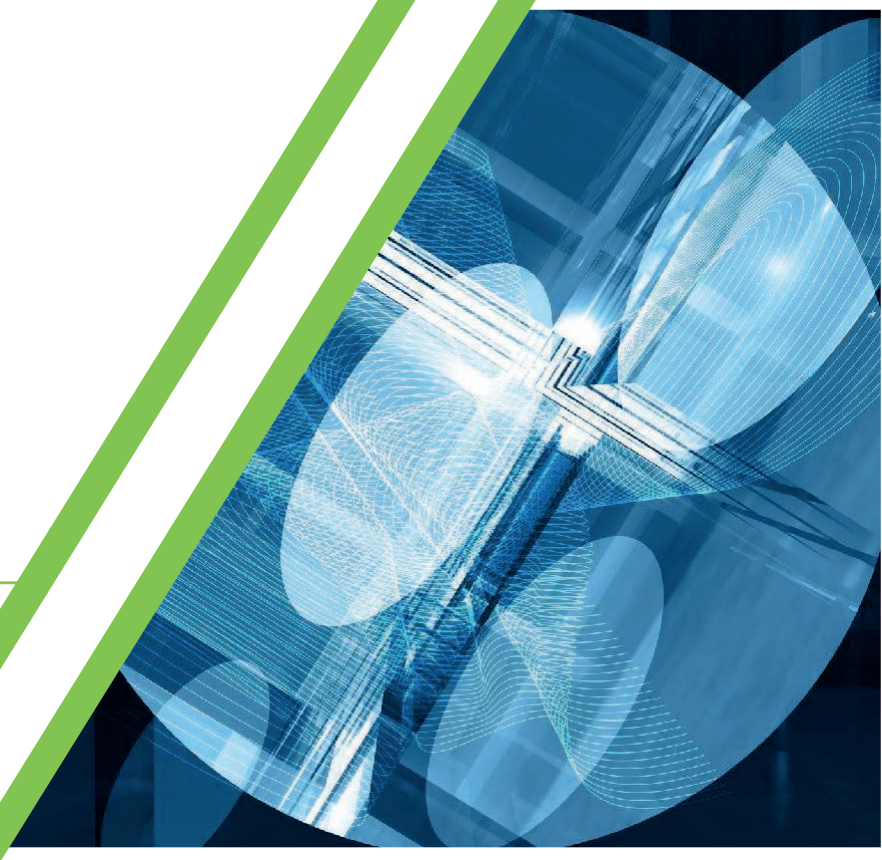
Recommendation of the Council on the Licensing of Genetic Inventions



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Adopted on 23/02/2006

Background Information

The Recommendation on the Licensing of Genetic Inventions was adopted by the OECD Council on 23 February 2006 on the proposal of the Committee for Scientific and Technological Policy. This Recommendation seeks to foster the development and delivery to the market of products and services based on genetic inventions, such as therapeutics and diagnostics, in order to more effectively and efficiently address healthcare needs. The Recommendation offers principles and best practices for the licensing of genetic inventions and is targeted at all those involved with innovation and the provision of services in health, and particularly at those involved in the licensing of such inventions. It is intended to assist Adherents in the development of policies as well as in their efforts to encourage appropriate behaviour in the licensing and transferring of genetic inventions.

THE COUNCIL,

HAVING REGARD to Articles 2 b) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to Rule 18 b) of the OECD Rules of Procedure;

CONSIDERING that advances in biotechnology and genetics offer much promise for sustainable growth and development;

CONSIDERING that genetics-based innovation may lead to the development of new products and services, including diagnostic tests, therapeutics and medications, and provide society with important benefits;

CONSIDERING that innovations in the biotechnology field, including genetic inventions as defined in this Recommendation, have increasingly been the subject of intellectual property rights;

CONSIDERING that the licensing and transferring of genetics inventions has and will increasingly have implications for future research and development, especially involving fundamental or new technologies as well as for access to the latest medical innovations;

CONSIDERING that governments and relevant public and private institutions (profit and not-for-profit) in OECD Member countries and non-member economies may benefit from international guidance on the licensing of genetic inventions;

CONSIDERING that the principles and best practices contained in this Recommendation aim to ensure that licensing and material transfer agreements as well as joint development activities are based on economically-rational practices, that help eliminate high transaction costs in line with competition law, and that serve the interests of society, shareholders and other stakeholders;

On the proposal of the Committee for Scientific and Technological Policy:

RECOMMENDS that Member countries promote good licensing practices and take due account and implement the principles and best practices for the licensing of genetic inventions which are set out in the Annex to this Recommendation and form an integral part thereof.

INVITES Member countries to disseminate this Recommendation among public and private (profit and not-for-profit) sector institutions that are involved in the licensing of genetic inventions.

INVITES Non-member economies to take due account of and disseminate this Recommendation among public and private (profit and not-for-profit) sector institutions that are involved in the licensing of genetic inventions.

INVITES Member countries, through their work in the Committee for Scientific and Technological Policy and its Working Party on Biotechnology, to periodically review the principles and best practices contained in this Recommendation.

INSTRUCTS the Committee on Scientific and Technological Policy to report to Council on progress made in implementing this Recommendation within four years of its adoption.

ANNEX

PRINCIPLES AND BEST PRACTICES FOR THE LICENSING OF GENETIC INVENTIONS

A. Scope

This Recommendation applies to the licensing of intellectual property rights[1] that relate to genetic inventions used for the purpose of human healthcare. Within this Recommendation, the term "Genetic Invention" includes nucleic acids, nucleotide sequences and their expression products; transformed cell lines; vectors; as well as methods, technologies and materials for making, using or analysing such nucleic acids, nucleotide sequences, cell lines or vectors. This definition is intended to be forward looking to encompass highly related future developments.

B. Principles and Best Practices

1. Licensing Generally

Principles

1.A Licensing practices should foster innovation in the development of new genetic inventions related to human healthcare and should ensure that therapeutics, diagnostics and other products and services employing genetic inventions are made readily available on a reasonable basis.

1.B Licensing practices should encourage the rapid dissemination of information concerning genetic inventions.

1.C Licensing practices should provide an opportunity for licensors and licensees to obtain returns from their investment with respect to genetic inventions.

1.D Licensees and licensors should have reasonable certainty over their rights and the limitations to those rights in relation to genetic inventions.

Best Practices

1.1 License agreements should permit licensees to develop and further improve the licensed genetic inventions.

1.2 License agreements should clearly set out which parties obtain, retain, receive and maintain ownership of, grant rights to and enforce intellectual property rights, including with respect to the improvements and new genetic inventions developed from the licensed technology.

1.3 Licence agreements should clearly set out which of the parties, if any, has the right to engage in collaborative research with third parties and set out the ownership of any intellectual property rights flowing from such collaborative research.

1.4 Confidentiality provisions should be carefully drafted so as to permit the dissemination of information pertaining to genetic inventions while taking into account the need to file patent applications, to protect undisclosed information and to capitalise on the inventions in the marketplace.

1.5 License agreements should not provide the licensor with exclusive control over human genetic information, including collections of such information, derived from individuals through the use of the licensed genetic invention.

1.6 Rights holders should be encouraged to agree to licensing terms and conditions that maximize the utilisation of their genetic inventions.

1.7 License agreements should clearly stipulate the duties, obligations and responsibilities of the parties and address the rights of the parties to use the improvements to the licensed genetic invention following any, including early, termination.

1.8 License agreements should define the roles and responsibilities of the parties in the commercialisation, if any, of the products and services arising from the use of the licensed genetic invention.

2. Healthcare and Genetic Inventions

Principles

2.A Licensing practices should seek to strike a balance between the delivery of new products and services, healthcare needs, and economic returns.

2.B Licensing practices should ensure that patients benefit from the highest applicable standards with respect to privacy, safety and good laboratory methods available pursuant to the laws of their jurisdiction or those of the jurisdiction of the service provider using the genetic invention.

2.C Licensing practices should not be used to restrict the choice of other products or services by patients and their healthcare providers.

2.D Licensing practices should encourage appropriate access to and use of genetic inventions to address unmet and urgent health needs in OECD Member countries and non-member economies.

Best Practices

2.1 Rights holders should broadly license genetic inventions for research and investigation purposes.

2.2 Rights holders should license genetic inventions for health applications, including diagnostic testing, on terms and conditions that seek to ensure the widest public access to, and variety of, products and services based on the inventions.

2.3 Licensing practices should permit national or local providers to use genetic inventions in order to provide healthcare services, even if the rights holder is based in another jurisdiction.

2.4 Licensing agreements relating to products and services incorporating personal health information should facilitate compliance by the licensor and the licensee with the highest applicable privacy and other relevant laws.

2.5 License agreements should not restrict access by the licensee's researchers to databases generated from licensed genetic inventions in their efforts to develop new therapies, products or services.

2.6 License agreements should permit licensees, for example healthcare providers, to offer patients flexibility and choice with respect to the selection of the type and nature of healthcare products and services.

3. Research Freedom

Principles

3.A Licensing practices should increase rather than decrease access to genetic inventions for research purposes.

3.B Commercial considerations in public research activities should not unduly hinder the academic freedom of researchers.

3.C Commercial considerations in public research activities and, in particular, the need to preserve the opportunity to seek patent protection on inventions arising from these activities, should not unduly limit the ability to publish in a timely manner the results of research.

3.D Commercial considerations in public research activities should not unduly limit the educational training of students.

Best Practices

3.1 License agreements should clearly delineate research areas, information and time frames in which researchers and students cannot publish or present papers or theses without violating confidentiality obligations. Licensors and licensees should inform all relevant individuals, including students, of the scope of confidentiality obligations in a timely fashion.

3.2 Licensors and licensees should educate their researchers with respect to intellectual property law, especially the effects of public disclosure on the patentability of inventions, confidentiality obligations and restrictions commonly contained in agreements.

3.3 Confidentiality provisions should provide that academic research arising pursuant to the license agreement can be freely published or disclosed, with as minimum a delay as possible, subject to the need to protect proprietary information disclosed to the licensee or arising from such research.

3.4 Delays in publications of academic research necessary, for example, for the filing of patent applications, should be limited and reasonable in the circumstances.

3.5 Confidentiality provisions in licensing agreements should be drafted as narrowly as suitable and should not prevent the possibility of reasonable disclosure in exceptional public health situations, in light of the objectives of the parties and the applicable law.

4. Commercial Development

Principles

4.A Foundational genetic inventions should be licensed so as to be broadly accessible.

4.B Licensing practices should be used as an effective means to create value for licensors and licensees through the development of new products and services from genetic inventions.

4.C Licensing practices should strive to overcome co-ordination problems resulting from the need to access multiple genetic inventions.

Best Practices

4.1 Should several licenses be required, license agreements should include a mechanism to set a reasonable overall royalty burden for genetic invention products and services, including research tools.

4.2 License agreements should include terms that maintain low barriers for access to genetic inventions. This may mean that such agreements do not include, for example, excessive up-front fees.

4.3 License agreements should avoid reach-through rights so as to foster broad and unencumbered utilisation of the genetic invention and so as to not discourage or stifle subsequent innovations.

4.4 Private and public sector participants should develop mechanisms to decrease transaction costs in acquiring rights to use technology.

4.5 Organisations that may enter into license agreements should educate their decision-makers about the opportunities to use the least restrictive licensing practices, as appropriate, as a means to maximise the benefits from genetic inventions for society, shareholders and other stakeholders.

5. Competition

Principles

5.A Licensing practices pertaining to genetic inventions should foster economic growth through innovation and substantive competition, while complying with the applicable competition laws.

5.B Licensing practices should not be used to expand the breadth of exclusive rights beyond the scope of the relevant intellectual property rights.

Best Practices

5.1 License agreements should avoid unduly restrictive tied-selling.

5.2 License agreements should avoid non-compete clauses in areas beyond the scope of licensed genetic invention.

5.3 License agreements relating to foundational genetic inventions should generally be non-exclusive to encourage broad access for researchers and patients and broad use of the genetic invention.

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[1] For the purposes of this Recommendation, intellectual property rights include patents, undisclosed information (also known as trade secrets or proprietary information), trademarks, and copyright.

Adherents*

OECD Members	Non-Members
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*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

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The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.