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Gene patents – short report

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A patent is a right granted to the owner of an invention, that prevents others from making, using, importing or selling the invention without permission of the patent holder. The leading aim of the patent system is to encourage and reward innovation.

The global cooperation in the biotechnology field is probably more needed than in other areas, in the intellectual property sector in particular. On the other hand, however, biotechnology seems to have greater sensitivity to changes and differences in patent law. It is because of their extreme dependency on patents. In this context, every even small change or inequality results in uncertainty about recouping the high costs of R+D. Any differences in international standards may harm patent holders who lack the certainty of knowing where and to what extent their patents will be valid.

At this time, despite the declarations of harmonization of patent law and the practice of the patent offices all over the world, the patentability of genes has been questioned in many countries. The patent regime in the field of genes is different.

The best known and recently read is the Myriad case in the United States.

The several-year struggle of Myriad Genetics, Inc. was ended in 2013 by the United States Supreme Court decision that held that isolated genetic sequences were not patentable. This decision is a huge shift in the legal treatment of gene patentability in the US – naturally occurring nucleic acids are not patent eligible merely because they have been isolated.

The Supreme Court statedthat an isolated gene cannot be covered by a patent, because it is a product of nature, only isolated from the environment of the genes adjacent to it, and such a solution is not an invention.

The case concerned human genes BRCA1 and BRCA2. Mutations in these genes are responsible, among others, for the formation of breast and ovarian cancer in women. The company Myriad Genetics owned a number of patents covering inventions relating to genetic tests that detect patients' certain dangerous mutations in BRCA1 and BRCA2. Based on results of such tests, doctors sometimes recommend prophylactic mastectomy of ovarian cancer to healthy women under threat. Myriad Genetics had exclusivity in the US to test the BRCA genes. Since research costs were huge (estimated at $ 500 million) the possession of patents was very beneficial. Yearly patent profits were estimated at 80% of its income for the whole year. This is an obvious example that without patent, genetic testing would cease to be profitable. According to the American Civil Liberties Union (ACLU), patents on the human genetic code inhibit the progress of medicine and Myriad Genetics, having a monopoly, prevented further development of BRCA testing. The main argument against Myriad Genetics patents was that nothing occurring naturally in nature can be patented. Myriad Genetics argued that the BRCA gene sequence has been isolated from the human body and it is a subject of protected invention. Before the hearing in the Supreme Court Myriad Genetics was supported by the whole genetic lobby, including, for example, companies producing genetically modified food. Interestingly, the administration of President Barack Obama, usually defending patent rights, in its opinion for the court claimed that parts of the human body cannot be patented, ultimately, the US Supreme Court upheld this argument and patents on isolated genes BRCA1 and BRCA2 were repealed.

As of this decision, examiners in the United States Patent and Trademark Office (USPTO) are now obliged to reject product claims drawn solely to naturally occurring nucleic acids or their fragments, whether isolated or not.

"The Supreme Court considered the patent eligibility of several claims directed to isolated DNA related to the human BRCA1 and BRCA2 cancer susceptibility

genes. The Supreme Court held that certain types? of Myriad Genetics' claims to isolated DNA are not patent-eligible, because they read on isolated naturally-occurring DNA that is a "product of nature". The Court held that "isolating a gene from its surrounding genetic material is not an act of invention". But the Supreme Court also held that claims limited to cDNA are patent-eligible because they are a type of man-made DNA composition that is not naturally-occurring; cDNA is not a "product of nature" and is patent eligible. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined" (Memorandum of the USPTO, June 2013).

The United States is a country with about 30% share of world's biotechnology. Will this case be an example for others to follow?

It seems unlikely that similar steps will be taken in Europe, however the patentability of genes within Europe looks differently already.

But first, back to history, in the European Union the biotech Directive was first proposed in 1988 (Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, 6 July 1998). In the face of extensive opposition from a number of groups, the European Parliament took about 10 years to reach a compromise. The legality of the biotech Directive was then challenged by the Dutch government. This resulted in the European Court of Justice ruling in 2001 (C-377/98) that the patenting of genetic material isolated from the human body does not contravene any principles of human dignity.

While in Europe there is no absolute bar on patenting genes which have been isolated from the human body, even if identical in a sequence to natural elements, obtaining patents that claim only isolated gene sequences is not unified. The rules of The European Patent Office (EPO) should be compared with the law and practice of European countries.

At present, DNA, RNA, genes and other components of the human genome are patentable under the European Patent Convention. Claims to DNA sequences have been held as acceptable by the European Patent Office on the condition that the basic patentability criteria are met. Just like any other invention, gene patents have to satisfy the patent requirements of novelty, inventive step and industrial applicability. But the patenting of biotech inventions, including genes and gene fragments, is also subject to specific requirements adopted by the European Patent Office and national patent offices corresponding to the biotech Directive. This requires that for a human gene sequence (or partial sequence) to be patented its industrial application must be shown in the patent application.

Although the biotech Directive has brought an obligation of uniformity for gene patenting, a few European countries introduced some limitations to their patent laws, although in compliance with the Directive. It needs some a short analysis of specific laws to compare and indicate the differences.

For example Germany, Italy and France have adopted the possibility of a purpose-bound patent protection, to limit unnecessary broad claims in directly-filed national patents.

In France, since 2004 the patenting of whole or partial human gene sequences per se has been banned. Claims directed to human gene sequences are limited to the specific applications disclosed in the patent application.

The German patent law of 2005 does not provide for absolute human gene protection, either. The subject of invention which is a human gene sequence (or partial sequence) present in the claims, must be limited to the use disclosed in the application. On this ground, in Germany, absolute substance protection is not available for human gene sequences as such, but this change corresponds to Article 5 of the Directive. The provision is as follows: *Where the subject matter of an invention is a sequence or a partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, the use thereof, for which industrial application is specifically described in subsection (3), shall have to be included in the patent claim* (Paragraph 1a, Section 1a, Patentgesetz).

Other countries (eg. Switzerland), go even further. Article 1b[1], part III of the Swiss patent law states: A naturally occurring sequence or a partial sequence of a gene is not patentable as such. Sequences that are derived from a naturally occurring sequence or partial sequence of a gene may, however, be patented as an in-

vention if they are produced by means of a technical process, their function is specifically indicated, and the further requirements are fulfilled (in force since 1 July 2008). It means that this limitations applies not only to human genes.

In the Italian patent law of 2010 limitations were introduced as well. The explanation is as follows: while Article 5 of the EU Directive states that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application, the Italian law states that the specific function, which has to be industrially applicable, of a gene or fragments thereof must be indicated, described and specifically claimed (Art. 81 quinquies.1.c IPC).

In Poland, some limitations in gene patenting are expected. Article . $93^2$2 of the Polish industrial property law is proposed to have the wording: the patent application on the sequence or a partial sequence of a gene in the description discloses the industrial use of the sequence in an independent claim indicating its further function. The Polish parliament will decide on the validity of that change in 2015.

Conclusion

It is worth noticing once more, that the patent system provides significant benefits to society by giving the necessary encouragement to those who invest in research resulting in inventions of real practical benefit which, in turn, lead to the development of useful products. Moreover, the public availability of the information contained in a patent application promotes scientific progress and innovation.

However, due to the specific properties of genetic material, in gene patents broad claims are granted very often, due to the nature of gene translation and transcription and protein synthesis. For example, patents on disease-related genes usually not only include claims on the nucleic acid sequence, but also on the protein, antibodies that can be later generated, the animal models etc.

On the other hand, there is a real possibility that the lack of patents on genes may result inleaving such inventions as secret, thus limiting further research related to their use, e.g. in gene therapy.

Patents on human genes have always raised practical and ethical concerns, particularly in Europe.

The European Society of Human Genetics (ESHG) emphasized several years ago the following significant aspects: "The public opinion is against the patentability of human genes. The research community is uncertain about the impact on their research projects in the field. Healthcare professionals are worried about the impact of patents on the cost of genetic tests. Industries, especially small and medium enterprises, are troubled about the difficulties resulting from multiple licenses necessary to develop a new diagnostic kit or a new drug. [...] the patenting and licensing system will be more easily accepted by the majority of geneticists and by the public, when the specific sensitivities around genetic testing, and of medicine and health care in general, are taken into account in the light of the increasing (and increasingly powerful) diagnostic possibilities coming online." (*Patenting and licensing in genetic testing, Recommendations of the European Society of Human Genetics*, Eur. J. Hum. Genet. (2008) 16: 405-411).

It seems that changes in the gene patenting all over the world follow this direction.