September 7, 2004

Mr. Carl-Michael Simon
Global Trade Department
Kommerskolleigum
P.O. Box 6803
S-133 96 Stockholm
Sweden

Dear Mr. Simon:

I write on behalf of the Biotechnology Industry Organization (BIO) in response to your request for views of European industry on proposed requirements to indicate the origin of material in patent applications. BIO is a trade association representing more than 1100 members in over 33 countries including Sweden and other Member States of the European Union. BIO members, many of whom are small and medium sized enterprises, depend on effective intellectual property systems to obtain capital and to recoup their investments in research and development.

The biotechnology industry is a dynamic, research intensive industry. In 2003, biotechnology produced more than 370 biotech drug products and vaccines currently in late stage clinical trials that target more than 200 diseases. Some biotechnology products – such as EPO, Herceptin® and Xigris® – have revolutionized the way society deals with cancer and other chronic diseases. Biotechnology is responsible for hundreds of medical diagnostic tests, which encompass everything from keeping the blood supply safe from AIDS to home pregnancy tests. Industrial biotechnology applications have led to cleaner processes that produce less waste and use less energy and water. Increased crop yields and decreased reliance on herbicides and pesticides benefit consumers through less expensive, safer foods.

The biotechnology industry operates in an environment that requires sufficient funding from public and private sources of basic and applied research, effective intellectual property protection standards (particularly patent law), efficient and secure technology transfer, measures that promote collaboration among diverse entities, and, critically, strong incentives for private investments for financing. Patent protection, which stimulates not only inventive activity but is essential to delivering new products and services to the market based on these inventions, is critically important to biotechnology. Investors recognize patents as important benchmarks of progress in developing product lines and revenues. Investment provides the life-

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blood of a research-intensive industry, and intellectual property protection serves as the enticement for private financing. The promise of a return on investment, rooted in patents on biotechnology inventions, helps to attract capital in these high-risk biotechnology products.

Indeed, many start-up biotechnology companies have been created based solely on the promise of their patent portfolios. The vast majority of biotechnology companies do not have products on the market; rather they have only patents or patent applications on what may eventually become a commercially viable product or technology. Patents protect the assets that entice investment, facilitate licensing, encourage collaborations and joint ventures, and promote technology transfer for further development of a promising technology or product. The capital generated as a result of this intellectual property supports companies as they invest the hundreds of millions of dollars and the decades necessary to develop successfully a commercial biotechnology product.

Confidence in the patent system by the innovation sector, the investment community and the consuming public is especially important. Consequently, we appreciate your efforts to obtain the views of industry on aspects of these important and controversial requirements for patent systems.

As a general matter, we note that our members have found it difficult to form definitive views on the topics presented in the invitation for comment. One reason for this is that so few of our members engage in bioprospecting activities. A second, more significant reason is that most of the questions posed concerning disclosure of the geographical origin of genetic materials are vague in several key respects (e.g., what would trigger an obligation, what is the specific nature of the obligation, what must be disclosed). As a result, the enclosed response represents the best efforts of our members to reply to your general inquiries.

We can observe that our members generally oppose proposals that would require the identification and disclosure of the origin of genetic materials in patent applications. The general basis for this view is that our members do not believe it appropriate to use the patent system to enforce obligations unrelated to substantive patent standards. Instead, our members believe that measures that directly regulate the activities in question should be employed, if such regulation is considered necessary.

Our members also believe that use of the patent system to indirectly regulate activities under the Convention on Biological Diversity will further discourage use or development of genetic resources, which would undermine one of the objectives of that Convention (i.e., the creation of "benefits" that can then be shared with a country that provides access to the resource). Moreover, based on our review of various "disclosure" proposals, we believe it likely that such requirements and associated sanctions would be structured in ways that would create unjustified risks to ongoing business enterprises, and several of these proposals appear to be inconsistent with both the spirit and letter of obligations in the TRIPS Agreement and other international agreements. As such, BIO members believe that any specific proposals would have to be carefully and independently evaluated.

We would be pleased to answer any additional questions that you may have.

Sincerely,

Stephan E. Lawton
Vice President and General Counsel
Biotechnology Industry Organization

Enclosure

Response of the

BIOTECHNOLOGY INDUSTRY ORGANIZATION

to the request for views from the

KOMMERSKOLLEGIUM

a. What are the advantages and disadvantages from your perspective of a requirement to indicate geographical origin?

(i) General Observations

Before addressing the question of special patent disclosure requirements, BIO and its members wish to reiterate their support for appropriate, transparent mechanisms to ensure that countries and private entities adhere to obligations they undertake under the Convention on Biological Diversity (CBD). As the CBD emphasizes, entities that wish to obtain access to and then to use genetic resources may do so only by reaching "mutually agreed" terms with the country providing access to the resource, both as to prior informed consent (PIC) and as to benefit sharing. BIO members have consistently expressed support for mechanisms that would permit them to readily comply with these requirements for prior informed consent and benefit sharing, and look forward to working with you and other governments to develop and implement such regimes.

As a general matter, it is premature to express a view as to whether a requirement to indicate the "geographical origin" of genetic materials in patent applications will have advantages or disadvantages without first resolving several important questions[1].

- First, what is the objective that is to be served by the requirement?

- Second, what is the specific nature of the requirement to disclose the "geographical origin" and when would it be implicated?

As to the first question, to the best of our knowledge, the sole justification for a requirement to indicate the geographical origin of a genetic material associated with an invention would be to implement obligations of the Convention on Biological Diversity (CBD). We note that special disclosure requirements, by definition, are not designed to, and will not, facilitate the examination of patent applications or advance the objectives of the patent system. The information that could be collected by such a requirement will not assist patent office officials, applicants, or the public in determining whether inventions meet the criteria for patentability, *i.e.,* novelty, inventive step, and industrial application. Nor do they provide any disclosure beyond that already required in patent applications that would be beneficial for patent

[1] We note that a number of these questions were raised in the invitation for public comment (e.g., what is the consequence of not complying with the requirement), and we provide our views on those questions below.

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purposes (e.g., to enable others to make the patented invention). As such, these requirements appear to serve only one function – to "facilitate" disclosure of uses of genetic resources that could implicate obligations to share benefits or to comply with prior informed consent requirements under the CBD. Whether a special new patent disclosure requirement would provide advantages or disadvantages, thus, must be measured with reference to its relationship to the activities governed by the CBD, and with respect to its ability to promote the objectives of the CBD.

The CBD has as one of its primary objectives the preservation of biological diversity. It sets forth several mechanisms to encourage countries to preserve biodiversity. One is the right of each country to "share" in the "benefits" that derive from use of its genetic resources to which the country has granted access. It is important to appreciate that under the Convention's model, private entities, such as companies or universities, are to play a critically important role – namely, collecting the resources, and performing research and development on them that might yield commercial or non-commercial "benefits."[2] This significant role cannot be discounted in discussions regarding the "merits" of a possible patent disclosure requirement. Indeed, without the *voluntary* participation of the private sector, particularly industry, the "benefits" envisioned under the Convention's benefit-sharing provisions will never materialize. Clearly, then, measures of any form that are designed to promote the objectives of the CBD – including "benefit sharing" – must be evaluated as to whether they will encourage or discourage the private sector to seek access to "genetic resources" and to undertake efforts to develop those resources into "benefits." Measures that discourage use of genetic resources– particularly those that make successful commercialization riskier or more likely to fail – would create serious disadvantages.

Answers to the second question (i.e., the nature of a possible new disclosure requirement and when such requirements would apply) invariably will influence our view as to whether a geographical origin disclosure requirement would offer advantages or would create disadvantages. In this regard, the only points of reference we have are proposals advanced by certain countries in international discussions or laws adopted in certain developing countries. Most of those proposals and laws would make the requirement applicable to any use of any genetic resource – regardless of its nature, the manner of its use by the patent applicant, or its relationship or contribution to a claimed invention – and would impose severe sanctions, such as refusal of the patent grant or revocation of the patent once issued.

As a general matter, we do not believe that a requirement to disclose the geographical origin of a genetic resource in patent applications will promote

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[2] Under the Convention, benefits can range from early sharing of research results, compensation for access to or based on successful commercial development of an invention derived from use of the resource, or even licensing of intellectual property rights. Under the explicit structure of the CBD, all of these arrangements regarding "benefit sharing" are to be worked out in advance between the involved parties (i.e., before access is granted). Indeed, the mutual agreement requirement found throughout the Convention is designed to reinforce that the process of collecting, evaluating and developing genetic resources is a cooperative effort that can yield mutual advantages to all parties.

achievement of any of the objectives of the CBD, and thus, such a requirement would not offer any actual advantages to governments or to the public. We also believe that special patent disclosure requirements present numerous disadvantages, as set forth below.

(ii) Measures that could create risks to securing enforceable patent rights will discourage companies from seeking access to or using genetic resources

Most disclosure requirements we have evaluated to date impose some form of a penalty for failing to disclose the "source" or "origin" of a genetic resource. Many of these disclosure requirements would permit a country to refuse to grant a patent or would permit third parties to invalidate the patent, where the patent applicant/owner did not comply with the disclosure requirement. The measures thus create the possibility that an entity that develops an invention that meets all patentability requirements could nonetheless have its patent refused or invalidated. If this were to occur, the innovator would not be able to enjoy patent exclusivity for the commercial embodiments of its invention. The consequence of loss of patent exclusivity is that third parties will be able to freely copy the technology and to "free ride" on the substantial investments that must be made by the innovator to develop and bring the new products and services based on the patented technology to market. Such an environment has been shown to strongly discourage innovators from undertaking the necessary research and development activities to create these new products and services.

We believe that special disclosure requirements will seriously diminish, and most likely eliminate interest from the private sector in bioprospecting for "genetic resources." We note that few companies presently conduct research programs based on screening of samples of "genetic resources" collected by bioprospecting (i.e., samples of naturally occurring plants, microorganisms and non-human animals collected by the entity from a country that is asserting sovereignty over its genetic resources). For example, the focus of most biotechnology companies is on discovery of the mechanisms of action of various human biological systems, and the design of agents and methods for treating disorders and disease linked to those mechanisms. Those investigations do not start with or depend in any way on use of a collected sample of a "genetic resource." Similarly, research in the agricultural biotechnology sector rarely is focused on collection and evaluation of samples of "genetic resources." Rather, it often is focused on use of sophisticated analytical tools (e.g., computer-based genomic analysis) using information generated by the company or obtained from the public domain. Alternatively, many agriculturally-focused companies use their own private collections of improved plant varieties and breeding lines that existed prior to the CBD, or were derived from those lines.

One common aspect of the disclosure requirements that we have reviewed is that they will invariably increase the cost and complexity of preparing and successfully obtaining patents. And, as noted above, most of these proposals impose the severe sanction of refusal of the patent or its revocation. Providing a new basis for competitors of a patent owner to attack patents that fully comply with patentability requirements (i.e., novelty, inventive step and sufficient disclosure) will create

significant new risks for innovators, particularly where the patent is essential to the successful commercialization of the technology. This will cause companies to avoid activities, such as bioprospecting or uses of genetic resources covered by the CBD, that could endanger potential patent rights, and to devote their limited resources toward other projects.

As such, we believe that a genetic resource disclosure requirement, particularly one that would create risks to obtaining or enforcing patents, will cause most companies to avoid use of resources that would trigger the disclosure obligation. This will, in our view, undermine the objectives of the CBD, which depend on the private sector having an incentive to use genetic resources in a way that will result in "benefits" that can be shared with countries of origin.

(iii) Current proposals impose obligations far broader than those that could be possibly justified under the CBD

As noted, BIO supports the objectives of the CBD and requirements reasonably designed to fulfill these objectives. Obligations for prior informed consent and for "benefit sharing" under the Convention can arise, however, only in well-defined circumstances. These are:

- that an entity, such as an individual or a company, seeks access to a sample of a "genetic resource" in a country that is a party to the CBD;
- that the sample is of a "genetic resource" of non-human origin[3];
- that the entity subsequently makes some use of the material in some manner, such as by conducting research on it or making use of it in other respects[4]; and
- that the sample is collected on or after the date that the Convention entered into force in the country from which the materials are collected (1992 for most countries).[5]

None of the proposals for a special patent disclosure requirement that we have reviewed to date reflect these fundamental conditions of the CBD. Instead, they would require disclosures to be made in applications regardless of whether the materials referenced in the application were human or non-human, or whether the materials were collected from a CBD party or not. Moreover, the obligations in these proposals would require disclosures with regard to materials collected at any point in time – despite the limitations in the Convention as to when PIC and benefit sharing

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[3] The Convention does not apply to human genetic materials. See, CBD Decision II/11, para. 2.

[4] As Article 16(3) of the Convention provides, any obligation to share benefits will arise only as a consequence of collection and use of a genetic resource. The benefit sharing obligations, moreover, are only those that are agreed upon by the party conducting the research and the country of origin.

[5] CBD Article 15(3). See also, *Handbook of the Convention on Biological Diversity*, prepared by the CBD Secretariat, 2001, p. 157.

obligations could theoretically apply.[6] These proposals also generally do not require that the use of the genetic resource result in the claimed invention. Indeed, the connection between the resource and the "invention" that is being claimed is often ignored, despite the fact that this connection must be clear in order for CBD obligations to be implicated in any way.

We consider it a serious disadvantage of these proposals that disclosure requirements would be imposed in applications that have no relationship to the genetic resources and activities governed by the CBD. Such proposals would impose serious burdens and risks for patent owners and patent applicants without any conceivable justification. For example, the large number of applications directed to nucleic acids, proteins and pharmaceutical compositions derived from human sources are *per se* outside the scope of the CBD. Yet, patent applicants would be required to comply with disclosure requirements for such applications and patents. Similarly, under many proposals, disclosures would have to be made even if the invention that is the subject of the patent application (and the patent claims in particular) does not actually use or derive from use of a genetic resource that has been collected through bioprospecting activities. Mandating disclosure of origin in such applications plainly cannot be justified under the CBD or any other rationale of which we are aware.

Indeed, it will be a significant challenge in any type of regime to define when disclosures would have to be made. A direct and clearly identifiable relationship between a "genetic resource" and an invention that is claimed in a patent application is a relatively rare occurrence. There will be significant uncertainty under any type of disclosure regime for patent applicants to know when a disclosure obligation arises. This uncertainty – because it could result in the denial or revocation of a patent– will strongly discourage biotechnology companies from conducting research on genetic resources.

(iv) Current proposals will prove ineffective in fulfilling the objectives of the Convention and the goals of advocates of a patent disclosure requirement

Some have suggested that patent disclosure obligations will facilitate the discovery of unauthorized uses of genetic resources, and will enable countries of origin to enforce benefit sharing and prior informed consent provisions arising under the CBD. Geographical origin disclosure requirements thus appear to be a substitute for access and benefit-sharing national laws.[7] In our view, this is a very inefficient and undesirable approach to obtaining information that could be readily identified by measures that directly regulate bioprospecting activities. Indeed, BIO and its

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[6] We note, for example, that the CBD entered into force in Sweden on December 16, 1993 – which means that its obligations would apply to collections of materials that occurred only on or after that date.

[7] Although twelve years have elapsed since the entry into force of the Convention on Biological Diversity, we understand that less than one-third of the Contracting Parties have an access and benefit-sharing regime. Yet, the vast majority of Contracting Parties actively urge the adoption of requirements to indicate source. Thus, it would appear that requirements to indicate geographical origin are intended to be a substitute for national laws.

members firmly believe that the only effective way to manage access and use of genetic resources is to create national mechanisms that directly regulate bioprospecting activities. Several countries have established such regimes, and others are presently developing their regimes. We have no reason to doubt the effectiveness of these regimes, which usually require entities to work through designated contact points prior to engaging in bioprospecting activities, and to agree to appropriate contractual terms governing prior informed consent and benefit sharing.

We also do not believe that patent disclosure obligations will actually help countries "enforce" obligations arising under the CBD. For example, very few uses of genetic resources will ever result in an "invention" that can be protected by a patent. Typically, many thousands or even hundreds of thousands of samples must be screened to identify potential leads for investigation. Once identified, those leads rarely yield compounds that merit serious investigation, and fewer still yield compounds that possess attributes that could merit the filing of a patent application. As such, very few patent applications are likely to be filed that concern inventions derived from uses of genetic resources governed by the CBD. Almost by design, then, a patent disclosure requirement will reveal only a small fraction of the possible "uses" of genetic resources that could occur that would be governed by the CBD.

We also note that not all "uses" of a genetic resource are driven by a commercial motivation. As such, many researchers never intend to use accessed genetic resources to develop commercial products and will not file patent applications. In such of situations, uses of genetic resources could occur that would yield "benefits"– including scientific knowledge – that could theoretically be shared with the country of origin. Yet, the uses will not be linked in any way to a patent application. A patent disclosure requirement thus will do nothing to identify such uses or to promote the sharing of benefits in any of these situations.

We also note that there typically is a period of several years between the date that a researcher might collect a sample of a genetic resource, and the date that an "invention" that could form the basis of a patent application could be identified. Furthermore, patent applications remain confidential for a fixed period following their filing date – typically 18 months. This means that patent applications – even were they to include information regarding the geographical origin of genetic resources – would not disclose "uses" of resources until many years after a sample of a genetic resource had been collected.

In view of these factors, we believe a patent disclosure obligation would be a highly ineffective tool for countries to use to assist their efforts in identifying uses of genetic resources or in regulating access to their genetic resources. In contrast, effective national laws that govern access and benefit-sharing can require benefits immediately and can require them whether or not commercial products or processes are ever developed using the genetic resources. Also, the level of benefits can be established to reflect the level of commercial success of any resulting products or process, if any.

(v) Current proposals inflict unjustifiable burdens on patent applicants.

Disclosure requirement proposals we have reviewed would apply to all patent applications in which products or processes derived from any use of any "genetic resource." Yet the vast majority of patent applications filed by BIO members claim inventions identified through research on human genetic resources or on genetic resources that are not governed by the Convention (e.g., either because the resource was not collected from a country of origin under the CBD, or because it was collected prior to the entry into force of the CBD). We believe that it is inappropriate and impossible to justify imposing a patent disclosure requirement on patent applications that concern inventions entirely unrelated to any activity governed by the CBD.

b. What are the advantages and disadvantages from your perspective of having some form of sanctions in cases where applicants fail to live up to such a requirement?

BIO and its members do not believe the patent system should be used as a mechanism to enforce obligations arising under the CBD. As noted, our members support measures that would directly regulate bioprospecting activities. We believe sanctions, should they be deemed necessary, should relate to the activity that is being regulated, rather than the inclusion or non-inclusion of information in patent applications.

As mentioned, BIO members do not believe that any substantial advantages will arise from the imposition of requirements to indicate the geographical source of genetic resources. Instead, because these proposed requirements invariably will increase the risk of a patent being denied or revoked, these measures will create serious disincentives to explore research on genetic resources. If the measures are applied generally, the disadvantages are even more severe.

As noted earlier, the vast majority of BIO members are small businesses, often with only a handful of employees. Most of the companies are many years away from having a product that will generate revenue. Virtually the only commercial asset that these companies have is their collection of patents and patent applications. These patents must provide secure exclusivity over the technology that the companies have developed. If a biotechnology company's patents can be denied or revoked, the company is left with virtually no commercial assets to use to attract capital needed for bringing products and services based on the technology to market. And, ultimately, the consequences of discouraging research and development by these companies are far more severe than the failure of the company. These companies are conducting research and development that could yield solutions to meet unmet medical needs, improve agriculture, and deliver important industrial solutions to the market.

As noted above, we see no advantages to requirements that are difficult to meet and could work to block issuance or cause revocation of patents. Our members also see numerous disadvantages – particularly a strongly negative impact of such requirements on research and development and commercial viability of biotechnology companies. For these reasons, our members generally are opposed to use of patent sanctions. Finally, our members take issue with the presumption that sanctions of any type are necessary or would be helpful. Since the conclusion of the CBD, BIO and its members have consistently supported the principles articulated in the CBD for

bioprospecting activities. BIO and its members, for example, supported the conclusion of the FAO International Treaty on Plant Genetic Resources, including measures in that treaty that call for benefit sharing when resources governed by the Undertaking are used. We are not aware of any situations governed by the CBD where any BIO member has not complied with requirements for prior informed consent or benefit sharing, or for that matter, has opposed inclusion of such requirements as a condition of being granted access. Thus, while we are grateful for the opportunity to provide our views on this issue, we request that the Government of Sweden further investigate the necessity for sanctions of any form.

c. There are a number of different sanctions being discussed. What are your views with regard to the following types of sanctions?

i. Sanctions *outside* of the patent law – for example in the form of fines or administrative fees,

ii. Procedural sanctions – for example a patent application would not be handled until sufficient information has been provided (if the information provided turns out to be incorrect this would not, at a later stage, affect the patent as such),

iii. A combination of i. and ii. above,

iv. A situation where the failure to provide accurate information could affect the validity of a patent if incorrect information was provided with fraudulent intent.

As mentioned in response to Inquiry b, we do not believe a requirement to indicate geographical origin in patent applications would give rise to any significant advantages. Consequently, we do not believe that any sanctions for non-compliance of this type of requirement are warranted or advisable. That said, BIO members believe that some sanctions would give rise to more disadvantages than other sanctions.

i. Sanctions outside of the patent law.

Of the four stated "options", sanctions outside the patent law are the least objectionable in principle. They are more "fitting" than the other options, given that the purpose of such sanctions would be to ensure compliance with the underlying obligations of the Convention on Biological Diversity, when those obligations have arisen. As we do not believe requirements to indicate geographical origin in patent applications are related to furthering objectives of the patent system or the CBD, we do not believe sanctions associated with such requirements are advisable.

In practice, however, it is impossible to evaluate the merits of fines or fees absent detailed proposals. For example, fines or fees for failure to indicate geographical source could be set at 10,000,000 € per patent application. This would be tantamount to denying access to the patent or refusing to grant a patent for most inventors even those employed by multinational enterprises. As such, BIO members would find such proposals objectionable.

ii. Procedural sanctions – for example a patent application would not be handled until sufficient information has been provided (if the information provided turns out to be incorrect this would not, at a later stage, affect the patent as such),

BIO members do not believe that procedural sanctions within the patent system are appropriate. In practice, procedural sanctions tend to have the same effect as substantive sanctions as demonstrated by the example provided in the Questionnaire. If an application is not examined because an applicant has not indicated the geographical origin of certain genetic resources, the lack of examination is tantamount to a rejection of the claims or an objection to the specification, both of which are grounds for refusing to grant a patent. This is the same result as if there was a substantive ground for refusing to issue a patent for failure to indicate geographical source.

It should be noted that most patent applicants operating in good faith will not know the geographical origin of every "genetic resource" referenced in a patent application. Those applicants would still be penalized for not submitting information that could not be obtained other than by conducting extensive research. Since the measures are being proposed as a means of "enforcing" perceived obligations under the CBD, our members believe that even proper disclosures, believed to be true at the time the patent application was filed, will give rise to significant and practical risks. In particular, because most proposals contain no time limitations, many countries will allow inaccurate disclosures to be a basis for attacking the patent. Competitors of our members, desiring to exploit the patented technology, will use these types of requirements to attack the patent, thereby increasing substantially the risks to our members' commercial viability.

It is possible that there may be some procedural sanctions that may not be tantamount to substantive sanctions, but we are not aware of any.

iii. A combination of i. and ii.

We object to this Option because it would contain Option ii, which we do not believe is appropriate.

iv. A situation where failure to provide accurate information could affect the validity of the patent.

BIO members are firmly opposed to measures that could affect the validity or enforceability of a patent. As noted earlier, our members see numerous disadvantages and no advantages of putting the validity or enforceability of a patent at risk for non-compliance procedural requirements unrelated to the patentability of the invention, including a requirement to disclose the origin of genetic resources. Moreover, as the loss of the patent will terminate the commercial viability of efforts to develop a genetic resource into a viable commercial product or service, such a sanction would fundamentally conflict with the objectives and goals of the CBD to develop such "benefits."

For these and other reasons identified above, BIO members do not believe sanctions that could affect the validity of a patent are appropriate or desirable. Instead, as noted above, should sanctions be deemed necessary to ensure compliance with obligations under the Convention, those sanctions should be structured to work outside the patent system, and should be based on the actual obligations in the Convention.