

GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS



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BACKGROUND

Biotechnology and genetics research have been the subject of extensive investment both by the public and private sectors, with the products and processes emerging from these efforts making a significant and increasing contribution to human health and health care. The science as well as health ministers of the OECD member countries concluded in the first part of 2004 that biotechnology will be a key driver for sustainable growth and development in the OECD member countries and beyond. To deliver on this potential and to access the desired benefits the technology offers society, a clear enabling environment and regulatory structure will be essential.

Biotechnological, including genetic, innovations have been the subject of intellectual property rights for decades. Over the last decade, as the number of such innovations has increased, their use in and importance for the human health care field has also grown. Recently, some countries have expressed concerns with how certain genetic inventions have been licensed and exploited, particularly for diagnostic genetic services in the human health care field.

In response, the OECD held a workshop in Berlin in January 2002 to investigate the impact on access to information, products and services for researchers, clinicians and patients resulting from an increase in patent applications filed and patents granted for genetic inventions used in human health care as well as the associated licensing practices for such inventions.¹ The impetus behind the workshop was the issue of whether intellectual property systems functioned effectively by encouraging the diffusion of information and technologies or were impeding access to genetic inventions. The workshop concluded that the intellectual property system, as applied to genetic inventions used for human health care purposes, functions largely as intended – stimulating innovation and the disclosure of information, and that there is no evidence to suggest a systemic breakdown in the licensing of such inventions. Nevertheless, some specific concerns were identified, and in particular with respect to access to diagnostic genetic tests.

OECD member countries, in consultation with interested parties, concluded that guidelines setting out the principles and best practices for the licensing of genetic inventions used for human health care purposes would be an appropriate and measured response to the identified difficulties. The development of these guidelines was endorsed by OECD's Committee for Scientific and Technological Policy meeting at ministerial level in January 2004 as well as by OECD health ministers at their meeting in May 2004. This political endorsement resulted in the adoption by the OECD Council of the Recommendation on the Licensing of Genetic Inventions on 23rd February 2006 (C(2005)149/Rev1).

1. From this workshop, the OECD published a report entitled *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (OECD, Paris, 2002) which outlined the discussions and conclusions flowing from the Berlin workshop.

PREFACE

1. These Guidelines offer principles and best practices for the licensing of genetic inventions used in human health care. They are 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. The Guidelines are intended to assist both OECD and non-OECD governments in the development of governmental policies as well as in their efforts to encourage appropriate behaviour in the licensing and transferring of genetic inventions. Overall, the Guidelines seek 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 health care needs in both OECD member and non-member countries.

2. These Guidelines apply to the licensing of intellectual property rights² that relate to genetic inventions used for the purpose of human health care. Within these Guidelines, 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.

Genetic Innovation and Human Health Care

3. Advances in biotechnology and genetics offer much promise for sustainable growth and development of economies and for society more broadly. Genetic innovations already play an important role in meeting health needs. Future advances will provide a better understanding of the interaction between environmental factors and genetic heritage, will lead to the development of new products and services, including diagnostic tests, therapeutics, and medications, and will contribute to more effective and efficient delivery of high quality health care more generally. Efforts need to be made to ensure that these advances deriving from a better understanding of genetics are made available to those who stand to benefit, both in developing and developed countries.

4. Progress in genetics and health-related biotechnology is not only increasingly valuable to health care, but also represents a significant and growing portion of OECD member countries’ economies. Developments in the field of genetics may also provide society with important results that may be transferred and may stimulate knowledge spillover effects of importance to the economy at large, both in developing and developed countries.

5. The genetics and genomics revolution and the development of products and services that has happened in its wake have been due to the work both of the public and private sectors, individually and in collaboration. Research thrives on collaboration and getting the most out of the genetics revolution will rely increasingly on efficient and effective exchange between those researching and developing new innovations – as well as with those that would use these

2. For the purpose of these Guidelines, intellectual property rights include patents, undisclosed information (also known as trade secrets or proprietary information), trademarks, and copyright.

innovations. It is this spirit of exchange and co-operative effort that lies at the core of these Guidelines.

Balanced Intellectual Property System

6. Innovations, in the field of genetics as in others, are typically protected via various forms of intellectual property rights, including patents. Innovations may also be protected through laws preventing the unauthorised transfer of undisclosed information, and through contractual provisions, such as those in material transfer agreements.

7. Generally, the patent system and other forms of intellectual property aim to encourage the development and dissemination of knowledge and innovations with a view to fostering scientific, technical and social progress for the betterment of society. While a rights holder may choose to exploit or commercialise such innovations directly, often these are also exploited or commercialised via licensing agreements, joint development activities or through material transfer agreements. Such agreements or activities allow the operation of the intellectual property system as they not only promote the commercialisation of and access to innovations, but also provide rights holders with the ability, if they wish, to achieve a return on their investment. All of these functions constitute an integral part of a balanced intellectual property system.

8. While there is no single model for the licensing or transferring of genetic innovations, the manner in which rights holders choose to carry out such activities 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. These Guidelines aim to provide parameters so as to ensure that licensing and material transfer agreements as well as joint development activities are based on economically-rational practices that help eliminate high transactions costs while complying with competition law and that serve the interests of society, shareholders and other stakeholders.

Nature and Structure of the Document

9. These Guidelines cover a broad reach of activities and are intended to be interpreted as appropriate to the circumstances. Moreover, these Guidelines are not intended to cover exhaustively all aspects of licensing practices in the field of biotechnology, including genetics. The Recommendation on the Licensing of Genetic Inventions was adopted by the Council of the OECD on February 23rd, 2006 (see C(2005)149/Rev1).³

10. The Guidelines are intended to be evolutionary in nature and should be reviewed in light of developments in genetic innovations, changes in business practices, and the needs of society. Thus, there will be a need for these Guidelines to be assessed, four years after adoption at the latest, and periodically thereafter, in order to ensure that they are fostering the desired objectives of stimulating genetic research and innovation while maintaining appropriate access to health products and services. They should at all times be read and applied in a purposive manner.

11. Part One sets out the Principles applicable to the licensing of genetic inventions together with the related Best Practices that were adopted as an OECD Council Recommendation. The Principles provide a framework within which to conceive of voluntary, market-oriented licensing arrangements with respect to genetic inventions used for the purpose of research and human

3. While a Recommendation of the OECD Council is a non-legally binding document, it represents an important political commitment on the part of the Member countries.

health care. The Best Practices are practical means for putting into place that framework. Part Two contains explanatory Annotations which elaborate on the Principles and Best Practices in Part One.

PART I: PRINCIPLES AND BEST PRACTICES FOR THE LICENSING OF GENETIC INVENTIONS

A. Scope

These Guidelines apply to the licensing of intellectual property rights⁴ that relate to genetic inventions used for the purpose of human healthcare. Within these Guidelines, 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.

4. For the purpose of these Guidelines, intellectual property rights include patents, undisclosed information (also known as trade secrets or proprietary information), trademarks, and copyright.

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 License 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.

PART II: ANNOTATIONS

Introduction

1. The Guidelines contain principles and best practices for the licensing of genetic inventions used for the purposes of human healthcare. They are 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. The Guidelines are intended to assist both OECD and non-OECD governments in the development of governmental policies as well as in their efforts to encourage appropriate behaviour in the licensing and transferring of genetic inventions.
2. The Principles and Best Practices outlined in this document aim to provide guidance not only on whether or not to license genetic inventions but also on the manner in which such licensing activity should be undertaken.
3. Generally, the patent system and other forms of intellectual property aim to encourage the development and dissemination of knowledge and innovations with a view to fostering scientific, technical and social progress for the betterment of society and to reward inventors. While it is often assumed that a functioning intellectual property system will encourage the making available of inventions, including genetic inventions, this may not always be the case. Concerns have been expressed that intellectual property rights holders do not always fully exploit these rights and the technology to which they pertain. Additional research on the interaction between the intellectual property system, research, and the accessibility of products and services would contribute to a better understanding of the role of the IP system.
4. While market forces and the patent system are generally expected to ensure inventions are readily made available, this is not always the case, particularly in the context of genetic inventions. It has been suggested that many factors may contribute to this conclusion including the lack of knowledge or experience of some licensors of genetic inventions, the fact that human genetics research crosses the boundary between basic research and commercial applications making the application of both formal and informal research freedoms unclear, and the fact that researchers often need licenses to many inventions in order to carry out research and development.
5. The purpose of these Annotations is to provide additional information on the Principles and Best Practices set out in the draft OECD Council Recommendation (C(2005)149/REV1) and generally follow that structure. While certain basic licensing terms and concepts are outlined herein, these Annotations should not be viewed as covering all aspects of licensing, material transfer or technology transfer agreements.

General Terminology

6. The Guidelines apply to the licensing of intellectual property rights that relate to genetic inventions used for the purpose of human healthcare. These intellectual property rights include patents, undisclosed information (also referred to as trade secrets or proprietary information), trademarks, and copyright.

7. Within the Guidelines, 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.

8. Within the definition, the reference to transformed cells or cell lines is intended to cover both genetically modified and non-genetically modified cells and cell lines. While the definition of the term genetic invention is intended to be broad, it is not intended to cover certain innovations, such as drugs/medicines. Although this definition of genetic invention is intended to cover the information derived from a nucleic acid (*i.e.*: a nucleotide sequence), the databases per se wherein such information is stored or maintained are not covered by this definition or these Guidelines.

9. There are different ways in which rights pertaining to genetic inventions may be transferred. A License Agreement is one such mechanism. In a license agreement, the licensor, typically the rights holder with respect to a patented invention, will grant to the licensee the right to use the patented invention according to the conditions outlined in the agreement and for a specified period in return for various considerations. Moreover, the license agreement and the scope of the licence may be worldwide or may be limited to certain jurisdictions. For example, the territorial limit may be for a country, a region (*e.g.*: European Economic Area) or even a particular region within a country (*e.g.*: California, United States). In addition, the license agreement may permit the licensee to use the technology for any purpose or for defined purposes.

10. The type of licence agreement concluded will depend on the nature and scope of the rights the parties wish to grant to each other and on the objectives of the transaction. One type, an *exclusive licence agreement*, provides the licensee with the exclusive rights to use the licensed technology and the associated intellectual property rights. In this type of agreement, the licensor itself does not retain the right to use the licensed technology and associated intellectual property rights and must refrain from granting licences to third parties. For example, an exclusive licence can grant the licensee the worldwide rights to commercialise a genetically modified protein. In a second type, a *sole or semi-exclusive licence agreement*, the licensor, in addition to granting the licensee the right to use the licensed technology and associated intellectual property, may retain the right to exploit the technology. There are different approaches to how a sole or semi-exclusive licence can create enclaves of exclusivity for each licensee. As mentioned in the preceding paragraph, this may be achieved, for example, through different licences covering different fields of use or through different geographical territories. In a third type, the *non-exclusive licence agreement*, the licensee is granted the right to use the licensed technology and associated intellectual property rights during the term of the license. However, the licensor retains the right to use the licensed technology and associated intellectual property right, and retains the right to grant other licences to third parties. In situations where non-exclusive licences are employed, for example for the licensing of diagnostics, there may be multiple licensees even within the same geographical territory.

11. Another mechanism is a Material Transfer Agreement (MTA). A Material Transfer Agreement, generally signed between a Provider and a Recipient, is used to document the transfer of materials, with or without information, either to an entity (*i.e.*: Recipient) and/or away from an entity (*i.e.*: Provider) subject to a number of terms and conditions. A MTA may cover materials with or without information that may or may not be protected by intellectual property rights. The Agreement may stipulate for which purposes the materials and/or information is to be employed and for which purposes their use is prohibited. For example, the MTA may prohibit the use of the material in research on human subjects or prohibit the use of material in research that is subject to licensing from any third party.

12. Similar to any contract, licensing, material transfer and technology transfer agreements are subject to and must respect various bodies of law, including contracts, competition/anti-trust, private international law/conflict of laws, etc. These types of agreements often contain provisions that will stipulate the applicable law in case a dispute arises with respect to the agreement. In other words, provisions in such an agreement may indicate the law of which country will govern the agreement and the dispute. Moreover, these types of agreements may also contain provisions that establish the procedure that the parties will have to follow should a dispute arise between them with respect to the agreement. For example, the dispute settlement provisions could require that the parties have recourse to non-judicial mechanisms, such as mediation and arbitration, prior to undertaking judicial action.

1. Licensing Generally

13. In some areas, in particular human genetic testing services, researchers have been faced with situations where they have had some difficulty in obtaining licenses for a reasonable fee. While the particular causes of these situations are disputed, the consequences to healthcare and to research are sufficiently important to merit attention.

14. In light of the above, the Principles encourage licensing practices that make available genetic inventions on a reasonable basis. In certain circumstances, such as in the cases of health crises or health emergencies, licensors or licensees may determine not to seek a financial return, thus determining to make the genetic inventions available for free or at cost.

15. The Principles provide that licensors and licensees should aim for the rapid dissemination of information about the nature and existence of genetic inventions, such as basic information about the substance, nature and uses of the genetic inventions. While the Principles recognise that it may often be commercially appropriate to license genetic inventions broadly, they also take into account that this may not always be the most viable option. That is, the Principles draw a distinction between the knowledge related to the existence and nature of genetic inventions and the rights to actually practice the inventions. The Principles also encourage parties to clearly stipulate the scope of license rights, especially to ensure that there is clarity with respect to freedom to operate.

16. While the Best Practices recognise the needs of licensors to adjust their licensing practices to meet market pressures, they encourage practices that grant more and a better defined freedom to operate to licensees. Where possible, licensors should generally permit licensees the freedom to operate (within the scope of their authority) so as to conduct research and development on health related products and services including those related directly to the licensed genetic inventions. To that end, intellectual property provisions in license agreements should state as clearly as practicable which party(ies) has title to which genetic inventions, has the responsibility to obtain, retain, receive and maintain ownership of and enforce intellectual

property rights, including with respect to the improvements and new resulting inventions, has the ability to grant licenses to those inventions, has the right to obtain revenue from those inventions, and has the ability to put into practice those inventions.

17. In recognition of the importance of disseminating knowledge about genetic inventions, the Best Practices suggest that confidentiality provisions be drafted to meet the dual goals of ensuring that information is quickly disseminated while protecting the interests of the rights holder to exploit their inventions through, for example, the filing of patent applications. This suggests that confidentiality provisions be clear about which information is included within the obligation, terms of use and the term of the obligation. Licensors and licensees should aim to have as narrow a confidentiality obligation as is consistent with the ability to file patent applications and maintain commercial advantage.

18. Human genetic information derived from individuals refers to information derived from the use of the licensed genetic invention. While there does not appear to be a generalised practice for patent holders to exert control over human genetic information derived from individuals, anecdotal evidence suggests that such a practice has occurred in certain situations. Since such information may provide valuable insight with respect to the functioning of the human body or the development and progression of diseases, the Best Practices recommend that such information be available to researchers and not controlled exclusively by the licensor. This dissemination may be even more appropriate of specific genetic data obtained in the context of diagnostic testing in laboratories. In other words, subject to the need to protect the privacy of patients and to meet the legitimate business needs of licensors and licensees, such information should be disseminated as widely as possible. Nevertheless, this wide dissemination is not intended to restrict the ability of developers of databases of human genetic information to realise commercial returns on their investments.

2. *Healthcare and Genetic Inventions*

19. It is important that licensors and licensees are encouraged to consider the possible impact of their license arrangements on the healthcare system and on patients. Licensors and licensees should, while meeting their economic needs, design their licensing arrangements so that patients have access to new health products and services and so that healthcare system administrators have reasonable flexibility to determine how best to implement new healthcare services and products.

20. The Principles encourage licensing practices that could promote a strong research environment and market for healthcare products and services. The broad licensing of genetic inventions is preferable in order to maximise the chances that a genetic invention will be widely used.

21. It is recognised that healthcare products and services as well as the use of genetic inventions may be subject to a variety of rules, standards and regulations including with respect to privacy, safety and good laboratory methods. Licensing practices should ensure that patients obtain the benefits of the laws in their jurisdiction or, where such benefits are greater, the laws of the jurisdiction of the service provider. However, when feasible, licensors should license genetic inventions to service providers within the jurisdiction. This would then provide patients with services in compliance with laws, standards and regulations dealing with safety procedures and privacy applicable within their jurisdiction. Health information gathered through the provision of services or in the conduct of research should be dealt with in accordance with the higher of the standards of the jurisdiction in which the patient resides or that where the information is used. As

with all other legislation, licensors and licensees should comply with privacy legislation applicable to the genetic invention and any information derived there from.

22. Genetic inventions may be useful in addressing ‘unmet and urgent health needs’ in both developing and developed countries. Further work on this issue, including the provision of some examples, may be appropriate as part of the report to the Council by the Committee on Scientific and Technological Policy.

23. Since genetic inventions often have many applications in clinical research and clinical practice, licensors should attempt, to the extent commercially practical, to license these inventions out broadly. This will facilitate both direct and more innovative uses of the genetic invention in the clinical and research areas while maintaining or expanding the economic return to the licensor.

24. In addition to a strategy of licensing broadly where appropriate, licensors should avoid, to the extent practical, limitations in license agreements that may reduce further research and clinical activity using the licensed genetic invention. For example, licensees should generally be entitled to combine products or services or to implement health services in the manner of their choosing. Moreover, genetic tests should be licensed broadly so as to support the delivery of comprehensive and integrated diagnostic testing services.

25. The Best Practices propose that licensors do not use their patent rights over genetic inventions in order to create proprietary databases of genetic mutations without providing reasonable access to those databases to other researchers. This could arise, for example, should a licensor require all genetic tests to be conducted at its laboratory and that patients using the test agree that the licensor can use the resulting genetic information for research purposes. Should this arise, the licensor should make the database available to others on a reasonable basis. However, as noted above, these Guidelines do not apply to databases *per se* or to their licensing. Moreover, the OECD is considering best practices in the area relating to the management and governance of human genetic research databases.

3. *Research Freedom*

26. Internationally, the importance of encouraging and not impeding the progress of research has been recognised in numerous international instruments, such as the UNESCO Recommendation on the Status of Scientific Researchers, 1974. The importance of research in the genetics field has also been recognised in international instruments such as the UNESCO Universal Declaration on the Human Genome and Human Rights, 1997 as well as the UNESCO International Declaration on Human Genetic Data, 2003.

27. The Principles recognise the importance of research activities in the public and private sector, whether individually or collaboratively. The complementary strengths of these sectors are critical to developing new healthcare products and services. Licenses can provide an important mechanism through which the public and private sectors cooperate on research projects and transfer knowledge and inventions so as to bring genetic inventions to the public.

28. Licensing and other agreements, including investigator/consulting agreements, material transfer agreements, database access agreements, and sponsored research agreements, as well as practices should ensure that the needs and interests of both private and public sector actors are met. Public sector actors should ensure that they maintain both the current and future research freedom for their researchers and their students. In this regard, licensing, material transfer and other agreements should contain sunset clauses, where appropriate, applicable to the confidentiality provisions contained therein. At the same time, they need to recognise that some secrecy may be necessary to meet commercial goals, such as obtaining appropriate legal protection over the genetic invention, including patents, or protecting undisclosed information.

29. As one of the goals of academic institutions is to train researchers, the Best Practices suggest that academic institutions ensure that students and researchers understand, in advance of conducting their research, whether and to what extent their work may be subject to obligations of confidentiality. To facilitate this, license and other agreements should clearly set out those research areas, information and time frames in which researchers and students do not have complete freedom to publish. Where researchers and students do not have such freedom, the license and other agreements should set out the mechanism through which permission to publish can be obtained. Any review period should be kept to the minimum.

30. In determining the scope of research freedom, consideration should also be given to the research defence (*i.e.*: commonly referred to as a “research/experimental use exception/exemption”) existing in numerous jurisdictions, either pursuant to the patent statute or created through jurisprudence. However, it should be noted that a research defence is not available in all jurisdictions and its scope varies considerably across the various jurisdictions. Generally, the research defence enables defendants being pursued in an infringement suit to allege that they are not liable for infringement because their activity with respect to the patented invention falls within the ‘research purposes’ permitted by this defence. However, the most complex aspect of this defence is the determination by the court of whether or not the alleged activity comes within the scope of the research defence as applicable within that jurisdiction. In jurisdictions where such a defence is available, a licence may be required to the extent that the research activity is not covered by the scope of any available research defence.

31. Academic institutions should ensure that researchers and students understand their responsibilities and obligations pursuant to different areas of law and agreements. For example, this could include information pertaining to confidentiality agreements, licensing agreements, patent law, trade secret law, etc. Therefore, the establishment of training programmes on

intellectual property in general and its management, including licensing strategies, for researchers, technology transfer officers and contract managers would be useful.

4. Commercial Development

32. In genetics, as in other fields, there are numerous revolutionary inventions, which have been designated in these Guidelines as “*Foundational Genetic Invention*”. For the purpose of these Guidelines, the term “foundational genetic invention” is a genetic invention which provides for a new field of research or medical practice. If such inventions were not broadly accessible at reasonable costs, a field of research or medical practice would be inhibited. Examples of foundational genetic inventions include polymerase chain reaction (PCR), the Cre-Lox system, a general nucleic acid probe useful in a variety of contexts such as a telomere probe, Cohen and Boyer’s recombinant DNA methodology and RNAi. In view of their far-reaching impact, the Principles advocate the broadest access to foundational genetic inventions.

33. Foundational genetic inventions may include certain research tools. For the purpose of these Guidelines, “research tools” may be considered a composition or method useful in conducting experiments. This term could embrace a broad range of resources that scientists use in the laboratory including, but not limited to, cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinational chemistry, genomic and proteomic libraries, drug and drug targets, clones and cloning tools, methods, laboratory equipment and machines, databases and software.

34. The Principles recognise that often the best mechanism through which licensors can extract value from and ensure use of patented genetic inventions is to license them to others. This will be the case particularly in situations where the licensee will require licenses for several genetic inventions. Licensors and licensees should take this need into account in their licensing practices and ensure that their contractual obligations do not, when considered together, effectively prevent research and development efforts.

35. Licensors should carefully consider when selecting to license a genetic invention on an exclusive basis, as they may present certain difficulties. In certain circumstances, exclusive licenses may be the only effective way of harnessing the value of a genetic invention and having the genetic invention commercialised. An exclusive licensing agreement could, for example, be appropriate when further R & D is required by private sector collaborators in order to actualise the genetic invention or to bring it to market. An exclusive licence may also be appropriate, for instance, where the product being developed requires considerable investment and its market is rather limited.

36. In situations where a licensor decides to exploit the genetic invention through the grant of an exclusive licence, the license agreement should contain sufficient safeguards to ensure that the genetic invention is sufficiently exploited. First, the exclusive licence could contain field of use and geographical limitation clauses that are well-defined and tailored to the objective(s) of the agreement. For example, an exclusive licence could contain a field of use clause which covers the use of the licensed genetic invention only in therapeutic protocols. This would allow the licensor to license the same genetic invention for other fields of use, such as for diagnostic testing or as a research probe, to other licensees. Second, the exclusive licence could contain provisions which ensure that the licensee is fully exploiting and/or sub-licensing the licensed genetic invention. For example, the licence agreement could include provisions establishing milestone payments or benchmarks, enabling the licensor to convert the exclusive licence into a non-exclusive licence or

enabling the licensor to reduce the scope of the exclusive licence, should the licensee fail to meet the conditions.

37. Generally, a licensor will grant a licence to the licensee in consideration for certain payments. There are different types of payments and the various types may be combined in different ways, often within one agreement. An up-front payment is a payment which is to be made when the licence agreement is signed. If no further payments are required, the licence becomes a paid-up licence. In the situation where the licensee must make certain payments if and when certain events occur (*i.e.*: milestones), these are called milestone payments. For example, these can be triggered after proof of concept, when phase II of clinical trials is initiated, etc. A royalty payment is an amount payable by the licensee and is dependent on the extent of the licensee's exploitation of the invention. Which combination of these payment mechanisms is chosen for a particular genetic invention licence will depend on the objectives and cost-benefit analysis of the parties to that particular transaction. For example, one licensee may be willing to pay a higher up-front fee for a lower or nil royalty burden over the life of the licence. Conversely, a different licensee in a similar situation may have agreed to no up-front payment but a higher royalty burden. As a means of ensuring that the licensed invention is exploited, a licence agreement may also contain provisions imposing penalty-fees or the termination of the agreement for lack of exploitation.

38. The Best Practices suggest that licensors and licensees should contemplate, in their payment provisions, mechanisms through which the total financial burden falling on licensees from the various licences is not prohibitive to the development and delivery of products and services. Mechanisms to achieve this include, for example, agreements that diminish the royalty payment payable to a licensor on a pro rata basis with other royalty obligations where the licensee is required to obtain licenses to other inventions for a fee. That is, the contract may contemplate a total royalty burden, expressed for example as a percentage of revenue or profits or as an absolute amount, which will be allocated on a pro rata basis by all licensors.

39. The Best Practices recommend that reach through rights ought to be avoided if they discourage or stifle subsequent innovation. For the purposes of these Guidelines, the term 'reach through rights' is used to refer to where the licensor seeks to obtain, via the licensing agreement, extensive rights in the licensee's research results and innovation developed using the licensed technology.

40. In certain circumstances, reach-through rights are not necessarily anti-competitive. However, reach-through rights may place a significant burden on final licensees that may diminish research or stifle product development. This is particularly true of clinical research and services. It must be recognised, however, that some terms that may superficially look like reach-through rights are not in substance reach-through rights. These include, for example, rights of first refusal over results of research using the licensed genetic invention or a deferral of compensation.

41. Through industry associations and through private arrangements in particular fields of technology, licensors and licensees should investigate mechanisms to make genetic inventions more accessible more quickly, thus reducing transaction costs. These transaction costs may include the human resource and financial costs of identifying licensors and negotiating multiple license agreements. Mechanisms to reduce these transaction costs may include patent pools or patent clearinghouses. In addition, industry associations may suggest standard clauses to reduce transaction costs. In all cases, licensors and licensees must comply with all relevant competition laws which often circumscribe such activities.

42. The Best Practices suggest that both licensors and licensees should develop training programmes, either individually or through industry associations, to train their decision-makers with respect to the value of licensing genetic inventions to meet financial and other objectives as well as for ensuring a strong research environment. Such training should include information on the value of non-exclusive licensing of genetic inventions.

5. *Competition*

43. Intellectual property and competition policy are complementary components for an efficient operation of the marketplace. Intellectual property rights, comparable to other private property rights, provide an incentive for the rights holder to invest in creating and developing innovations as well as encouraging their efficient use and dissemination within the marketplace. One of the aims of competition law is to prevent anti-competitive behaviour that impedes the development, production and diffusion of products, technologies and services while recognising that certain arrangements between parties to a license agreement can promote the efficient development and delivery of products and services.

44. The Principles recognise the importance of competition law as a complementary means of achieving a strong research and development base with respect to genetic inventions. The Principles encourage licensees and licensors to become aware of the application of these laws and to conform to them. Moreover, it is recognised that compliance with these Principles and Best Practices is independent of an assessment of the agreement in question under applicable competition law(s). The Principles also recognise the importance of market participants acting in such a way as to avoid unduly impeding the development of new and perhaps competing products and services based on genetic inventions, even if such acts do not violate competition law(s).

45. The Best Practices suggest that certain practices, such as tied-selling, not be undertaken in a manner that is too restrictive. Briefly, tied-selling arises when the licensor offers to provide a licence to the licensee on the condition that the licensee also acquire from the licensor, or an authorised third-party, another product or service. Generally, competition law does not prohibit tied selling *per se* since, in certain circumstances, it may encourage the formation of arrangements that more efficiently deliver products and services to the marketplace. At the same time, it is recognised that tied selling may have anticompetitive effects, in particular where the licensor has substantial market power. Along the same lines, in the context of human healthcare, some evidence seems to sustain the position that tied-selling does not necessarily promote the efficient delivery of product and services. Thus, in this context and in order to discourage anti-competitive behaviour, it is recommended that unduly restrictive tied-selling be avoided, especially where alternative products and services are not available. This recommendation against unduly restrictive tied-selling should be viewed in light of the corollary Principle 2.C which stipulates that licensing practices should not be used to restrict the choice of other products and services by patients and their healthcare providers.

46. While the Best Practices recognise the importance of such contractual provisions as non-compete or similar clauses, they discourage their use where such provisions would impede innovation and restrict competition. Generally, non-compete clauses, as the nomenclature indicates, will create an obligation for one of the parties to not compete with the other party with respect to a particular aspect of the transaction. In the context of human healthcare, as in other areas, there may be different types of non-compete clauses. For example, a licensor may impose on the licensee the restriction that the latter not acquire or use technologies that compete with those licensed by the former. Similar to the tied-selling clauses, non-compete clauses are not *per se* prohibited by competition law since they may encourage the exploitation of the licensed

technology for the development or commercialisation of new products or services. Nevertheless, it is suggested that licensors and licensees evaluate the practical effects of non-compete clauses on the ability for new products and services to enter the marketplace.

47. The Best Practices also suggest that, to ensure a strong research base and as a supplement to competition law, licensors should consider licensing those genetic inventions that comprise base or platform technologies broadly. Mechanisms such as patent pools, patent clearinghouses or standard contractual provisions may be of assistance in implementing this best practice. Once again, licensors and licensees must be aware of limitations on such arrangements contained within competition law.

GLOSSARY

The following definitions are provided for ease of reference:

Exclusive Licence – provides the licensee with exclusive rights to use the licensed technology and the associated intellectual property rights and the licensor must refrain from granting licences to third parties.

Foundational Genetic Invention – is a genetic invention which provides for a new field of research or medical practice.

Licensee - the entity to whom the rights are granted via the license agreement.

Licensor - the rights holder and the entity granting the rights via the licensing agreement.

Material Transfer Agreement – generally signed between a Provider and a Recipient, is used to document the transfer of materials, with or without information, either to an entity (*i.e.*: Recipient) and/or away from an entity (*i.e.*: Provider) subject to a number of terms and conditions.

Non-exclusive Licence – the licensee is granted the right to use the licensed technology covered by the licensed intellectual property rights during the term of the license. However, the licensor retains the right to use the licensed technology and associated intellectual property right itself and retains the right to grant other licences to third parties.

Reach-through Rights – where the licensor seeks to obtain, via the licensing agreement, extensive rights in the licensee's research results and innovation developed using the licensed technology.

Research Tools – may be considered compositions or methods used in conducting experiments. This term could embrace a broad range of resources that scientists use in the laboratory including, but not limited to, cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinational chemistry, genomic and proteomic libraries, drug and drug targets, clones and cloning tools, methods, laboratory equipment and machines, databases and software.

Sole or Semi-exclusive Licence – the licensor, itself, may retain the right to exploit the licensed technology and creates certain enclaves of exclusivity for the licensee(s).

APPENDICE

This Appendice references, in a non-exhaustive manner, websites containing models of various types of agreements, including licensing agreements and material transfer agreements. The purpose of making available these references is to provide assistance in the negotiation and drafting of agreements. However, these references to model agreements are made available for information purposes only and should not be seen as providing legal advice or counsel.⁵

The provision of these references for information purposes should not be viewed as endorsement of these model agreements by the OECD or its member countries. Moreover, as these model agreements were drafted, for the most part, prior to the publication of these Guidelines, they may not necessarily reflect or be in line with all the principles and best practices contained in the OECD Council Recommendation. Wherever there appears to be a contradiction between the language of the model agreements and the OECD Council Recommendation, the latter should be viewed as predominating.

The websites referenced below are maintained by authors independent of the OECD and readers should take note that some websites may be updated only infrequently. The website references are categorized alphabetically according to the type of agreement.

1. Confidentiality Notice/Agreement

<http://ott.od.nih.gov/cda.html>

<http://www.gtrc.aist.go.jp/jp/link/data/himitsuhoji.doc>

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

http://www.unitectra.ch/en/infos_forscher/8_219.htm

2. Collaborative Agreements

<http://www.ost.gov.uk/link/collabguidance.pdf>

<http://www.ost.gov.uk/link/modelcollabagree.pdf>

http://www.innovation.gov.uk/lambertagreements/files/Lambert_Agreement_1_ink.doc

http://www.innovation.gov.uk/lambertagreements/files/Lambert_Agreement_2_ink.doc

http://www.innovation.gov.uk/lambertagreements/files/Lambert_Agreement_3_ink.doc

5. The drafting and negotiation of agreements may be complex and parties are invited to contemplate resorting to appropriate legal counsel.

http://www.innovation.gov.uk/lambertagreements/files/Lambert_Agreement_4_Ink.doc

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

<http://www.unitectra.ch/medien/CIDFormE050702.doc>

3. *Consortium Agreements*

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

4. *Consultancy/investigator Agreement*

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

http://www.unitectra.ch/medien/CLINICAL_STUDY_AGREEMENT_050531.doc

5. *Cooperative Research and Development Agreements*

<http://ctep.info.nih.gov/forms/CRADA-Model.doc>

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

6. *Database Access Agreements*

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

7. *Licensing Agreements*

http://www.crd.ynu.ac.jp/www04/chizai/kisoku/kisoku12_2.rtf

<http://www.innovation.gov.uk/lambertagreements>

<http://ott.od.nih.gov/modelagr.html>

http://intramural.nimh.nih.gov/techtran/ott_license.html

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

http://ott.od.nih.gov/lic_gen_inv_FR.html

http://www.unitectra.ch/en/infos_forscher/8.htm

http://www.geo.unizh.ch/departement/services/it/esri/download/license/E201_202-02.pdf

8. *Material Transfer Agreements*

<http://www.sangaku.titech.ac.jp/03keitai/file/oil-jutakukenkyukeiyaku-1.doc>

http://www.innov.kobe-u.ac.jp/intellectual/inte/seika_hinagata.doc

<http://www.sanger.ac.uk/Teams/Team38/mta-information.shtml>

<http://ott.od.nih.gov/modelagr.html>

http://ott.od.nih.gov/MTA_model.html

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

http://www.unitectra.ch/en/infos_forscher/8_219.htm

http://www.unizh.ch/botinst/Devo_Website/curtisvector/MTACurtisVector.pdf

http://www.unitectra.ch/medien/MTA_050209.doc

9. *Non-Disclosure Agreements*

<http://www.patent.gov.uk/patent/info/cda.pdf>

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

10. *Patent Assignments*

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

11. *Sponsored Research Agreements*

http://www.abpi.org.uk/publications/pdfs/Model_Clinical_Trial_Agreement_Final.pdf

http://www.innovation.gov.uk/lambertagreements/files/Lambert_Agreement_5_lnk.doc

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

http://www.unitectra.ch/en/infos_forscher/8_219.htm

http://www.unitectra.ch/medien/CLINICAL_STUDY_AGREEMENT_050531.doc

12. Technology Transfer

http://www.cest.ch/Publikationen/2003/CEST_2003_7.pdf

<http://sri.epfl.ch/en/page1275.html>

http://www.unitectra.ch/medien/RICHTLINIEN_1.pdf (in German)