Brief Explanation of the Working Party on Biotechnology's Project on Best Practice Guidelines for the Licensing of Genetic Inventions

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As a follow on to the publication of the report *Genetic Inventions, IPRs, and Licensing Practices*, the Working Party on Biotechnology gave the OECD Secretariat a mandate to develop guidelines for good licensing practices in order to facilitate access to, and the diffusion of, technologies for the public good. The report concluded that the problems that exist with access to genetic inventions often have more to do with licensing than with the patent system *per se*. Licensing practices are rapidly changing as companies, public institutions, governments and civil society grapple with the complexity of intellectual property protection for genetic inventions. For this reason, the report suggested that:

> "governments [should] consider the development of good practice guidelines or codes of conduct. Good licensing practices are already being developed by [some] public sector organisations for internal use […]. Guidelines [should] be developed in consultation with industry to determine the limits of acceptable licensing practices".[1]

These Guidelines would be voluntary, non binding recommendations, and would serve as examples of good practices. They would be a self-regulatory solution to some of the problems associated with the patenting of genetic inventions.

The OECD's Working Party on Biotechnology has thus set up a Steering Group of experts to develop Best Practice Guidelines for the Licensing of Genetic Inventions. The Steering Group met in May 2003 to discuss how the WPB could take forward a dialogue between governments and with industry, the research community, and other interested parties, on the scope and nature of "good licensing practices" as well as on the process for developing these guidelines.

The Steering Group decided to hold a working meeting in November 2003 in order to draft Best Practice Guidelines for the Licensing of Genetic Inventions. The proposed expert meeting would involve approximately 30 participants. Participants could include public sector research groups and technology transfer officers, health ministries, clinicians, biotechnology companies and pharmaceutical firms, and patient advocacy groups. A number of speakers would be asked to comment or make presentations on common licensing practices and how these might be improved.

The Secretariat, with the help of external consultants, is drafting a background document as a starting point for discussions of the Guidelines. The background document will present cases of genetic invention licensing, illustrating both good and problematic practices. It will identify the characteristics or clauses within licenses that are deemed by some as problematic. If feasible, the paper will propose some topics and initial wording for the draft Guidelines.

At the November Expert meeting, participants will be asked to discuss the cases raised in the background paper, giving a sense of how common such licensing practices are and what working solutions are being adopted. Some participants will be asked to comment on particular aspects of genetic invention licensing. The objective of the expert meeting would be to agree topics and draft wording for the Guidelines.

It is anticipated that some further iteration would be required with experts and/or Steering Group members once a draft set of Guidelines is generated. Once there was a general level of agreement the draft Guidelines would be brought back to the OECD's Working Party on Biotechnology for agreement on any next steps (for example, whether and how to proceed with a stakeholder consultation meeting).

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1. OECD (2002). Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies. OECD: Paris. (http://www.oecd.org/pdf/M00038000/M00038462.pdf).