BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

December 6, 2005

The Honorable Robert Portman
United States Trade Representative
Office of the United States Trade Representative
600 17th Street N.W.
Washington, DC 20508

Dear Ambassador Portman:

I am writing on behalf of the Biotechnology Industry Organization (BIO) to convey the views of our members on intellectual property issues that will be addressed in Hong Kong at the Ministerial Conference of the World Trade Organization (WTO). We are particularly concerned over proposals that would erode the ability of our companies to obtain and enforce patent rights, thereby stalling the development of innovative technologies and products. In this regard, BIO strongly opposes amendments to the TRIPS Agreement or to U.S. patent law that would create new grounds for refusing or challenging patents. We urge you, as the representative of the United States at these forums, to strongly oppose such proposals, as well as proposals that would create a mandate for negotiations for such amendments.

BIO is a trade association representing more than 1,000 biotechnology companies, research institutions and related organizations involved in the development of innovative health-care, agricultural, industrial and environmental products and processes. Our members, many of whom are small companies five to 10 years away from having a marketable product, rely on intellectual property protections to attract investment capital as they work on developing innovative technologies or products. Any uncertainty in the protection of their fundamental asset—their intellectual property—is likely to deter investors.

The purpose of this letter is to express BIO's concerns about some proposals that would create new uncertainties in the protection of our members' intellectual property and to outline our efforts to address this issue by developing BIO's voluntary *Guidelines for Members Engaged in Bioprospecting*. These proposals, which we understand will be considered in Hong Kong at the Ministerial Conference of the World Trade Organization (WTO), involve identification of genetic source or origin of living materials referenced in patent applications.

Specifically, these proposals would require patent applicants to identify the genetic origin or source of any living materials referenced in their patents. Further, in some instances, the proposed amendments to the Agreement on Trade-Related Aspects of Intellectual Property

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(TRIPS) would demand that companies supply proof of prior informed consent from the country supplying either the living or genetic material (or both) as well as the details of an access and benefit-sharing agreement. Failure to do so would allow a country to refuse to grant a patent on an otherwise meritorious invention and would allow unjustified challenges on valid patents. Thus, if adopted, these proposals would erode the ability of our companies to obtain and enforce patent rights, thereby frustrating the discovery and development of innovative technologies and products.

We understand these proposals are being made in the interest of deterring bio-piracy and of promoting the sustainable use of biodiversity within the proposing countries' borders, as well as the equitable sharing of the benefits arising from use of genetic resources. BIO supports these underlying goals. In addition, BIO disapproves of any intentionally "bad acts" that would frustrate these goals. BIO members are just as concerned about such abusive activities as are the countries that have brought these proposals to the table. However, if WTO member countries agree to the proposals as written, it will weaken and, in some instances, abolish patent rights.

The world's patent systems should not be used as an enforcement mechanism to force compliance with obligations of the Convention on Biological Diversity. We believe that this approach 1) will not achieve the goals stated by its proponents, and 2) will deter the biotechnology industry, which offers novel technologies for addressing global issues in health, agriculture and the environment, from continued innovation in areas implicated by the proposed disclosure requirements. This will harm both the innovators and the owners of genetic resources.

For these and other reasons which will be further elaborated in the attached document, BIO urges you to oppose efforts to amend the TRIPS Agreement or to U.S. patent law that would create new grounds for refusing or challenging patents. Please feel free to contact me or any members of my staff with any questions or concerns you may have.

Sincerely,

James Greenwood

James C. Greenwood
President and CEO

BIO Observations on Proposals Concerning
Genetic Resources and Traditional Knowledge

Overview of the Issue

Several developing countries[1] have made proposals to amend the TRIPS Agreement, or to establish a mandate at Hong Kong for negotiations to make such amendments. The Government of Peru, for example, has tabled a proposal[2] to amend Articles 27 and 29 of the TRIPS Agreement to permit invalidation or revocation of patents if the patent owner fails to identify:

(i) the country of origin of biological genetic resources (i.e., samples of living materials), and/or traditional knowledge associated with inventions referred to in patent applications;

(ii) proof that those resources or traditional knowledge were obtained by the applicant with "prior informed consent"; and

(iii) proof that the applicant will share or has shared benefits obtained from use of those resources and traditional knowledge equitably with the providers of the resource or knowledge.

Under these proposals, a patent applicant that failed to disclose the required information would be refused a patent. In addition, if the patent owner is shown to have provided inaccurate information, the patent would be revoked. The special disclosure requirement is thus designed to be a penalty for those entities that collect and use genetic resources but do not report on such activities.

The debates in Geneva are grounded on many significant misunderstandings and errors of fact. Specifically, the motivation for these proposals to amend the TRIPS Agreement is the belief that there is a significant amount of bioprospecting activity that is being conducted now by companies and researchers, and that many of the new products being sold today or in development were made possible by this bioprospecting activity. Neither point is true.

Although our Members conduct a diverse range of research and development in the fields of agriculture, healthcare, industrial engineering and environmental remediation, only a few of them engage in "bioprospecting" (i.e., the collection and evaluation of samples of genetic resources). Most BIO Members instead conduct research using modern research tools. The era of high volume screening of extract of plants to discover new drugs was an era that preceded the birth of the biotechnology industry. As a result, only a handful of companies seek to discover new drug candidates, industrial products or agriculturally relevant insights from bioprospecting.

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[1] Such group of developing countries – all Members of the WTO - is composed by Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe.

[2] This proposal will be addressed in more detail in a separated document attached.

Similarly, a cursory review of the products currently in development or being marketed reveal that very few emanate from "bioprospecting" activities. For example, most new biotechnology drugs are protein drugs, such as monoclonal antibodies. These products are based on study of human genetic or protein materials, not materials collected by bioprospecting. Moreover, very few products being sold today or in development by the biotechnology industry were made possible by from the analysis of samples of materials collected through bioprospecting.

Those BIO members that are engaged in bioprospecting activities have a long history of respecting the rights of the providers of genetic resources, and a strong record of providing equitable benefits to those providers. For example, Shaman Pharmaceuticals Inc. had successful partnerships with resource providers well before the creation of the CBD. The initiatives of other groups like the NIH administered International Cooperative Biodiversity Group (ICBG) who require industry participation have agreements based on CBD principles. Cameroon, Nigeria, Vietnam, Laos, Suriname and Madagascar are examples of countries whose local communities enjoyed the benefits of clear and reliable partnerships with the ICBG members.

The biotechnology industry brings to the table human resources and innovative technologies for the sustainable use of the resources of biodiverse countries. However, BIO members are hesitant to pursue research in these areas in large part due to the uncertain intellectual property environment in these countries. Nevertheless, for those members that are contemplating bioprospecting, BIO recently has promulgated guidelines to help them think through the access and benefit sharing process. These guidelines are designed to facilitate efforts by our Members to comply with international and national requirements regarding collection and use of genetic resources and traditional knowledge. Given the diversity in scope, character and nature of these varying national and international requirements, BIO believes it is important to articulate for our Members procedures and substantive standards which enable them to meet the expectations of the international community for proper conduct in the area of bioprospecting. A copy of the guidelines and a brief summary of their features is provided for your convenience in Annex A.

Problems with Current Proposals

1. The Proposals Cannot Be Justified by the Convention on Biological Diversity

The justification offered by developing countries for special patent disclosure requirements is to enable them to ensure compliance with rights and obligations defined in the Convention on Biological Diversity (CBD). An accurate review of those rights and obligations shows that these proposals cannot be justified on this basis.

The CBD confirms that countries have sovereign rights over genetic resources within their territories. The CBD envisions that countries can use that authority to prevent unauthorized access to their genetic resources. The CBD, in particular, envisions that entities wishing to obtain samples of these resources must first obtain the authorization of the government or the custodian of the resources. In the course of doing so, the entity and the government/custodian will reach "mutually agreed terms" that govern the access to and use of those resources. One

such issue will be "benefit sharing" namely, the sharing of commercial and other benefits that arise in the course of the analysis of the resources, or in the development of products or services based on use of those resources.

The CBD provisions, however, are limited in several important ways.

First, the CBD does not apply to materials obtained from "humans" or human genetic material *per se*.

Second, the CBD is not unilateral in its obligations. Instead, obligations to share benefits only arise if a prospective user of the resources agrees to them. The "remedy" for countries in dealing with users who do not accept the terms they require is built into the agreement; namely, the country can refuse to provide access its resources.

Third, the CBD applies only to samples of materials collected after the CBD has entered into force in the country in question. Since the CBD itself came into force in 1993, its obligations cannot apply to materials actually collected before 1993 in any country.

Finally, the CBD, contrary to the claims of certain NGOs, does not place a priority on its obligations relative to obligations countries have under the TRIPS Agreement to protect intellectual property rights. Indeed, as BIO has maintained since the CBD was established, the CBD references to intellectual property confirm the fact that adequate and effective intellectual property protection standards facilitate realization of the goals of the CBD (i.e., to promote use of genetic resources and the benefits that may ensue from that use).

These limitations are critical to appreciate and evaluate the proposals on the table in Geneva. In particular, these limitations make clear that the proposals on the table bear no realistic relationship to the CBD objectives they purport to implement.

- Each proposal under consideration would require patent applications to provide information concerning <u>any</u> type of living materials referenced in their patent application. The disclosure obligation would thus extend to both human and non-human genetic resources. This is plainly inconsistent with the limitation of the CBD to non-human genetic resources.

- The obligations would apply regardless of whether the patent applicant actually collected the samples of resources from the country of origin. This similarly is inconsistent with the CBD's structure that imposes obligations to share benefits only if the patent applicant collects the materials from the country of origin.

- The obligations apply to genetic resources regardless of when those resources were obtained. This is inconsistent with the CBD, as obligations can only arise with respect to samples of genetic resources collected after the agreement comes into force in each country in question.

By failing to limit the scope of disclosure obligations to the parameters reflected in the CBD, the proposals would unfairly and improperly punish patent applicants. For example, a biotechnology company that obtains a sample of living material from a commercial provider who imposes no restrictions on use of those resources could nonetheless find themselves, years after they were provided that resource and after they have spent hundreds of millions of dollars developing a new product, at risk of having their patent rights challenged. This despite the fact that the ostensible country (or countries) of origin never asserted any claim of ownership or control over the resources. And, under the structure of the proposals, the fact that the provider obtained the resource before the CBD even existed would not matter.

The proposals thus are far broader than necessary to secure compliance with the CBD. The obligations and thus the penalties would extend far beyond any possible justification under the CBD.

2. The Proposals Ignore the Practical Realities of "Genetic Resources"

Living organisms do not respect territorial boundaries. And territorial boundaries change over time. Most living organisms, therefore, have multiple "origins." This is one reason why significant scientific challenges exist in determining the "country of origin" of a "genetic resource." Indeed, the answer to the question of what an organism's "origin" depends very much on the answer to the question "as of what year?"

Establishing that the genetic resource can be shown to exist today in a country also does not establish that the material used by a researcher had its "origin" in that country. And even if a researcher obtains a genetic resource directly from where it occurs *in situ* today, at best this researcher will know of only one country of origin for that resource. Thus, even though a scientist disclosed the origin it was able to deduce, a third party or a country could attack that disclosure and invalidate the patent by proving that the living organism has another origin. All of these points underscore the fact that the motivation of the proposals – that a particular country of origin would have some claim for compensation for use of a genetic resource having its origin in that country – is extremely weak. Simply put, proving that an organism has its origin in a particular country has essentially no connection to the question of whether that country has a claim under the CBD related to access and use of that resource.

These proposals also ignore the fact that most researchers work on living materials obtained from privately owned collections (*e.g.,* collections maintained by their employers, research entities, or brokers) or from public gene banks. And, importantly, most of these collections – and most of their resources – predate the CBD. The geographical origin of most samples of materials stored in these collections simply is not known.

Sometimes, the materials that researchers obtain or use are not naturally occurring. Rather, they are the products of experimentation involving many individual biological materials. Often, the specific materials used to create the resource are unknown and, when known, information about the geographical origins is unknown. To complicate matters, a specific biological material may have an origin in more than one country. Thus, even if a researcher

knows which materials have created a specific resource, that researcher may not be able to identify one country of origin.

It would be unfair to sanction these researchers for failing to provide information of questionable value and accuracy that is extremely difficult to obtain. The arbitrary and inaccurate nature of "origin" determinations provides a very troubling risk for patent owners. Under the standards proposed, patents could be invalidated despite "good faith" scientific compliance with the requirement.

3. Patent Disclosure Requirements Will Not Help Countries Police Bioprospecting Activities

Even if the proposals were to be limited to securing compliance with the CBD, use of the patent system as an indirect way of regulating bioprospecting is inefficient and impractical. The proposals, if implemented, thus would not help countries monitor collection or use of genetic resources or associated traditional knowledge. One reason is that only a tiny fraction[3] of materials that could be studied or evaluated will lead to patentable inventions. A second is that most collection activity that is conducted today concerns taxonomical and generalized academic research[4] which does not lead to patentable inventions or patent filings.[5] Thus, the system would result in reporting on only a tiny fraction of the relative small volume of collection activities that occur today, yet would impose immense costs to the resource-limited biotechnology industry to implement.

It is important to recognize that even if a researcher develops a commercial product or process, the time period between the date that a researcher accesses a specific genetic material and the filing date of a patent application in which a product or process derived from use of that genetic material is claimed is often very long, often two to five years. And, under most systems, patent applications are not published until 18 months after they have been filed. As a result, reports on collection or uses of genetic resources will occur many years after the use or collection has occurred.

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[3] It seems to us that the proposed patent disclosure requirements are intended to be a substitute for access and benefit-sharing national laws and our Members believe that this is a very inefficient approach. As we said, the vast majority of researchers never find a commercial use for the resources they access and, therefore, do not seek patents for them. Others never intend to use accessed genetic resources to develop commercial products and will not seek patents either. Still other researchers may find a commercial use but may protect their commercial processes or products through trade secrets and not seek patents.

[4] Experience proves that researchers obtain value from use of the genetic resources and should share benefits at an appropriate level. In our opinion, requirements in the patent system to indicate geographical origin will do nothing to promote the sharing of benefits in any of these situations. Even worse, such requirements will discourage the early disclosure of inventions through the patent system, especially those inventions that promote the sustainable use of genetic resources or the conservation of resources – primary objectives of the Convention.

[5] Thousands of resources screened by Merck and INBIO pursuant to their 1992 agreement have not been used to date in any commercial product and have not led to patentable inventions.

If the true motivation of countries were to develop systems for monitoring collection and use of genetic resources, far more direct and effective solutions would be proposed. The patent system is very far-removed from the activity that these countries seek to regulate. More effective systems would focus on the activity that is to be regulated – collection and use of resources – rather than attaching a monitoring system that by its design will ignore the vast majority of the conduct that is to be regulated. Such systems would simply regulate access to and impose requirements for reporting of uses of genetic resources. They also would target the entities that collect these resources, including those researchers that do taxonomic and other academic research, as well as the institutions that conduct large scale collection and cataloging of specimens of genetic resources. And, if an international oversight structure for such activity were viewed as being necessary, it could be devised to be implemented directly, rather than indirectly through the patent system.

4. Patent Disclosure Requirements Will Frustrate the Goal of the Convention to Promote Use of Genetic Resources that May Create Benefits that Can Be Shared

Patents are important commercial assets because they provide a means for a company to recoup the millions of dollars it will spend in discovering, developing and bringing to market a new biotechnology product. In the life sciences area, it routinely costs more than half a billion dollars, and more than ten years to bring a new drug to market. Diagnostic products similarly require extensive investments and years to bring to market, given the need to satisfy strict regulatory review requirements. Similar obstacles exist in the agricultural and industrial biotechnology sectors. For example, the process of developing a new biotech crop routinely takes more than a decade, and millions of dollars of investments.

Biotechnology companies use their patents to prevent unauthorized use of the inventions they develop in the course of their research and development activities. BY doing so, they can leverage the market demand for their new products to deliver the best commercial returns for their investors. Without patents, competitors could immediately exploit the technology, without having to bear any of the costs or risks of developing the products. It is only through the ability of the innovator to forestall this competition that companies can justify making the investments at the outset of a research and development project.

As described above, special patent disclosure requirements will create unquantifiable risks for patent owners. They will enable parties – likely competitors of the patent owner – to invalidate patents by showing that the origin of a genetic resource, which may not even be related to the invention protected by the patent, was not "properly" disclosed. Thus, if a biotech company, without any intent to conceal the origin of materials it actually uses, inaccurately identifies the origin of any biological material referenced in the patent disclosure, it could lose its patent. As such, most biotechnology companies will simply avoid bioprospecting to avoid placing their patent rights – one of their most important commercial assets – at risk.

Special disclosure requirements will plainly frustrate one of the objectives of the CBD. Specifically, under the CBD model, providers and users of resources are to cooperate in a transparent and mutually agreed manner with regard to genetic resources. The CBD envisions

that users of the resources will obtain them with consent and approval of the providers. It also assumes that these users will conduct research and development concerning those resources that will result in benefits that can be shared. Under the CBD, providers and users of genetic resources thus are dependent on each other to achieve the goal of creation and sharing of benefits. If there are no benefits created in the first instance, providers of resources will not realize any gain.

Because special disclosure requirements will drive prospective users away from bioprospecting, these requirements will plainly frustrate one of the central objectives of the CBD. Thus, rather than providing a way to enable developing countries to gain benefits from providing access to their resources, these proposals will extinguish whatever nominal commercial interest there may be in these undeveloped uncollected resources. If no entity collects, studies and develops a genetic resource into a commercial product, no benefits will be created that can be shared.

5. Claims of "Bio-piracy" Are Not Justified or Supported by Fact

Developing countries have justified their demands for a special patent disclosure as being necessary to combat "rampant" bio-piracy. They define bio-piracy as the use of genetic resources and associated traditional knowledge without requiring compliance with the provisions of the CBD (IP/C/W/420, para. 1). These countries claim that numerous examples exist where a genetic resource having its origin in their territory has been collected and used without their authority. For example, Brazil and others point to the patents related to turmeric, the neem tree, hoodia, and ayahuasca as examples of "bio-piracy" (IP/C/W/429/Rev.1, para. 3). Similarly, the Government of Peru lists many patent documents describing inventions that are related to plants found *in situ* in Peru (IP/C/W/441/Rev.1), and suggests through their citation that the inventions disclosed in these applications are based on genetic resources or traditional knowledge acquired through bio-piracy.

As the developing countries must acknowledge, the filing of a patent application provides no insight into whether there has been an act of bio-piracy. This is because these applications generally do not indicate whether or not the individuals associated with the application actually collected the materials from the country in question, whether the materials are subject to the CBD or not, whether the inventions concern actual use of the materials or information in the public domain, or whether the inventors had authorization to use the resources. For example, based on our review, the examples in Peru's submission concern materials that are readily and publicly available over the Internet from Peruvian sources. If the problem is that these Peruvian genetic resource suppliers have acted in a manner inconsistent with Peruvian law, the Government of Peru can take direct action against them to stop these unauthorized transfers. It is also important to observe that many cited patent applications have been filed by institutions or individuals that are from the country in question. If these individuals have collected and used materials in contravention to national laws or regulations, they can be directly pursued as citizens of these countries. No information, however, has been provided by these countries that they have taken any such steps.

Certain countries have expressed particular concerns over the grant of certain patents in the United States. As noted above, the filing of an application or the grant of a patent provides no information on whether bio-piracy has occurred. More significantly, the concerns that these patents have been improperly granted will not be remedied in any way by a disclosure requirement. On the one hand, if the disclosure of the source leads to information that is relevant to patentability, that information – not the disclosure in the patent – will be the basis for revoking the patent. However, the disclosure of origin will do nothing to facilitate accurate examination of these applications. Instead, the proper way to address these types of concerns is to develop efficient means for reviewing the validity of these patents and development of better collections of information that can be used in examination of these applications.

6. The WTO TRIPS Agreement is Not the Proper Forum for Resolving Concerns over Bio-piracy

Despite the extremely diverse nature of concerns that have been expressed over bio-piracy and compliance with principles articulated in the CBD, developing countries have proposed only one "solution" – a special patent disclosure requirement. As explained above, a patent disclosure requirement will not be an effective mechanism for monitoring unauthorized collection or use of genetic resources. A patent disclosure requirement also will undermine one of the primary goals of the CBD, namely, the promotion of use of genetic resources, and the subsequent creation and sharing of benefits.

BIO has participated in discussions devoted to the effective implementation of the CBD in a number of organizations, including the Convention on Biological Diversity, the World Intellectual Property Organization and the Food and Agriculture Organization. These discussions have revealed the complexity of the issues associated with bioprospecting. They have also provided valuable insight into the practical difficulties of the patent disclosure requirement.

BIO believes the case has not been made that a problem has been proven to exist that justifies amendment of the TRIPS Agreement and the patent systems in more than 120 WTO members. The examples of "bio-piracy" do not shed any light on whether there has been an improper or authorized use of genetic resources. The entities that are filing these patent applications also are not biotechnology companies. The proposals that have been made to date also bear no relation to obligations that could arise from the CBD. The proposals that have been made to date will impose immense and unjustified burdens and risks on biotechnology companies, the vast majority of which are small businesses, and will eliminate any interest in bioprospecting by our members.

Although it is fundamentally opposed to patent disclosure requirements or any other use of the patent system to "police" compliance with the CBD, BIO is prepared to explore appropriate national and international systems that promote compliance with CBD-based systems. BIO's willingness to work in a constructive manner on such systems reflects the commitment of its members to adhere to the highest standards of conduct. That exercise, however, must be based on facts and transparency. It also must be structured to enable a legitimate comparison of the strengths and weaknesses of the various proposals for promoting

compliance with the CBD principles. To date, this has not occurred in the WTO, and cannot occur in an environment that is focused only on enforcement through the patent system.

Accordingly, BIO believes discussions on mechanisms to ensure compliance with CBD obligations undertaken in WIPO and in the CBD should be permitted to continue, and the results of those exercises evaluated before taking further action on patent disclosure proposals. We note in particular that the CBD has been tasked with developing an international regime on access and benefit sharing, including the possibility of special disclosure requirements in patent applications. While BIO Members believe that special disclosure requirements are not warranted, it appears that it would be more efficient and more effective to consider the issue as part of the overall access and benefit sharing regime instead of a discrete issue within the WTO.

7. The Proposed Patent Disclosure Requirements Will Harm Those Who Rely on The Patent System To Protect Their Inventions, Those Who Own Genetic Resources, and Ultimately Will Frustrate The System's Objectives

The proponents of mandatory patent disclosure requirements relating to genetic resources and/or traditional knowledge are concerned about bio-piracy and believe imposing such requirements will facilitate benefit sharing. We have discussed why that will not happen. In addition, the proposed disclosure requirements, if implemented, will harm those who rely on the patent system to protect their inventions and those owners of genetic resources.

These requirements will also frustrate the underlying objectives of the patent system itself, i.e., to promote the progress of the useful arts.

In particular, imposing the proposed disclosure requirements on patents relating to the discovery and development of products implicating genetic resources would likely cause scientists to focus their talents and energy on other areas of research, i.e., those not requiring genetic resources from other countries. This is particularly true given the potential forfeiture of patent rights for inadequate disclosure and the difficulty in ensuring appropriate disclosure. Thus, the potential value of many such resources would not be exploited to benefit society and would be lost, at least for some time.

Further, interest in collaborating with the owners of genetic materials to benefit both owner and inventor/developer would be stifled. Such an outcome is not only possible but likely, given the requirement for strong patent protection to make the large investment needed to develop biotechnological products, particularly in the healthcare area. Countries rich in genetic resources that can be used to provide novel agricultural, environmental or energy products, will lose the opportunity to sustainably exploit such resources. Thus, such patent disclosure requirements if implemented would harm both the inventor/developer and the genetic resources owner.

Just as significant, venture capitalists and other investors would invest their money elsewhere and avoid risking their capital on research and development of products implicating genetic materials. In the past, the investment community has responded to uncertainties in the value of patents by shifting their investments to other, less patent-dependant areas. For example, the

biotechnology industry lost $5 billion in market capital in one day, when Former President Clinton and Prime Minister Blair issued a statement that genetic information should be publicly and freely available. The capital markets misread the statement to mean that genetic materials should not be patented and withdrew their investments from biotechnology research. This loss of capital took many years to undo. We will never know how many products were not developed as a result of this misunderstanding.

Ideally, the patent system is designed to promote disclosure of inventions so that others can work to improve upon them in exchange for a limited period of exclusivity. If a patent is declared invalid, the exclusivity period is lost. Keeping inventions secret has always been an option—one that has been used when the ability to obtain strong patent rights has been in question. Thus, those who continue to work in areas implicating genetic resources may choose the trade secret route rather than patenting, if threatened with the potential loss of patent rights. In cases in which the source of the genetic resources is not easily identified, the trade secret option may be particularly attractive. Once that route is chosen, society loses the benefit of disclosure and the genetic resource owner loses any opportunity to share in benefits.

There is also the potential for financial harm to those working in the relevant field. First, there would be the cost of gathering the data necessary to make the required disclosures and to seek a benefit sharing agreement. While in some cases such costs may be minimal, in others they could be tremendous, for example, when the original source of the material is not known or the owner cannot be identified.

In addition, such requirements would provide an additional avenue for attacking the validity of a patent, benefiting infringers much more than the owners of the genetic materials. Thus, costs of litigation would increase. And the penalty, if the disclosure is found inadequate would be the loss of patent rights rather than a penalty that would provide any compensation to the owner of the genetic resources. Thus, in such a case, the harm caused to the patent owner could be tremendous without any benefit to the resources owner.

8. More Appropriate and Viable Solutions Are Already Being Explored

Many countries are already beginning to implement national regimes for access and benefit sharing in order to comply with CBD principles. Implementation of national laws - outside of the patent system - that address the objectives shared[6] by the Members is one way to proceed. In this regard, contracts provide the most appropriate method of capturing the agreement between, and meeting the specific needs of, providers and the users of genetic resources. This in turn will better ensure the equitable sharing of benefits. In this regard, we

[6] These objectives include: (1) ensuring authorized access to genetic resources, i.e., that prior informed consent is obtained; (2) achieving equitable sharing of the benefits arising from the use of traditional knowledge and genetic resources; and (3) preventing the issuance of erroneously issued patents.

support the allocation of resources to building the capacity[7] of national governments and providers rather than establishing ineffective regulatory requirements in the patent systems.

Such an approach is far more practical than attempts to use the patent system to regulate bio-prospecting activities. Proposals to create special patent sanctions will not effectively promote equitable benefit-sharing, but will simply discourage use of genetic resources, especially those uses that lead to new methods of conservation of these resources and new sustainable uses of these resources.

BIO thus opposes establishment of a mandate in the Hong Kong Ministerial Meeting to devise an amendment to the TRIPS Agreement in connection with a special disclosure requirement.

[7] The *Bonn Guidelines* is a good resource in this regard since it provides adequate international direction for such national legislation. However, enhanced international programs for helping developing countries enacting and implementing effective regimes and for concluding contracts for access to genetic resources are recommended, especially when there are no legislative alternatives available.