

# **Dissenting Opinion on Expert Group Report on the Scope of Protection in Europe of Patent Claims Directed to Nucleic Acid-Related Inventions**

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This document is a dissenting opinion to the Expert Group Report on the Scope of Protection in Europe of Patent Claims Directed to Nucleic Acid-Related Inventions (hereinafter referred to as the “Report”) of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973).

Some members of the Expert Group could not consent to the *Report* and its opinion, even though these members share the expert group's unanimous view that the CJEU decision in *Monsanto v Cefetra* was right in rejecting Monsanto's complaint.

However, this dissenting opinion does not share the majority's view that only absolute protection for nucleic acids is in accordance with the Directive 98/44/EC. In contrast, we argue that the CJEU in its *Monsanto* decision did effectively introduce purpose- or function-limited protection for DNA sequences.

## **Summary**

**The CJEU decision in *Monsanto C-428/08* has provided a general, authoritative, clarifying statement for the interpretation of the Directive 98/44/EC which confirms that protection for DNA sequences is limited to the purpose or function of a novel DNA sequence which the inventor has discovered, plausibly, credibly, and sufficiently described in the patent application, and for which an industrial application was provided. Thus, the absolute product protection doctrine established for chemical substances has no validity for DNA sequences, and has been expressly rejected by the CJEU.**

**The reasons and rationales for both the CJEU's and the national legislator's abolishing of absolute product protection for gene sequences are based on important legal, scientific, fairness, public policy, science and innovation arguments.**

**By clarifying that "absolute protection to the patented product as such" is not possible, the CJEU provides for EU wide harmonisation of the protection for DNA sequences/ nucleic acids related inventions and prevents the law from being interpreted differently in the national jurisdictions. It thus ensures uniform and coherent application of Directive 98/44/EC. Moreover, it brings EU law in line with international legal developments, and hence is fostering international legal approximation.**

## Reasons and rationales for restrictions of patent scope for DNA

As stated in the *Report*, five countries - Germany, Italy, France, Luxembourg and Poland - in their national implementation of Directive 98/44/EC passed amendments in legal texts to specify and clarify the wording of said Directive. Despite of the differences in the way these amendments were phrased, they share a common purpose, namely the reduction of scope of DNA sequences and other nucleic acid-related inventions (See explanation in Annex).

The CJEU in its decision *Monsanto v. Cefetra*, C-428/08, answered Question 2 as follows:

**"2. Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it."**

The CJEU decision in *Monsanto C-428/08* has thus provided a general, authoritative, clarifying statement for the interpretation of the Directive 98/44/EC which confirms that protection for DNA sequences is limited to the purpose or function of a novel DNA sequence which the inventor has discovered, plausibly, credibly, and sufficiently described in the patent application, and for which an industrial application was provided. Thus, the absolute product protection doctrine established for chemical substances has no validity for DNA sequences, and has been expressly rejected by the CJEU.

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In specifying and clarifying the scope of protection for gene sequences, DNA and other nucleic acid molecules as such, the Court also took into account scientific developments and insights which were gained after the Directive 98/44/EC was passed in 1998. Some of this scientific knowledge which also prompted several national legislators to pass amendments in legal text shall shortly be mentioned and recapitulated.

## Scientific developments and their impact

- The publication of the complete sequence of the human genome in 2001, and the complete sequencing of the genomes of many other organisms such as animals, plants, bacteria and viruses has effectively destroyed the novelty of claims directed to the nucleic acid molecules which form part of these genomes.
- The inventive step, therefore, can only consist in disclosing a specific function of the DNA sequence, and in providing an industrial application for this function. As more and more DNA sequences became known and characterised, it had also become possible, through bioinformatic homology searching and other tools, to guess about the function of a newly discovered DNA sequence. In order to prevent speculative assertions of functions in patent applications, the patentability requirements have to be applied strictly, and the inventive step cannot consist in just providing the structure of the DNA sequence.<sup>1</sup>
- The human genome sequencing consortium in 2001 also rectified previous assumptions about the numbers of genes in the human genome. While in the 1990s it was assumed that the human genome is comprised of 100,000 genes, in 2001 it was revealed that the human genome only contained 30 to 40,000 genes (hardly more than a thread worm who contains 20,000 genes), a number later even corrected downwards to 20 to 25,000 genes.<sup>2</sup> Once more, this elucidated the fact that the regulation *between* different DNA sequences as well as between genes and the environment, inter alia via epigenetic factors, is decisive for the function of the gene in a complex pathway of an organism or for the role of a specific gene for a certain disease. Since then, a lot more evidence for the multi-functionality of DNA sequences has been gathered. Thus, it became evident that first, the 'cake' to be distributed was much smaller as previously assumed, and second, that granting all possible functions of a DNA sequence to the first inventor, as the absolute protection doctrine prescribes, would overly reward this inventor and deprive all other inventors from just reward.
- Moreover, there were other reasons why scientists argued that it should not be possible to obtain patent protection on all potential functions of biological material, such as a gene, and that patent protection should be restricted to specific functions. Among others, a major change in the scientific paradigm from a causal towards a systemic theoretical perspective on genes occurred. The old so-called "central dogma" in genetics ("One Gene, One Enzyme Hypothesis") was modified and largely replaced by a more complex model which states that one DNA sequence can code for many different proteins. There are several post-transcriptional mechanisms (such as RNA editing or alternative splicing) that allow for genes to potentially make multiple

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<sup>1</sup> Straus, J. 2001b: Produktpatente auf DNA-Sequenzen - Eine aktuelle Herausforderung des Patentrechts, in: *GRUR* 10-11: 1016-1021, on p. 1019; Krefft, A.R. 2003: Patente auf human-genomische Erfindungen. Cologne.

<sup>2</sup> International Human Genome Sequencing Consortium 2001: Initial sequencing and analysis of the human genome, in: *Nature*, vol. 409, 15.2.2001: 860-921 on 898-901; Pearson, Helen 2006: What is a gene? In: *Nature*, vol. 441: 398-401.

polypeptides. This enables the human genome which contains around 22,000 genes to produce somewhere between 500,000 to 1.5 million different proteins.

- Meanwhile, it became clear that the old, linear and causal model between genotype and phenotype was only valid for some monogenetic characteristics and a number of relatively rare diseases. Hence, genes are no longer described as a certain sequence of the DNA but as *functional unit*, and thus in relational terms. Therefore, the old assumption that a gene can be characterised by merely giving the "letters" of its DNA sequence, had to be overturned.

## Legal Implications

- This also implies that the subject matter of a patent application for a DNA sequence is not the DNA sequence as such, but the DNA sequence in combination with the function which it codes for, like for instance the production of a certain protein or the coding for a certain disease. Hence, the subject matter of the patent is the functional unit, that is the DNA sequence tied to the function. This in turn means that the scope of protection is also affected, because the claims can only claim the scope of the functional unit, not all other functions which were not revealed and are often not even known to the inventor. Therefore, in this case, the patentability issue is inextricably linked with the scope of protection.
- Furthermore, it has been rejected to simply equate DNA sequences or genes with chemical compounds. Even though it is true that DNA is a biochemical substance (nucleic acid), the essence of what makes genes special is that DNA encodes information, and hence DNA is a carrier of information from which different products, such as proteins, emerge. Thus, it has been argued, that »the fact that genes are essentially just genetic information makes the issue of patenting them very different from that involved in the isolation of other chemical compounds«<sup>3</sup>. Moreover, the nucleic acid as substance is less important than its informational component. It is also important to emphasise that the inventive step for a DNA sequence does not consist in the mere isolation of the sequence but in the characterisation of its function.

## Fairness, Innovation, and Public Policy

- Apart from these scientific facts and their legal implications, the restriction of scope to the function of a DNA sequence has also been defended by arguments which are related to fairness and to an anticipatory impact assessment of the public policy and innovation consequences of DNA patents too broad. The fairness argument says that granting the first inventor all possible functions of a DNA sequence would overly

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<sup>3</sup> Nuffield Council on Bioethics (NBC) 2002: *The ethics of Patenting DNA*. U.K., p. 28.

reward the inventor, and would not do justice to other inventors who may invest the same or even more efforts, time and financial investments in revealing another function of the same DNA sequence.

- While granting patents on diagnostic and therapeutic inventions based on DNA sequences may result in a great benefit to society, it also presents a multitude of risks,
  - that overly broad patent rights will stifle and jeopardize scientific progress;
  - that it will restrict access in ways that discourage “follow-on” innovation;
  - that it will lead to industry concentration in a way that hurts patients, consumers or citizens, for instance by raising the prices for diagnostic tests, biomarkers and drugs.
- Scientists have been concerned that patents granted too much upstream in the research process could be detrimental to academic freedom.
- Moreover, economists argued that too early and too broad patent protection carries the risk that the temporary monopoly is unnecessary to produce the innovation, or that it is broader or lasts for longer than is necessary to encourage future scientific progress. Therefore, it is necessary to strike the right balance between patentability issues, scope of protection, and the public domain.
- This list of risks could be continued. Therefore all patent laws contain clauses and rule with exceptions, limitations, and restraints designed to prevent such risks. The restriction of patent scope forms such a preventive element.
- While patent law is guided by the assumption that patents foster innovation and diffusion of knowledge, it must be taken into consideration that patents can also impede scientific progress. Much debate and scientific literature has been devoted to patents on "research tools" and to "reach through claims" which can create broad dependencies and may block research and development. "Patent thickets" may be the result of a multitude of overlapping patent rights which in turn can increase transaction costs or lead to royalty stacking which may make the industrial application of an invention prohibitive.

## Conclusions by national legislators

Taken all these considerations together, the five national legislators (Germany, Italy, France, Luxembourg, Poland) have taken a wise and appropriate decision to explicitly restrict the scope of DNA patents to the function or purpose of the respective DNA sequence as disclosed and revealed, and thus to avoid too many dependencies for additional and follow-up inventors.<sup>4</sup> These measures are not only legally covered by the Directive 98/44/EC, in

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<sup>4</sup> These legislative processes were based on expert reports and intense deliberations in national parliaments. For *France*, see *CCNE (Comité Consultatif National d’Ethique) 2000: Avis sur l’avant-projet de loi portant transposition, dans le code de la propriété intellectuelle de la directive 98/44/CE du Parlement européen et du Conseil, en date du 6 juillet 1998, relative à la protection juridique des inventions biotechnologiques. N°64 – 8 Juin 2000*, and the letter by *President Jacques Chirac* to the President of the European Commission from 30 June 2000. For the *German* debate see in particular

particular its Article 5(3), but also by the general fact that patent protection is based on a social contract, and that it would be contrary to the *quid pro quo* forming the foundation of the patent system to tip up this balance, and to overly reward the inventor.

The fact that not all national legislators amended the wording of the Directive does not mean that they opposed the solutions enshrined in the laws of some member states. On the contrary, it must be emphasised that discussions and challenges to gene patents and to absolute protection in scope for DNA have taken place in many more EU member states. Just to mention the *UK*, where the Royal Society and the Nuffield Council warned against adverse effects to science.<sup>5</sup> In *Denmark*, the Ethics Council<sup>6</sup> after broad public discussion issued two critical reports. In the *Netherlands*, critical voices were raised in an interdepartmental working group<sup>7</sup>, and in *Sweden* several research councils critically debated absolute product protection for DNA.<sup>8</sup>

Some EU member states decided for other legislative measures to address the concerns and problematic issues of unbalanced patent protection, especially for genes. Belgium, for instance, introduced a compulsory licence for purposes of public health, and extended the scope of the research exemption by allowing it not only for research 'on' but also for research 'with' the patented product or process, an exemption which also covers research tools.<sup>9</sup> The same broad exemption is valid in Italy, and the Netherlands exempts academia in a wider sense from patent infringement.<sup>10</sup> Austria also discussed the concerns about gene

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the highly influential statement of the Parliamentary Study Commission on Law and Ethics in modern Medicine (*Zwischenbericht der Enquete-Kommission »Recht und Ethik der modernen Medizin«*. Teilbericht zum Schutz des geistigen Eigentums in der Biotechnologie«. BT-Drs. 14/5157, 25 January 2001). For the long parliamentary debates, expert hearings and the very intense debate in the patent law community with over 50 scientific articles in legal journals see Schneider, I. 2010: *The European Patent System. Shifts in Governance through Parliaments and Civil Society* (Das Europäische Patentsystem. Wandel von Governance durch Parlamente und Zivilgesellschaft), Frankfurt/New York. See also the subsequent prevailing opinion in the German legal patent literature which supported and confirmed functional restriction of patent scope for DNA (Kraßer, R. 2004: *Patentrecht*. Munich, (5th Edition), p. 233.

<sup>5</sup> Nuffield Council on Bioethics 2002: *The ethics of Patenting DNA*. U.K.; Royal Society 2003: *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science*. London.

<sup>6</sup> DCE (The Danish Council of Ethics) 1994: *Patenting human genes: A Report*. Copenhagen. DCE (The Danish Council of Ethics) 2004: *Patenting human genes and stem cells*. Copenhagen.

<sup>7</sup> Interdepartementale Werkgroep 2005: *Ethische aspecten aan octrooiverlening voor biotechnologische uitvindingen*, Amsterdam, NL, 23-6-2005.

<sup>8</sup> SNCME 2002: The Swedish National Council on Medical Ethics: *Opinion on Directive 98/44/EC on the legal protection of its biotechnical inventions, and its implementation in Sweden*, Stockholm, 25.02.2002; SOU 2006: Oinskränkt produktskydd för patent på genteknikområdet. Delbetänkande av Kommittén om patentskydd för biotekniska uppfinningar.

<sup>9</sup> *Loi Belge* du 28 avril 2005. – Loi modifiant la loi du 28 mars 1984 sur les brevets d'invention en ce qui concerne la brevetabilité des inventions biotechnologiques.

<sup>10</sup> See: Kupecz, András et al. 2015: Safe harbors in Europe: an update on the research and Bolar exemptions to patent infringement, in: *Nature Biotechnology* 33: 710–715, see Table 1 for other EU countries; [http://www.nature.com/nbt/journal/v33/n7/fig\\_tab/nbt.3273\\_T1.html](http://www.nature.com/nbt/journal/v33/n7/fig_tab/nbt.3273_T1.html).

patents and introduced a patent ethics committee to regularly monitor respective national patents and to report to both Government and Parliament.<sup>11</sup>

As mentioned in the *Report*, the European Parliament issued two resolutions which also raised concerns about adverse effects of DNA patents, and respectively called for purpose-bound protection.<sup>12</sup>

## Conclusion by the CJEU and legal implications

We assume that the Court of Justice of the EU was aware of these aforementioned scientific insights, arguments and debates, and therefore took question 2 of the Monsanto case as an opportunity for clarification and EU wide harmonisation. Such judicial activism by the CJEU, even though at times criticised, is not uncommon but rather the rule in the EU.

Even though some observers complained about the way the CJEU has phrased its decision in the Monsanto case, and many had wished for a more extended and precise guidance, there is no doubt that the CJEU judgement is a turndown for absolute product protection for DNA sequences.<sup>13</sup>

The CJEU rightly based its decision mainly on Article 9 of Directive 98/44/EC, because this is the article related to patent scope. However, for a correct interpretation and application of the decision, Article 9 must be read in combination with Article 5.

The fact that the CJEU's Monsanto decision was not often cited in national patent law cases does not render it irrelevant or incorrect. In contrast, the rule of law, respect for the separation of powers in the EU, and for the EU's Court of Justice as important institution of the union, calls for adherence of its judgement.

We therefore regret that the majority of experts could not be convinced to take up affirmative interpretations and supportive rationales to the Monsanto ruling and, more generally, to the restriction of patent scope for gene sequences.

If we approach this case from an international perspective, this opens up a broader horizon as we can see that similar debates and concerns were raised internationally. The U.S. Supreme Court, in the BRCA gene Case 'Association for Molecular Pathology v. Myriad Genetic' stated that „merely isolating genes that are found in nature does not make them patentable“.<sup>14</sup> This decision and other U.S. Supreme Court case law have sought to countervail overly extensive patent protection. Australia has a long tradition in broad expert

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<sup>11</sup> Beschluss der Bioethikkommission beim Bundeskanzleramt vom 6. März 2002. *Stellungnahme der Bioethikkommission zur Frage der innerstaatlichen Umsetzung der Biotechnologie-Richtlinie*. Wien, Österreich.

<sup>12</sup> European Parliament 2005: *Resolution on patents for biotechnological inventions*, Point 5, [www.europarl.europa.eu/sides/getDoc.do?jsessionid=3CEC3F2B9A6DB6F08C3C22BFF958CBFE.node2?pubRef=-//EP//TEXT+TA+P6-TA-2005-0407+0+DOC+XML+V0//EN](http://www.europarl.europa.eu/sides/getDoc.do?jsessionid=3CEC3F2B9A6DB6F08C3C22BFF958CBFE.node2?pubRef=-//EP//TEXT+TA+P6-TA-2005-0407+0+DOC+XML+V0//EN)

<sup>13</sup> Cf. Lamping, M 2010: Case Notes. Purpose-bound patent protection for genes, *EJRR* 4, 445-450.

<sup>14</sup> Association for Molecular Pathology v. Myriad Genetic, Inc., 133 S.Ct. 2107 (2013).

and parliamentary debates on gene patents<sup>15</sup> as well, and in 2015 the High Court of Australia unanimously held that the claims to isolated BRCA1 genetic materials are invalid under Australian patent law, thus also abolishing patents for merely isolated genes which as such are considered natural products and non-eligible for patents.<sup>16</sup>

In conclusion, a functional restriction of the absolute scope of DNA patents is far from being noncompliant with the Directive 98/434/EC but on the contrary, it is an affirmation of the spirit and letter of the EU's Biotech patent Directive. Thus, the CJEU's Monsanto ruling is not only an important step in harmonising respective EU law but also brings EU law in line with international legal developments, and hence is fostering international legal approximation.

28 April 2016

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<sup>15</sup> ALRC (Australian Law Reform Commission) 2004: *Gene Patenting and Human Health*, (ALRC 68), Australian Government, Sydney; ALRC (Australian Law Reform Commission) 2004: *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99). Australian Government, Sydney.

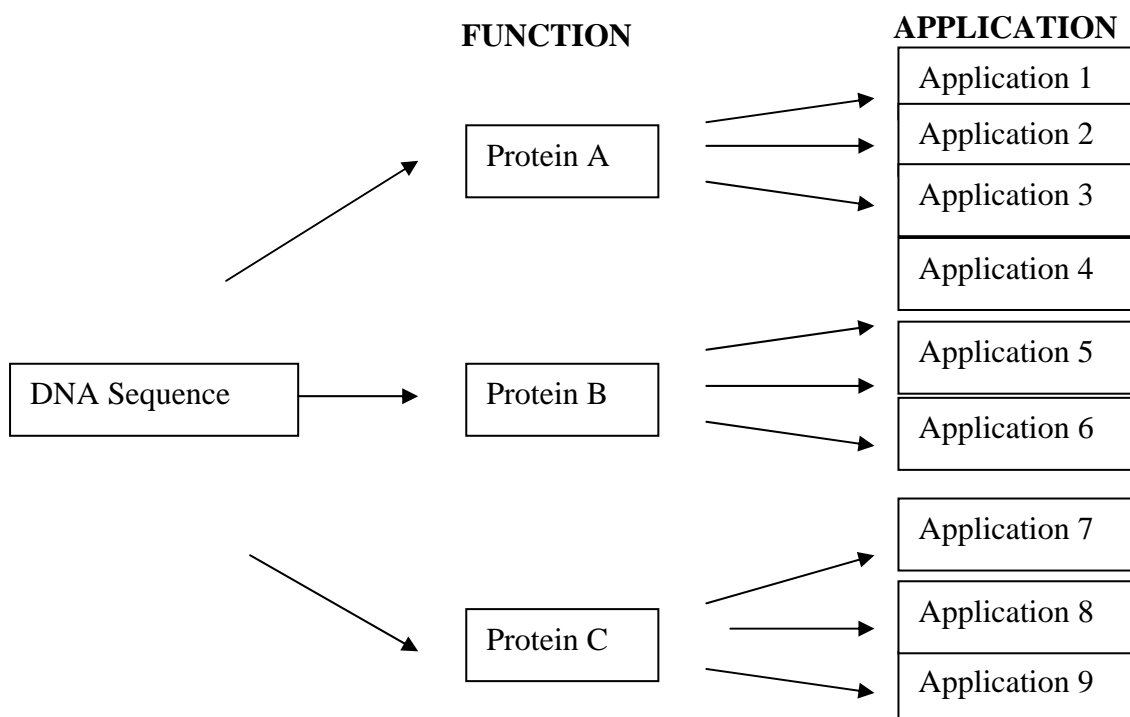
<sup>16</sup> *D'Arcy v Myriad Genetics Inc*, [2015] HCA 35, 7 October 2015, S28/2015.



## ANNEX to dissenting opinion

The old 'composition of matter' patent doctrine for chemical substances which was applied by analogy to gene sequences, entails patent protection for all other functions and industrial uses of a particular DNA sequence if just one function (e.g., a protein produced) and one industrial application (e.g., a genetic test or gene therapy) is disclosed, even if the patentee has no knowledge about these other functions and applications. In contrast, function-bound protection ties the DNA sequence as functional unit to the function (protein or disease) disclosed in the patent application (= patent eligibility) and therefore restricts the scope of the patent to the industrial applications of this functional unit.

**Graph 1: Absolute and function-bound protection for protein-encoding DNA**



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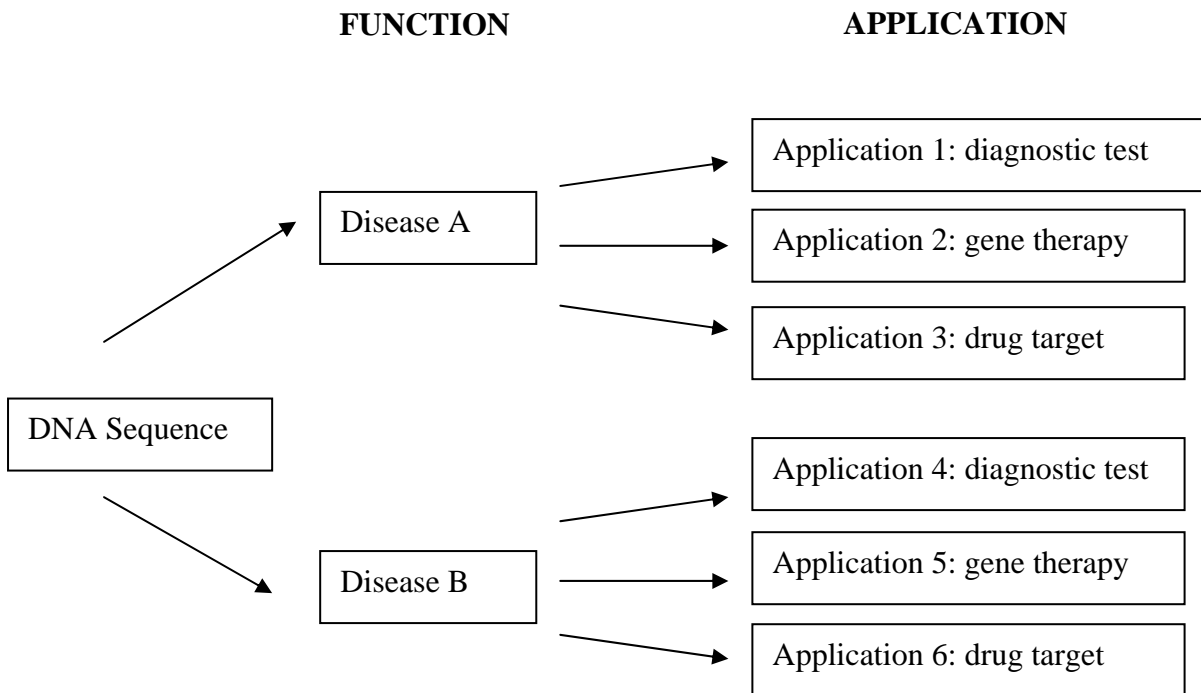
### **Absolute product protection:**

Disclosure of a DNA sequence and one single function (DNA + protein A) grants patent protection for all other functions (protein B, C, ...) of this sequence as well as all the applications for it (Applications 1-9, in principle endless)

### **Function-bound product protection:**

Disclosure of the DNA sequence as functional unit with a function (DNA + protein A) grants patent protection for all the applications (1 to 3) related to this DNA sequence + protein A. An inventor disclosing the DNA sequence as functional unit with another function (DNA + protein B) can receive a non-dependent patent and claim all the subsequent applications (4 to 6).

**Graph 2: Absolute and function-bound protection for DNA and disease**



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**Absolute product protection:**

Disclosure of a DNA sequence and a single disease (DNA + disease A) grants patent protection for all other functions (disease B, C, ...) of this DNA sequence as well as all the possible applications for it (Applications 1-9, in principle endless).

**Function-bound product protection:**

Disclosure of the DNA sequence as functional unit with a disease (DNA + disease A) grants patent protection for all the applications (1-3,...) related to this DNA sequence +disease A. An inventor disclosing the DNA sequence as functional unit with another function (DNA + disease B) can receive a non-dependent patent and claims to all the subsequent applications (applications 4 to 6,...).