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We present herewith a brief outline of the OECD Draft guidelines for the licensing of genetic invention.

Biotechnology and genetics research have been the subject of extensive investment by both the public and private sectors. The products and processes emerging from these efforts make a significant and increasing contribution to human health and health care. The science and health ministers of the OECD member countries concluded that biotechnology would be a key driver for sustainable growth and development. 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.

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 innovations, such as therapeutics and diagnostics, in order to more effectively and efficiently address health care needs in both OECD member and non-OECD countries.

These Guidelines apply to the licensing of intellectual property rights 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

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.

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 states' 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.

The genetics and genomic 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 innovations. It is this spirit of exchange and cooperative effort that lies at the core of these Guidelines.

Balanced Intellectual Property System

Innovations, in the field of genetics as elsewhere, are typically protected via various forms of intellectual property rights. Most commonly, inventions are the subject matter of patents. However, innovations may also be protected through laws preventing the unauthorized transfer of undisclosed information, and through contractual provisions, such as those in material transfer agreements.

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 commercialize such innovations directly, often these are exploited or commercialized via licensing agreement, 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 commercialization of and access to innovations, but also provide rights holders with the ability, if they wish, to achieve a return on their investment. Each of these functions constitutes an integral part of a balanced intellectual property system.

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 in line with competition law, and that serve the interests of society, shareholders and other stakeholders.

The preamble of the Guidelines offer principles and best practices for the licensing of genetic inventions used in human health care. It also seeks to foster innovations, such as therapeutics and diagnostics, in order to more effectively and efficiently address health care needs in both OECD member and non-OECD member countries. Again the guidelines apply to the licensing intellectual property rights that relate to genetic inventions and innovation. It approaches the balance between intellectual property system and nature of invention. As the patent system and other forms of intellectual property aim to encourage the development and dissemination of knowledge. The Preamble has two parts,

Part 1: Principles and best practices for the licensing of genetic inventions

The Guideline contains explanatory annotation for each section of principles and best practices. The Guidelines are proposed to assist both OECD and non-OECD governments in the development of governmental policies and efforts to support appropriate behaviour in the licensing and transferring of genetic invention. The principle provides a framework within which to conceive of voluntary, market–oriented licensing arrangement with respect to genetic inventions used for the purpose of human health care. The principles of general licensing practices should foster innovation in the development of new invention related to human health care and should ensure therapeutics, diagnostics and other product and services employing genetic invention. 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 in line with competition law, and that serve the interests of society. 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. This development of guidelines for the licensing of genetic inventions was a priority. The needs and concerns of all those involved with innovation and the provision of services in health, and particularly at those involved in the licensing of genetic inventions. These include, but are not limited to, public and private sector entities involved in the licensing or transfer of biotechnological inventions, health authorities, patients and patients groups, researchers, clinicians, and intellectual property rights holders.

Part 2: Annotations

The rise in the number of patents for genetic inventions can be a sign of dynamism in a new technological sector. The Guidelines apply to licensing of intellectual property rights that relate to patents, undisclosed

information, trademarks and copyright. Its also pertains to genetic inventions, which should foster economic growth through the innovation and substantive competition. In the area of genetic testing, the researcher has faced situations of difficulty in obtaining licence for reasonable fee. The principles provide that licensors and licensees should aim for the rapid dissemination of information about the nature and uses of the genetic inventions. It recognizes the importance for licensors and licensees to obtain a commercial return on their investment with respect to genetic inventions.

It also recognizes the importance of licensors and licensees being encouraged to consider the best possible impact of their license arrangement on the health care system and on patients. The licensing practice should also promote the strong research environment and market for health care products and services. The healthcare product and services as well as the use of genetic inventions may be subject to a variety of rules, standards and regulations regarding privacy, safety and good laboratory methods. The genetic invention facilitates the innovative uses in clinical and research areas while maintaining or expanding the economic return to the licensor.

The principles recognize the importance of competition law as a complementary means of achieving a strong research and development base with respect to genetic invention. It also encourages the licensees and licensors to become aware of the application of these laws and best practices and independent assessment. The contractual provisions as non-compete or similar clauses discourage the innovation and restrict competition. It encourages the exploitation of licensed technology for the development or commercialization of new products or services. Thus, it is suggested that licensors and licensees evaluate the practical effect of non-compete clauses on the ability for new products and services to enter the marketplace. The strong research base and as, a supplement to competition law, licensors should consider licensing those genetic inventions that comprises base. The best practice also assists the mechanism of patent pools; patent clearinghouses or standard contractual provisions.