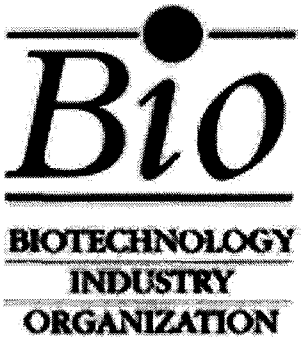

Comments of the Biotechnology Industry Organization

On the

Guidelines for Licensing of Genetic Inventions

Organization for Economic Cooperation and Development (OECD)

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** BIO has no objection to the public dissemination of these remarks on the Draft Guidelines.

General Observations

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide the OECD and OECD Member States with its views on the above-captioned draft guidelines. BIO is an international organization with more than 1100 members, and represents the interests of a broad array of biotechnology companies and organizations throughout the world. BIO member companies are engaged in the research and development of innovative biotechnology products for use in healthcare, agricultural, industrial and environmental applications. While BIO Members may have diverse views on the issues that are addressed in the licensing guidelines, they share a common view as to the legitimacy of patent eligibility for genetic inventions, and in the unrestricted use of those patent rights as part of commercial activities to exploit their investments in research and development of products and services based on genetic inventions.

Specific Observations

1. Observations on the Preamble

The Guidelines indicate that they 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." The Guidelines are also indicated as being directed to entities in both the public and private sector.

BIO believes that the Guidelines were developed with the intention of providing examples of licensing practices that reflect some degree of consensus as being appropriate. But because the Guidelines are directed to Governments as well, BIO believes it is important that the Guidelines affirm certain key points.

First, BIO believes the Guidelines should affirmatively state that legislation and regulations that limit or influence licensing practices by public or private entities are <u>not</u> being recommended. BIO strongly believes that the free-market process which governs licensing practices produces the best results for society, including both commercial and non-commercial. The open licensing environment also yields the best hope for patients, as it is the most effective means of stimulating development of new products and services to address unmet medical needs. BIO accordingly encourages the OECD to incorporate into the Preamble an emphasis on the important role of economic incentives for product development, particularly those that derive from free market principles.

Second, in nearly all OECD countries, genetic inventions may be patented if they meet patentability requirements (i.e., novelty, inventive step and industrial application). To the extent that the OECD guidelines also are directed to developing countries, they should emphasize and advocate the inclusive eligibility for patenting of genetic inventions in all countries. It should go without saying that if one cannot obtain effective patent coverage for a genetic invention, there is

no relevance of the licensing guidelines. Accordingly, BIO encourages the OECD to add a passage to the Guidelines that emphasizes the importance of maintaining patent systems that permit the patenting of the full range of genetic inventions addressed by the Guidelines.

Third, the Preamble should be revised to emphasize the benefit to the public of patent systems, particularly in their role of providing for an early dissemination of scientific advances in research and development. BIO Members are significant users of the patent system, and accept as a condition of such use, the fact that patent applications they file will be published long before rights are granted (i.e., 18 months from first filing). BIO Members have a close relationship with the academic and public research community, and actively publish in the scientific literature in addition to through the patent system. Since a primary public benefit of the patent system is the early dissemination of the results of scientific research that result in inventions, it seems appropriate to make clear in the preamble that the goals of early dissemination of information on genetic inventions is facilitated by the use of the patent system. BIO Members will continue to use the patent system if they can obtain patents that yield practical economic value. Consequently, BIO encourages the OECD to revise the preamble to better explain how the use of the patent system serves the goals of the Guidelines in promoting rapid dissemination of advances in genetic research.

2. *Observations on Section 1 ("General Licensing Practices")*

BIO is in general agreement with the principles set forth in section 1 of the guidelines.

BIO also generally supports the best practices listed in the Guidelines, with the following reservations.

- Item 1.5 suggests that license agreement should not "systematically provide the licensor with exclusive control over human genetic information derived from individuals through the use of the licensed genetic invention." BIO is unclear why this specific element has been included in the best practices section, as it does not seem to be a common practice of owners of patents to exert such control. Moreover, there are instances where developers of databases of information used for research will need to retain the capacity to license access to the database; to do so, those entities will need to possess exclusive rights in the database collection. BIO encourages the OECD to either delete this provision, or to clarify that it is not intended to restrict the ability of developers of databases of human genetic information to realize commercial returns from their investment.

- Item 1.6 provides that "right holders should seek the full exploitation of their genetic inventions." While BIO endorses this concept, the concept may be better expressed as being an endorsement of the use of licensing agreements to effectively exploit rights they have in their genetic inventions. In particular, BIO would encourage the OECD to revise this point to provide that: "rights holders should be encouraged to set licensing terms and conditions so as to maximize the commercial exploitation of rights they have in genetic inventions."

3. Observations on Section 2 ("Health Care and Genetic Inventions")

BIO has a number of concerns with the principles and best practices as they are expressed in section 2.

First, BIO plainly supports the principle that patients should benefit from the highest applicable standards with respect to privacy, safety and good laboratory methods. It is unclear how the issue of patent licensing could be perceived to be inconsistent with such principles. The oversight roles proposed in the guidelines are best handled by the Institutional Review Boards, ethical boards and other regulatory functions whose role it is to provide this oversight and not the licensor.

Second, BIO has concerns with the manner in which principle 2.C has been expressed. This principle, particularly in light of points 2.1, 2.2 and 2.4, seems to suggest that licensing practices now prevalent in OECD countries somehow restricts patient and healthcare provider choices.

In reality, the biotechnology industry is a highly competitive industry. The result of that competition is that a wide variety of products and services based on genetic inventions is being developed and brought to market. Competition, which is enhanced through the intellectual property system and legitimate licensing practices, is a key factor in stimulating this developmental activity. The result of this competitive environment is the delivery to the market of more choices for patients and healthcare providers. Preserving the ability of innovators to employ a variety of licensing practices – including exclusive licensing – is critical to achieving the innovation and development process. BIO accordingly believes the principles and the best practices should affirm that licensing practices, including use of exclusive licensing, results in development of more products and services, which in turn enhances patient and healthcare provider choices.

BIO also specifically recommends that certain sections be amended to reflect these observations. In particular:

- BIO recommends that point 2.1 be revised as follows: "patent holders should license genetic inventions for research and investigation and ~~clinical diagnostic~~ purposes broadly, and should seek to license them for other applications, including clinical diagnostic testing, on terms and conditions that seek to ensure the widest public access to, and variety of, products and services based on the invention.

- BIO recommends that point 2.4 be revised as follows: "License agreements should encourage ~~permit~~ licensees to develop a diverse range of health care products and services based on genetic inventions that can be made available to~~,~~ ~~for example~~ health care providers, in order to offer patients flexibility and choice ~~with respect to the selection of the type and nature of health care products and services~~."

BIO also believes that point 2.2, as presently expressed, appears to be inconsistent with the general stance taken in the Guidelines, and, because of its lack of clarity, should be deleted. In particular, this paragraph appears to promote licensing practices that would permit national or local providers to use genetic inventions, apparently under any conditions, to provide health care services. Initially, it is unclear whether the terms "national or local providers" is intended to refer to government authorities, or private entities. In either case, BIO believes this point does not reflect sound licensing practices. Certainly, BIO supports the use of products and services that its Members develop that are based on genetic inventions. BIO also supports policies that ensure that government and non-governmental entities will have access to these products and services. But, BIO Members believe that licensing practices should give developers of products some say over the terms and conditions of the use of the product or services. Given the complexity of the issue, BIO recommends that either this paragraph be deleted, or that it be rephrased to remove the suggestion that licensing practices would entirely exempt national or local providers from compliance with any conditions regarding use of a patented genetic invention.

4. Observations on Section 3 (Research Freedom)

BIO generally supports section 3, as drafted. BIO observes that the section correctly observes that reasonable restrictions are appropriate in a research setting, including conditions that preserve the ability of a company or sponsor of research to procure patents or to protect the confidentiality of information that could form the basis of a commercially valuable trade secret. Moreover, given the strong history of the industry of publishing the results of its research, and the traditionally close affiliation between the biotechnology industry and the academic community, BIO can generally support the principle that results of research activity involving genetic inventions be disseminated through publication of research results.

5. Observations on Section 4 (Commercial Development)

BIO generally supports section 4 of the Guidelines. BIO notes that the Guidelines correctly observe that licensing decisions in any particular situation must be carefully evaluated and calculated to yield the maximum likelihood of commercial success in product development. BIO would encourage the OECD to add an additional principle that encourages the use of the appropriate combination of licensing conditions, including exclusive and non-exclusive licensing or conditions on fields of use of the patented invention, that maximize the likelihood of commercial success in product development.

BIO notes that certain of the best practices are expressed in a manner that could be significantly improved. For example, in paragraph 4.2, it is suggested that low barriers for access to genetic inventions be made available under all circumstances. In certain circumstances, such as development of a new drug, the best practice will be not to permit use of the patented invention, or to carefully control use of the patented genetic invention. That does not preclude non-exclusive licensing for other uses, but certainly the context of a proposed use of the patented genetic invention will dictate the most appropriate licensing terms (if any) that should be employed. BIO encourages the OECD to revise the best practices to reflect the reality

that the intended use of the genetic invention must be part of the decision about the nature (if any) of the license that should be granted.

BIO also notes that the best practices do not address a common practice in the industry; namely, where the patent owner permits use of a patented genetic invention, the request that the patent owner be given a right of first refusal to license an invention made using the patented genetic invention. In many instances, this type of licensing practice – which is not a "reach through" claim – promotes effective commercialization of the patented invention. BIO would, accordingly, recommend that distinguishes this type of licensing condition from a pure reach through right, and endorse it as being conducive to the development of new products and services based on the genetic invention.

6. Observations on Section 5 (Competition)

BIO generally supports section 5 of the Guidelines. As was the case in earlier sections of the Guidelines, BIO believes the principles and best practices are expressed in terms that could be improved. For example, point 5.1 suggests that license agreements should avoid "unduly restrictive tied selling." It would be advisable to explain, in the best practices, what the phrase "tied selling" could mean, and in which instances licensing terms should avoid such conditions.

7. Observations on Part II (Annotations)

BIO believes that Part II should be revised to reflect the comments made above in relation to the Guidelines.

BIO would also like to revisit the annotation in Part II after the guidelines and best practices have been finalized.