APPENDIX
Background and Explanation Concerning WIPO Discussions on Genetic Resources and Intellectual Property

In 1991, the United Nations Environment Program (UNEP) concluded a new international agreement to govern biological diversity – the Convention on Biological Diversity (CBD). Among other things, the CBD established that countries have sovereign rights over non-human "genetic resources" found in their territories. It also specified that the collection and use of genetic resources is to occur on mutually agreed terms, meaning that countries can demand that individuals collecting these resources agree to conditions in exchange for granting access to their resources.

In the years since the CBD was established, countries have developed a wide variety of approaches for regulating the collection and use of their genetic resources. Perhaps in view of this, a protocol to the CBD was concluded last year to clarify the scope and operation of the Convention's "access and benefit sharing" provisions (the "Nagoya Protocol"). The Nagoya Protocol creates a new international regime governing access and benefit-sharing associated with genetic resources, and specifically addresses cross-border enforcement of national systems for regulating genetic resources.

BIO and PhRMA have long supported the principles embodied in the CBD and the Nagoya Protocol and the appropriate implementation of those principles, as follows. First, consistent with the CBD principle that benefits must be shared on mutually agreed terms, countries cannot retroactively and unilaterally impose obligations from their national regimes on private parties. Second, the CBD and Nagoya Protocol have important boundaries on their scope. For example, the agreements regulate only non-human genetic resources, and only those genetic resources collected after the entry into force of the relevant agreement. Third, measures to implement access and benefit sharing terms must be consistent with the adequate and effective protection of intellectual property rights.

The proposals made in WIPO, however, have many practical and conceptual flaws. The proposals would require patent applicants to disclose the source or origin of any genetic resources or traditional knowledge upon which an invention is based. Further, some proposals would also require that evidence of prior informed consent and/or fair and equitable benefit-sharing also must be provided. However, in many cases, it will not be possible for a patent applicant to knowingly comply with such requirements. For example, exhaustively determining the source or origin of a genetic resource – which may include cell lines or other genetic resources that have been available on the open market for decades – is a complex, costly, time consuming and ultimately uncertain exercise. In many cases, it may be impossible to determine.

Moreover, the proposals, if adopted, will undermine the objectives of the CBD. A measure that raises the possibility of denial or revocation of a patent will cause inventors to avoid the activity that carries that risk. In this case, it means that researchers will avoid use of collected genetic resources and thereby undermine the creation of benefits to be shared. These proposals also will provide a powerful incentive to encourage third parties to attack and invalidate patents. If those

attacks succeed, both the patent owner and the provider will lose out, given that these third parties will have no obligation to share benefits.

The proposals also are uniformly overbroad. No attempt is made to limit obligations to genetic resources actually governed by the CBD (i.e., samples of non-human materials that are collected by the patent applicant after the CBD entered into force and after its provisions are implemented in national law). Similarly, the sanction demanded – denial or revocation of the patent – is plainly excessive and inappropriate. In fact, it would be unprecedented for the United States to endorse or impose this type of sanction for conduct entirely unrelated to the merits of the invention or the process of obtaining the patent.

Moreover, by focusing exclusively on inventions, the proposal will not address at all the far greater number of uses of genetic resources that do not lead to patents. For example, the highly touted International Cooperative Biodiversity Groups (ICBG) program, managed by the Fogarty Center in the National Institutes of Health since 1992, has reportedly involved analysis of thousands of samples of genetic resources with the goal of guiding natural products drug discovery, crop protection science, bioenergy and other research toward international collaborative models involving benefit-sharing consistent with the CBD model. Yet, there have been only a handful of discoveries resulting in active granted patents, and no products based on this research have reached the market. Thus, by its very design, a disclosure requirement could cover only a tiny fraction of the activities that advocates say are occurring, despite the substantial burdens and uncertainty these requirements would impose on all patent applicants. In addition, research and development resulting in patentable inventions generally takes place over a long period of time, sometimes decades, after the initial sourcing of materials (which may have been unrelated to the current research). The link between sanctions in the patent system and incentives to comply with national access and benefit-sharing laws at the time of sourcing is highly speculative at best.