or otherwise produced by means of a technical</p> | No Guidelines made by Italian Patent Office. |

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| | <p>process.</p> <p>Art. 81 quinquies(1)(c) IPC states that the specific function, which has to be industrially applicable, of a gene or fragments thereof must be indicated, described and specifically claimed.</p> <p>Excerpts from the ITALIAN CODE OF INDUSTRIAL PROPERTY (Legislative Decree N°30 of 10 February 2005, Text effective as from 2 September 2010, as amended by Legislative Decree N°131 August 2010):</p> <p>Section IV-bis Biotechnological Inventions</p> <p>81-quater. Patentability. 1. The following may be patented provided that they meet the requirements of novelty and inventive step and are susceptible to industrial application: [...] d) an invention relating to an element isolated from the human body or produced otherwise, through a technical process, even if its structure is identical to that of a natural element, provided that its function and industrial application are concretely indicated and described. A technical process is understood as a process which only human beings are capable of carrying out and that nature by itself is not able to perform;</p> | |
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| | | <p>[...]</p> <p>81-quinquies. Exclusions. 1. Subject to the exclusions set forth in Article 45(4), the following may not be patented: a) the human body, from the moment of conception and in the various stages of its development, nor the mere discovery of one of the elements of the body itself, including the sequence or partial sequence of a gene, in order to guarantee that patenting rights are exercised with respect for the fundamental rights and integrity of man and the environment; [...] c) a simple DNA sequence, a partial sequence of a gene, used to produce a protein or a partial protein, unless an indication and description is provided of a function useful for evaluation of the requirement of industrial application and the corresponding function has been specifically claimed; each sequence is considered independent for patent purposes in the event of sequences that overlap only in the parts not essential to the invention. [...]</p> | |
| LI | NO | See under "CH" | |
| LT | NO | <p>No purpose/function limited protection for DNA sequences is specially mentioned in Lithuanian Patent law.</p> <p>Excerpt from THE REPUBLIC OF LITHUANIA PATENT LAW 18 January 1994 No. I-372, Vilnius</p> | <p>NO</p> <p>Correspondingly examination of purpose/function limited protection for DNA sequences is not specified in national Guidelines for examination. (Regulations on Submission, Examination of Patent Applications and Issuance of Patent)</p> |

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| | | <p>(as last amended on 23 December 2010 by Law No. XI-1261):</p> <p>Article 4. Patentable Inventions Patents shall be available for any inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The following shall not be regarded as inventions: [...] 5) existing in a natural environment the human body or its element, including the sequence or partial sequence of a gene, at the various stages of its formation and development. This provision shall not apply to an element isolated from the human body or otherwise produced by means of a technical process, as well as to the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element [...]</p> | |
| LU | not clear | <p>The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability.</p> <p>Excerpt from the Law of July 20, 1992 Amending the System for Patents for Invention, as amended by the Law of April 7, 2006:</p> <p>Art. 5ter 1) The human body, at the various stages of its</p> | NO |

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| | | <p>formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.</p> <p>2) An isolated element of the human body or otherwise produced by a technical process, including the sequence or the partial sequence of a gene, can constitute a patentable invention, even if the structure of this element is identical to that of a natural element.</p> <p>3) Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realization and the exploitation of this particular use. Such use must be disclosed in the patent application in a concrete and precise manner.</p> | |
| MC | NO | | NO |
| MK | NO | <p>There is NO purpose/function limited protection of nucleic acid sequences in the patent legislation of Macedonia.</p> <p>Excerpt from the LAW ON INDUSTRIAL PROPERTY:</p> <p>Patentable inventions Article 25 [...] (3) An invention shall not be considered as invention within the meaning of paragraphs (1) and (2) of this Article if it is:</p> | <p>The Macedonian patent office does not perform substantive examination. Consequently, there are NO guidelines for examination of purpose/function limited protection for nucleic acid sequences.</p> |

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| | | <p>[...] 4) human body in different stages of its formation and development or simple discovery of one of its elements, including a sequence or a partial sequence of a gene. [...] 5) Element which is isolated from the human body or produced by means of a technical process containing a sequence or a partial sequence of a gene may also be protected by a patent when the structure of that element is identical with the one of the natural element, whereby the industrial applicability must be contained in the description of invention included in the application form. [...]</p> | |
| MT | NO | <p>Isolated nucleic acid sequences may be patented, so long as the industrial application of the sequence is disclosed in the application as filed.</p> <p>Excerpts from the Patents and Designs Act, Cap 417 Laws of Malta:</p> <p>Art. 4 [...] (5) A patent shall not be granted in respect of: [...] 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:</p> | NO |

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| | | <p>Provided that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element; [...]</p> <p>Art. 15 [...] (2) (a) Where an application refers to an element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene, the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. (b) When the application concerns a sequence or a partial sequence of a gene used to produce a protein or part of a protein, it is necessary to specify which protein or part of protein is produced or function or sequence it performs. [...]</p> | |
| NL | NO | <p>A function/use of nucleic acid and/or protein sequences must be mentioned in the application in order to meet the requirement of industrial applicability. No need to include this in the claim.</p> <p>Excerpts from the Dutch Patent Act:</p> | <p>NO, the patent office guidelines do not say anything about purpose/function limitation of claims.</p> |

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| | <p>Article 2a [...] 2. Invention referred to in paragraph 1 at least include inventions concerning: [...] b. a part of the human body that is isolated or obtained otherwise via a technical process, including the sequence or a partial sequence of a gene, even if the structure of that element is identical to that of a natural element; [...] Article 3 1. No patent shall be issued for: [...] b. the human body in its various stages of its formation and its development, as well as the sole discovery of one of its parts, including a sequence or partial sequence of a gene; [...] Article 25 [...] 3. If an invention relates to a sequence or partial sequence of a gene, the description shall contain a concrete description of the function and the industrial application of that sequence or partial sequence. In the event that a sequence or a partial sequence of a gene is used for the production of a protein or partial protein, the description of the industrial applicability</p> | |
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| | | shall contain a specification of the protein or partial protein that has been produced and its function. [...] | |
| NO | NO | <p>No, there is no explicit purpose/function limitation in the Norwegian Patent Act.</p> <p>Excerpt from the Norwegian Patents Act:</p> <p>Section 1 a. The human body, at all of 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. An element which is isolated from the human body or otherwise produced by means of a technical process, including the sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a naturally existing element.</p> | <p>The Guidelines contain a general requirement that the industrial applicability of the invention should be disclosed in the application:</p> <p>3.3.7 Industrial applicability The description shall explicitly state how the invention shall be utilised industrially, if this is not obvious from the description of the invention or it immediately is evident from the nature of the invention (see T870/04). In view of the broad meaning of the term “which is industrial applicable” in the patent Act section 1, 1st paragraph, see chapter IV, point 3.1.[Guidelines], it must in most cases be expected that how the invention is industrial applicable will be self-explanatory such that an explicit description of this is not necessary. But it may be cases, e.g. concerning methods for testing, where the industrial applicability is not obvious and where this if that is the case must be clarified.</p> |
| PL | not clear | <p>According to Article 93² of recently amended Polish Industrial Property Law which came into force on December 1, 2015:</p> <p>[...]</p> <p>2. In a patent application concerning a sequence or a partial sequence of a gene, the industrial application of the sequence must be disclosed in the patent description, and additionally its function is to be</p> | <p>No. There are no Guidelines for Examination in Poland of purpose/function limited protection for nucleic acid sequences.</p> |

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| | | <p>indicated in the independent patent claim.</p> <p>3. In order to fulfil the industrial applicability criterion in a case of use of a sequence or a partial sequence of a gene for production of a protein or a protein part, it is to be defined in the description of the invention which protein or which part thereof is produced and what is their function.</p> | |
| PT | NO | <p>The Portuguese Industrial Property Code does not specifically mention limitations to the protection of nucleic acid sequences.</p> <p>Only Article 54(c) refers to the specific case of sequences or partial sequences of genes:</p> <p>Article 54 Special cases of patentability</p> <p>1. The following shall be patentable: [...]</p> <p>c) A new invention, involving an inventive step and being susceptible of industrial application, concerning any element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element, provided that the industrial application of a sequence or partial sequence of a gene is expressly stated and specifically explained in the patent application; [...]</p> | <p>However, the guidelines for examination of the Portuguese Patent Office include some provisions related to this matter:</p> <p>1.5.1.3 Protection of DNA sequences</p> <p>For the DNA sequence of an organism or for a protein found in nature, it will be necessary to find an industrial application. The clarification of the function of the respective DNA/protein sequence may be sufficient, but it must be based on viable methods, such as functional studies (Article 57 EPC) and only in this way will it be possible to patent one or more genes or portions thereof. In these cases, a sequence of nitrogenous bases (A, G, C and T) must be provided, which is to be inserted in programmes for this purpose (e.g. http://www.ncbi.nlm.nih.gov/blast/Blast.cgi) so that it will be aligned with the genome sought and make it possible to assess the criteria of novelty and/or inventive step. For this purpose, it is important that this sequence be submitted in digital format.</p> |
| RO | NO | No purpose/function limited protection for nucleic | There are no Guidelines for Examination in Romania, but The |

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| | <p>acids sequences, but Romanian Patent Law 64/1991 requires that its industrial application be disclosed in the patent application.</p> <p>Excerpts from Law No. 64/1991 on Patents (as amended up to Law No. 83/2014):</p> <p>Chapter II - Patentable Inventions</p> <p>Art. 6 [...] (2) Inventions in the field of biotechnology shall be patentable if they relate to: [...] d) an element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.</p> <p>Art. 8 (1) Patents shall not be granted under this Law in respect of: [...] c) the inventions having as a subject-matter the human body in its various stages of formation and development, as well as the mere discovery of one of its elements, including the sequence or partial sequence of a gene; [...]</p> | <p>Implementing Regulation of the Patent Law 64/1991, also mentions in art 72(3) that:</p> <p>The industrial applicability of a sequence or of a partial sequence of a gene shall be concretely disclosed in the patent application, by indicating the specific function of the sequence or partial sequence.</p> |
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| | | <p>Art. 12 [...] (2) The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application.</p> | |
| RS | NO | <p>Excerpts from The Patent Law: Human Body and its Elements</p> <p>Article 8 The human body, at any stage of its formation and development, and the simple discovery of one of its elements, including sequences or partial sequences of genes, shall not be regarded as invention that can be protected by a patent. An element isolated from the human body or produced by means of a technical process, including the sequences or partial sequences of genes, may be patentable, even where the structure of that element is identical to that of a natural element. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application on the day of its filing.</p> | <p>NO, the examination Guidelines do not concern purpose/function limited protection for patentable sequences.</p> |
| SE | NO | <p>A function/use must be given in order to meet the requirement of industrial applicability, but this use does not have to be included in the claim and does not, arguably, limit the protective scope of a claim.</p> <p>Excerpts from The Patents Act:</p> | <p>NO, the patent office guidelines do not say anything about purpose/function limitation of claims.</p> <p>Excerpt from the Guidelines: B5, 3.2 [...] In order for a DNA sequence or partial sequence of a</p> |

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| | | <p>Article 1 b. The human body at the various stages of its formation and development, as well as the mere discovery of one of its elements, including the sequence of a gene or a partial sequence of a gene, cannot constitute a patentable invention. An isolated element of the human body or an element otherwise produced by means of a technical process, including a gene sequence or a partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical with that of a natural element. (Act 2004:159).</p> <p>Article 8, second paragraph: [...] If the invention relates a gene sequence or a partial sequence of a gene, the application must, however, always indicate how the invention can be applied industrially. The description shall be sufficiently clear for it to be carried out by a person skilled in the art with the guidance thereof. [...] (Act 2014:289)</p> | <p>gene to be patentable, the application must specify how it is susceptible of industrial application (see § 8 PL of the second paragraph fourth sentence). For example, if a sequence or portion of a gene sequence is to be used to produce a protein, the description should specify which protein that is to be produced, and which function the protein shall exercise.</p> |
| SI | NO | <p>The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability.</p> <p>Excerpt from the Decree on the Legal Protection of Biotechnological Inventions: Article 5</p> | NO |

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| | | <p>(1) 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.</p> <p>(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> <p>(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.</p> | |
| SK | NO | <p>However, the industrial applicability of DNA sequences has to be described in the patent application.</p> <p>Excerpts from Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (The Patent Act, consolidated version 2009):</p> <p>Article 5 Patentability of inventions [...] (2) Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological</p> | NO, the examination Guidelines do not concern purpose/function limited protection for patentable sequences. |

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| | <p>material is produced, processed or utilised, including cases when invention relates to [...] d) an element isolated from a human body or produced by other means of a technical process, including a sequence or partial sequence of a gene also in the case when the structure of such element is identical with a structure of a naturally existing element. [...]</p> <p>Article 6 Exceptions to patentability (1) Patents shall not be granted to [...] d) inventions relating to human body in different stages of its formation or development or relating only to discovery of some elements of human body, including sequences or partial sequence of a gene, with an exception pursuant to Article 5(2)(d), [...]</p> <p>Article 38 Special provision on application of biotechnological invention [...] (7) If a sequence or partial sequence of a gene is a subject-matter of an application, industrial applicability of an invention must be explained in the application.</p> | |
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| SM | NO | <p>There is no purpose/function limited protection in San Marino.</p> <p>Excerpt from LAW n. 79 of 25 May 2005 - Industrial Property Consolidation Act:</p> <p>Article 2 (Subject-matter of the patent and exclusions from patentability) [...]</p> <p>4. The following inventions are not patentable: [...]</p> <p>d) inventions concerning the human body, at all of 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. [...]</p> | The patent office has also NOT issued any guidelines in respect of that. |
| TR | NO | There is not any limitation or any case law related to this subject. | No. The Turkish Patent Institute does not have any guidelines for examination of purpose/function limited protection for DNA sequences. |