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Ausschuss für Biotechnologische Erfindungen
Committee on Biotechnological Inventions
Commission pour les Inventions en Biotechnologie

epi Biotech Committee position paper concerning purpose/function limited protection of nucleic acid sequences

1. An overview was made of the national laws in the EPC contracting states on nucleic acids (see Annex).
2. In three countries namely France, Germany and Italy there is purpose/function limited protection for nucleic acid sequences set forward for national patent applications filed in these countries. At least in France and Germany, national patents applications for these inventions are rarely filed.
3. In Switzerland/Liechtenstein there is no literal purpose or function limitation of the protection of nucleic acid sequences in the patent law. However, the examination guidelines suggest to grant a patent only for those parts of a nucleic acid sequence derived by technical means from a naturally occurring sequence, that perform the purpose or function mandatorily disclosed in the specification as filed.
4. In Luxemburg DNA sequences are considered as chemical compounds. However, national patent applications for these inventions are rarely filed. The LU law specifies that 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 French law seems more restrictive than the LU law, as the French law excludes from patentability "d) the total or partial sequences of a gene taken as such". There is no equivalent to this in the LU law.
5. In Poland since December 1, 2015 new regulations came into force which define the requirement of specifying the function of a claimed gene in independent patent claim according to our PL member. The effects of the new regulations have not been tested before administrative and civil court.
6. In general, the epi biotech committee is of the opinion that purpose-bound protection for patentable nucleic acid molecules should not be introduced for EP patents. The EPC has no rules which point in this direction. There is no need to treat nucleic acid molecules any different than other types of compounds in terms of available patent protection and such a different treatment would be unfair to innovators in biotechnology and contrary to art 27 of TRIPS provisions which establishes the principle of non-discrimination as to the type of invention and field of technology.
7. The contribution to the art of an inventor who invents a new compound with a useful practical/technical application is not only that useful practical/technical application but also the new compound itself. The inventor's disclosure of the new compound enables others to make new and further inventions with that same compound, e.g. other useful applications of the compound, which would not have been possible had the first inventor not disclosed the compound. New applications that may be discovered by others following the disclosure of a new compound by a first inventor may also be eligible for protection even in cases where

Chair Ann G.Y. De Clercq
epi Secretariat · Bayerstrasse 83 · 80335 Munich · Germany
Phone +49 89 242052-0 · Fax +49 89 242052-20
info@patentepi.com · www.patentepi.com

Direct Phone: +32 9 280 2340
BiotechCommittee@patentepi.com

absolute protection of the compound has been granted. This allows the further progress of science and technology and is an important justification for absolute product protection.

8. In this respect DNA molecules or genes are chemical compounds, they do not differ from "conventional" chemical compound because there are numerous examples of "conventional" chemical compounds having more than one or many different practical applications. Moreover, also not all genes are multifunctional. The multi-functionality argument is thus not specific for DNA molecules or genes and should thus also not be a reason to treat them differently.
9. A further thought is that at least for human genes the whole issue of purpose-bound protection has become obsolete since the publication of the human genome sequence in 2000. Since then absolute product protection for human genes has become practically impossible because such claims would no longer be novel. Thereby de facto only purpose-bound protection is available for human genes. The same holds for genes from all the other organisms whose genome sequences have been and are being published at an ever increasing rate. Arguably, if absolute product protection for DNA would no longer be available there would be less incentive to sequence new genomes and those sequences would become available at a lower rate, thereby slowing down progress of science and technology.
10. For example in Germany, Spain, Austria, Denmark and Greece there has not been compound protection for chemicals before basically the advent of the EPC and its harmonized counterparts in the early contracting states. Now the system of compound, first and second medical use contributions has been successfully established and the industry does not have any problems with the situation in principle. The system works so well in practice that they would not want to revert to the old situation anymore. Thus, the benefit seems to dominate any possible shortcomings.
11. Research would not be hampered due to absolute product protection for nucleic acid sequences, because there is experimental use exemption. This allows research for, e.g., identifying new properties of "old" and tentatively patented compounds.

Ann De Clercq

Chair epi Biotech Committee

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