BIO
BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

May 6, 2002

The Honorable James Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Washington, D.C. 20231

Dear Director Rogan:

The Biotechnology Industry Organization (BIO) represents over 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. We understand you will be representing the United States in continuing consultations on a patent law treaty at the World Intellectual Property Organization (WIPO) that will continue in Geneva this week. We urge you to work towards an international agreement that would make it easier for our companies to obtain strong, predictable patent rights on a global basis. Such rights are pivotal to the survival and growth of the biotechnology industry. Several specific points of interest to the biotechnology industry are noted below.

BIO believes any patent harmonization treaty should include provisions that entitle a patent applicant to obtain patents in all treaty member countries through a simplified procedure once a patent is granted in a first examination authority and meets the requirements of the treaty. The granting process should be as short and as uncomplicated as possible, and should be linked to the Patent Cooperation Treaty (PCT) system, with its accepted application requirements and its network of international preliminary examination authorities.

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First, we note that several developing countries are seeking to include special disclosure requirement in the treaty for biotechnology inventions. The special requirements would impose new burdens on patent applicants in our sector to identify the "genetic origin" of living materials that may have been used to develop an invention. Related proposals would require our companies to prove compliance with "prior informed consent" provisions relating to the use of information obtained from indigenous cultures.

BIO is firmly opposed to inclusion of any new disclosure requirements in the treaty along the lines of these proposals. The common feature of these proposals is the assumption that it is appropriate to punish parties that violate national rules on collection and use of biological materials by revoking patents. The advocates of these proposals also assume that companies in our industry routinely engage in unauthorized collection activities, a suggestion that we find deeply offensive given the exemplary track record of our industry. Including a provision in the treaty that could lead to loss of patent rights due to the subjective assessments envisioned in these proposals would render the treaty unacceptable.

The treaty has raised the possibility of harmonizing patent eligibility on the standards defined in Article 27.3 of the TRIPS Agreement. Article 27.3 of TRIPS allows countries to elect to not grant patents for certain process inventions and for plant and animal inventions, regardless of whether the invention is otherwise patentable. BIO believes a harmonized standard for patent eligibility should be broadly inclusive for all inventions, including, in particular transgenic plant and animal inventions. As such, we would oppose a treaty that makes permanent the exclusions in the Article 27.3 of the TRIPS Agreement.

BIO understands that some countries have sought to include exceptions and conditions in the treaty linked to public health and ethical concerns. We do not believe the treaty should attempt to solve the complicated social and ethical issues associated with use of certain types of technology. Under Article 27.2 of TRIPS, countries may elect to not grant patents on inventions where their Government has prohibited use of the technology. This standard is logical and workable, and we see no need to alter it. For this reason, we would be opposed to new provisions in the draft treaty that would prohibit the granting of patents on ethical or related criteria, particularly if such proposals depart from the standard reflected in Article 27.2 of TRIPS.

Finally, we note that recent discussions have raised the possibility of harmonizing practices regarding the timing of deposits of biological material. In particular, the United States has been asked to support a standard under which deposits would have to be made prior to or at the time of filing of the patent application, rather than prior to the issuance of the patent (which is current U.S. practice). We do not believe there are any material benefits that would justify adoption of less-forgiving foreign standards regarding timing of deposits. We note that in all systems, the inventor must establish possession of the biological material prior to the filing of the application if a deposit is deemed to be necessary to meet adequate disclosure requirements. The only difference between the U.S. and foreign systems is the timing of the deposit of a sample of that material. Since the deposits are not inspected or otherwise relied upon by patent offices for assessment of compliance with patentability requirements, we do not believe there is a compelling need for offices to require deposits of materials prior to the filing of the application. As such, we would support a standard in the treaty that would allow the United States to retain its more flexibility standard regarding timing of deposits.

Numerous other issues remain under discussion in the negotiations. We have previously communicated our position on these issues, and note that in many respects, we share many of the views of other organizations of U.S. patent interests. We refer you to our past communications for our views on these other issues.

In conclusion, we reiterate our strong support for your efforts to negotiate a new treaty that will create a more harmonized and efficient global patent system.

Sincerely,

Carl B. Feldbaum
President
Biotechnology Industry Organization

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