



**Illinois Biotechnology Industry Organization
Government Affairs Policies
2008**





iBIO Government Affairs Policies 2008

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A Letter from iBIO's President & CEO David Miller

I am pleased to submit to public policy makers *iBIO Government Affairs Policies - 2008*. At iBIO, one of our goals is to achieve public policy that will make Illinois a good place to conduct world class life sciences research, commercialize the resulting discoveries, and make certain that our state and the Midwest prosper from this important work.

What is biotechnology? It's the application of what we know about biology to making the world a better place. The basic categories are medical, agricultural, industrial, and environmental. Many people use the term "life sciences" interchangeably with biotechnology.

The State of Illinois is fortunate to have developed a wide range of bioscience industrial activity. Challenges remain. Alongside our enviable prowess in research and substantial collection of global corporate headquarters is juxtaposed a well-documented below-average ability to translate new discoveries into startup companies that locate, grow, and stay in Illinois. There are also resource and process issues impeding companies' establishment of new processing and manufacturing facilities. These are important problems. They are problems, however, I am certain we can overcome.

To the extent our state and region realize their potential in these important realms, every part of Illinois will benefit from new jobs, wealth, and breakthrough products. Economists estimate that for every life sciences job we create, 5.7 more are generated by the economic activity it produces.

More importantly, biotechnology provides life-saving and life-enhancing products not just for Illinois, but for people world wide. When we succeed at being our best as a biotechnology community we serve humankind everywhere.

Substantial progress in biotechnology can only be optimized through teamwork and leadership among three key sectors. The government's contributions-- good legislation and regulatory practices, plus sound public investments in programs and infrastructure-- -- must be joined by effective corporate actions and research institutions generating excellence in commercializable research.

This document outlines iBIO's views on the public policies we need in order to achieve greatness in biotechnology. iBIO looks forward to working with local, state, and federal officials—both elected and appointed—who are dedicated to playing their part in our historic effort.

We are proud to be represented in Springfield by the well respected lobbying firm of Neil Flynn and Associates. I have a legal background and have also registered as a lobbyist on behalf of our association. At the federal level, we work closely with the national BIO organization on legislative and regulatory matters important to the Illinois economy. And iBIO's powerful automated grass roots lobbying system allows our members to quickly and easily weigh in on matters of importance to the community.

During 2007, iBIO was blessed with strong leadership from Chairman Dr. Norbert Riedel, Corporate Vice President and Chief Scientific Officer of Baxter. I am very pleased to report that Norbert Riedel will continue his service as iBIO's Chairman during 2008.

Sincerely,

A handwritten signature in black ink, appearing to be 'D. Miller', written over a horizontal line.

Illinois Biotechnology Priorities

Guiding Considerations

iBIO's specific policy and public investment recommendations serve the following guiding concepts. Our association will respond to new measures in a manner supportive of these general guidelines.

Turning Limitations into Strengths

- A. Illinois state and municipal leaders should work energetically with private and research sector counterparts to improve our ability to create, grow, and retain biotechnology startups. Its many strengths notwithstanding, Illinois has tended to take on the role of a colony when it comes to new company development; that is, we have sent technology developed here and good people trained and educated locally to other states, where their startup companies have combined these elements with special programs and needed financing to generate jobs, wealth and excitement. This amounts to a giveaway of taxpayer financed resources to other communities. We recommend working with the private and research sectors to make Illinois a net importer, not exporter, of talented people and commercializable technology. This policy document recommends several specific programs for achieving this goal.
- B. Illinois should strive to make its manufacturing and processing site approval processes among the best and timeliest in the world. The state has done a superb job in attracting headquarters of high technology companies as well as research park development firms. However, the processes associated with approval of manufacturing and processing sites create long delays before revenues can be generated from those facilities and render projects financially unfeasible. In Illinois, it takes a minimum of a half year longer to get such a site approved than it does in neighboring jurisdictions, sometimes much more. This is of particular concern in the area of biotechnology solutions in the ag-industrial sector, because Illinois is the leading state for production of biomass- material from living plants from which products such as ethanol and other applications can be made.

Education, Training and Research

- C. Illinois should restore the fiscal integrity of its State Government. iBIO views as a matter of increasing concern the State's low funding levels for public education. Although the State of Illinois enjoys among the highest total state revenues of any state—fifth in the U.S. according to one study—it is among the very lowest in rank in its funding for public education. Support for public education has been a victim of a deepening State fiscal crisis, a crisis characterized by a burgeoning public debt load and the State's diminishing ability to maintain basic state obligations. According to the Alliance for Excellent Education, Illinois graduated only 76.3% of the students in 2006 that started high school in 2002. There were thought to be 39,000 dropouts in the state in this period of time.

In iBIO's view, the State's ability to address the needs of its school children—as well as its ability to make appropriate investments in its centers of higher education and research, as well as basic government services and capital improvements in roads,

bridges, and other public infrastructure-- will be continue to be degraded until the State Government puts its fiscal house in order.

Doing so will involve difficult choices and iterations constituting imperfect solutions. Unless Illinois successfully takes on this challenge, however, its ultimate—and otherwise achievable—success at becoming one of the world’s top biotechnology centers will be pushed out of reach; none of the programs in the following sections will be feasible.

- D. Illinois should continue its strong track record of investing heavily in life sciences research infrastructure. Successful new technological products come from a research base capable of generating breakthrough discoveries. The best researchers are attracted to the best research facilities. Both political parties in Illinois have demonstrated an appreciation of this important principle.
- E. Illinois should fund a competitive salary structure for faculty and researchers at all state-funded education and research institutions. Over 40 US states have made biotechnology an important priority in their economic development plans, and competition for talent, especially top-tier research talent, has become especially keen.
- F. Illinois should invest heavily in developing science and math skills in its public schools and community colleges. In biotechnology fields, jobs at all levels-- from entry to senior management—enjoy higher wages and better income growth than private sector averages. Our children and young adults need adequate preparation for these career opportunities. This requirement is not limited to preparation for private sector jobs in our urban areas. It is also of particular concern to our food and agricultural subsectors, which are increasingly influenced by advances in technology.
- G. The state should fund and encourage programs which conduct educational outreach to minority and underserved sectors of our community. Biotechnology is still a very young set of enterprises, and industry needs access to talent from all sources. Also, it is in our community’s interest to make the economic fruits of life sciences careers available to all citizens.
- H. The state should seek to tie education and training programs at all levels to actual and developing industry needs. Doing so is critical if our young people are to find employment for their skill sets and if our taxpayer dollars are to be spent effectively. iBIO’s education and training unit, the iBIO Institute, an IRS certified not-for-profit, was developed in part to assist with this effort. The funding of State programs in education is equally important in workforce development in all biotechnology sectors: medical, agricultural, industrial, and environmental.
- I. Illinois’ federal delegation should assist the state in capturing Illinois’ fair share of education, training, and research dollars. It is reasonable for the Illinois community to expect an appropriate allocation of federal tax-funded program dollars.

Marketing Chicago and Illinois

- J. Municipalities and the state should fund marketing efforts at the BIO International Convention and similar venues with the aim of increasing international awareness of

local assets. Competition for the world's attention from other jurisdictions is very keen. Illinois' many assets may go unappreciated unless it reaches out for needed mindshare.

- K. Municipalities and the state should shun policies, programs, regulations, and tax measures which are considered unusually burdensome by firms located and/or doing business in Illinois. The promotional value of many good programs can unfortunately be completely undone by measures which cause firms uncertainty about the safety of their intellectual property or the prospects for a reasonable return on their Illinois investments. iBIO believes that the correction of the State's fiscal problems, noted in section C. above, can be accomplished without invocation of oppressive or highly anomalous means.

Criteria for Making State Investments

- L. We recommend Illinois invest in programs which build on existing strengths. For example, Illinois has one of the strongest public and private research infrastructures in the United States, but it ranks very low in the acquisition of Small Business Innovative Research (SBIR) funding for its small companies, and SBIR grants are important source of early-stage capital. A program to move Illinois into the top-10 ranking among states in SBIR funding would thus leverage the substantial investment already made at a comparatively small cost.
- M. Illinois should invest in programs and projects that leverage funding from the federal government, private sector, and philanthropic sources. As noted earlier, the greatest progress in development of a biotechnology center here can be made when different concerned elements of the community form effective partnerships. Making certain that Illinois has made demonstrable progress in life sciences economic development between the BIO 2006 conference and its return in 2010 provides a partnering opportunity for the community. The Council for Agricultural Research (C-FAR) is an important state program for research at our state colleges and universities. Recently its funding levels have been cut back severely. iBIO recommends restoring funding to this important program.

Investment Priorities

iBIO recommends that the state of Illinois make the following specific investments:

- A. State Matches for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grants – iBIO supports state programs which leverage Federal monies for our small businesses at a very early stage of development through:
1. Coaching companies in the mechanics of obtaining the grants, and
 2. Matching of Phase I and Phase II SBIR-STTR grants.

These programs are in operation in other states. In recent years, Illinois has been ranked below 20 other states in dollars awarded under the SBIR program, behind states with substantially less in the way of research capabilities, including Alabama and New Mexico.

We specifically urge the state to develop a concerted effort to achieve top-10 status for Illinois in these kinds of grants before the BIO 2010 Chicago Convention. We applaud the Department of Commerce and Economic Opportunity's recent initiation of programs in this area, and encourage their expansion.

- B. Early Stage Biotech Seed Funding – Numerous states have either enacted or have pending legislation to encourage or directly support the creation of venture funds that invest in biotechnology. Investment funds can be created through a variety of different mechanisms.
1. iBIO supports the development of a state income tax loss credit for accredited angels along the lines of a model which has proved successful in Wisconsin. Under the plan, investors who make investments in companies commercializing new technologies receive credits against state income tax.
 2. iBIO also supports state legislation creating the ability for small companies to sell Net Operating Losses at a discount to larger firms. The effect of this program, which has proven successful in New Jersey, is to stretch the working capital of our small companies. Because the working capital thereby created is used principally for salaries, the funds generate additional tax revenues, so that the fiscal impact on the state is minimal.
 3. We encourage Illinois to enact a jobs-creating mechanism which provides tax credits for research expenditures and for the purchase of equipment for research and manufacturing. Such jobs-creating credits need to be defined to cover biotechnology and other R&D industries' needs. Early stage life sciences companies with no revenues should be allowed to use their tax credits to offset sales taxes or income taxes as described in the previous paragraph.
 4. We recommend state contributions to a professionally managed very early seed stage fund or fund of funds, to be established from public and private sources.
 5. iBIO applauds the state's investment in organizations such as Illinois VENTURES and the Illinois Regenerative Medicine Institute (IRMI) which provide resources to researchers and entrepreneurs at very early stages so that these startups can become eligible for seed and venture capital.
 6. iBIO supports state funding which supports innovation by providing short term tax advantages for revenues generated through commercialization in Illinois of patented inventions whose patents were generated here.
- C. Expedited and Proactive Site Permitting Processes – Many manufacturing facilities associated with life sciences developments are best situated in the Midwest, owing to the proximity of skilled labor, superior access to US and world markets, and sources of raw material inputs.

According to data from the University of Iowa, Illinois is the US leader in the creation of biomass, plant material from which ethanol, biodiesel and other products are derived. Iowa is second, and a group of Midwest states are essentially tied for third.

Our state can benefit greatly—and public and private revenue sources secured, by new fabrication plants for new pharmaceuticals, medical supplies, as well as fermentation plants and other facilities for developing fuels and industrial products such as plastics from agricultural commodities.

Due to efforts to cut back on government expense, Illinois has made it impossible for government employees to timely process permit applications for such facilities. Recently new plants for converting biomass into plastic, and some ethanol plants, have been committed to neighboring states because the delays of bringing revenues on line in Illinois render such facilities unfeasible here.

Other Midwestern states have adopted expedited and proactive permitting processes and programs which assist companies in swiftly obtaining regulatory approvals for these facilities. For Illinois to remain competitive, it must emulate these best practices. iBIO encourages adequate funding of permitting agencies and development of proactive assistance programs so Illinois can compete effectively for these job-creating facilities.

- D. Municipal Financial Assistance – iBIO supports municipal incentives that afford financial assistance for commercial laboratory space to emerging biotech companies. iBIO applauds as excellent examples of such innovative programs Tax Incremental Financing (TIF) and Industrial Revenue Bond (IRB) programs for the life sciences instituted in the City of Chicago under the leadership of Mayor Richard M. Daley, as well as the strong leadership of the Village of Skokie under Mayor George Van Dusen which led to creation of a \$10 million TIF project for the sparkling new Illinois Science + Technology Park.
- E. Investments in Wet Labs, Greenhouse Space and Other Facilities. iBIO supports development of adequate facilities for the commercialization of life sciences discoveries. Although viable companies, including startup firms, can pay rent for appropriate wet labs and office space, they often find it very difficult to finance the improvements necessary to outfit the space for their special needs. Venture capitalists will rarely provide funds for real estate developments required by these companies. And competing cities and states are offering Illinois companies appropriate facilities at low rents in order to attract the innovation and job creation these emerging firms provide.

Illinois has made a great deal of progress in this area over the last two years, though state and municipal investments in such projects as the conversion of the Pfizer facilities at Searle Parkway in Skokie to multi-tenant and specialized uses; development of wet lab space and related facilities at the Illinois Institute of Technology; Technology Commercialization Center funding for “graduate” facilities to be located across from the University of Illinois incubator at the Chicago Technology Park; development of additional incubation space in the Research Park at the University of Illinois, Urbana-Champaign and infrastructure capital to develop Phase III of the Research Park at the University of Illinois, Champaign; modernization of Illinois’ AgriScience and Technology Field Lab in the South Farms at Urbana-Champaign including the proposed BioProcessing & BioRefinery Research Lab; expansion of similar projects in Peoria, Rockford, and near Southern Illinois University.

As these and other developments become fully-occupied, this need will be recurrent. Addressing these requirements remains an ongoing priority for the state.

- F. Investment in marketing Illinois at the BIO International Conventions. iBIO salutes the leadership of DCEO Director Jack Lavin in securing strong financial backing for the 2006 and 2010 events, as well as his support for state marketing efforts in intervening conferences. Financial contributions have also been made by the Department of Agriculture under Director Charles “Chuck” Hartke, and by the City of Chicago under the leadership of Mayor Richard M. Daley. We urge the State of Illinois and City of Chicago to provide appropriate investments in these conventions on an ongoing basis. They are the world’s gathering places for learning about the many assets our community has to offer.
- G. Funding for iBIO Institute Education, Training and Research Projects. The new iBIO Institute requires project funds for initiatives such as updates and expansions of the first-ever Illinois Life Sciences Directory, created by iBIO during 2004. This directory represents the first successful effort to locate and identify all the firms in Illinois contributing to the development of this important jobs-creating industry. It is an important preliminary step in building our state community and improving Illinois’ access to investors and scientific collaborators.

In addition to such specialized research, many education and training programs are now being planned for K-12 and community colleges, industry workers and those seeking to enter the industry, including entrepreneurs, and the general public. In addition, the iBIO Institute intends to develop special outreach programs for minority and other underserved segments of our community. It is important that all sectors be afforded the opportunity of securing employment in the relative high-paying jobs created by biotechnology companies. All of these programs represent superb investments of state and municipal dollars which, along with corporate support, will inspire philanthropic commitments to this important work.

iBIO acknowledges with gratitude the contributions towards such programs made by the Department of Commerce and Economic Opportunity in connection with the BIO 2006 Chicago event.

In addition, iBIO recommends the following investments by the US government:

- H. Lock improvements on the Upper Mississippi and Illinois Rivers. iBIO supports the Illinois Corn Growers Association, the Illinois Farm Bureau, and the Illinois Soybean Association in their call for proposed lock improvements on the Upper Mississippi and Illinois Rivers in order to speed delivery of Illinois ethanol and specialty agriculture products to markets outside the state at a lower cost and with less pollution compared to road or rail transportation. Congress recently overrode a presidential veto of the Water Resources Development Act (WRDA) which provides an important first step in allocating funds for this critical project. iBIO encourages Congress and the White House to make the follow on investments, because substantially greater funding will be required beyond the \$1.9 Billion provided by WRDA.
- I. SBIR Funding for Venture Backed Startup Firms. Currently, the Federal Government’s interpretation of funding regulations prohibits SBIR grants for

companies which are more than 50% owned by venture investors. This outcome makes it difficult for emerging companies to obtain needed working capital during periods when other sources of funding are scarce. iBIO supports revision/re-interpretation of SBIR funding provisions to correct this situation.

Reinstatement of practices fully in line with the legislative intent of the SBIR program does not require additional funding. Rather, the call here is for optimization of the program through the funding of companies whose products show sufficient promise to have warranted substantial venture investment.

Specific Policy Principles

iBIO will advocate in favor of measures which support the specific policy principles, and vigorously oppose bills which contravene them.

General & Medical Principles

- A. Price Controls. iBIO supports market-based reimbursement for biotech products. Legislators should not permit the federal or state government to set price controls on biotechnology research products.
- B. Prescription Benefit. iBIO applauds Medicare's modernization and the addition of a prescription drug benefit to the program. iBIO supports continued attention to this issue and efforts to expand the program through future iterations as the nation gains experience with the administration of these benefits and as financial conditions continue to improve. iBIO also supports inclusion of prescription coverage in all federal health care programs.
- C. Physicians' Judgment. iBIO supports reimbursement policies that ensure providers receive sufficient payments so that their decisions are based primarily on the most appropriate care for patients and not solely on the cost of the therapies involved.
- D. Prior Authorization Requirements. iBIO recognizes the fiscal restraints facing Illinois which require efforts to rein in escalating health care costs resulting from growing Medicaid enrollments, the availability of unprecedented numbers of remedies generated by progress in medical discovery, and the high cost of development and regulatory approvals for new medicines. In some circumstances it will be appropriate under state regulations to require prior authorization of a drug's use in order to verify that the use is mandated by that condition and that no lower-cost effective substitute is readily available.

iBIO favors establishing prior authorization requirements in a timely, transparent, and science based manner, with input from physicians specializing in the treatment of the targeted disorder. iBIO opposes prior authorization practices which unduly burden physicians and patients, particularly in instances where the condition is life-threatening, and particularly where alternative treatments are limited or non-existent.

iBIO recognizes that in some instances private payer groups employ the same cumbersome practices to avoid or delay payment for prescribed remedies, to the detriment of patients' health and the efficiency of medical practitioner's ability to serve the ill and injured. iBIO strongly prefers that payer organizations self-police

against such harmful practices; in the event, however, that remedial legislation or regulations against such practices are required as a last resort, iBIO will support such measures.

- E. Unnecessary state regulation of marketing practices. iBIO strongly objects to state regulation of sales and marketing practices of our member companies providing medical solutions. We believe that our members can help to serve a vital role in helping to educate physicians about some of the breakthrough medicines that have recently been developed—and that this form of communication should not be stifled. Moreover, varying state limitations or disclosure requirements could significantly increase compliance costs for manufacturers without providing additional benefits to the public.

Improper industry sales and marketing practices are already subject to strict penalties under the federal Anti-kickback Act and other statutes. The Department of Health and Human Services Office of Inspector General (OIG) has developed a compliance policy guideline (CPG) that delineates those contacts between physicians and manufacturers that raise problems of fraud and abuse. iBIO supports full compliance with the CPG, as well as the PhRMA Code for Interactions with Health Professionals, as a means of mitigating any areas of concern.

- F. “Prescriber Data Privacy” Legislation. Prescriber-identifiable data, medical data assembled and cross-referenced by private companies who acquire it in raw form mainly from pharmacies and sell it to others for commercial and non-commercial purposes, is used to track disease patterns and treatment, conduct research and clinical trials, engage in economic analyses, targets leaders in medical fields for approval and use of new prescription drugs and through sales efforts conduct physician detailing.

In such cases, patient privacy is not threatened. Prescriber data acquired by pharmaceutical companies have been stripped of patient identifiers in accordance with the HIPAA Privacy Rule.

The ability to identify physicians who prescribe specific drugs enables education of doctors regarding new treatments for targeted indications. It also facilitates notification of physicians when safety issues—such as proper dosage concerns—are discovered, particularly in the case of “off label” applications of the medicines. Drug companies also provide physicians with new information on best practices.

Since 2001, several states have introduced legislation seeking to prohibit use of prescriber-identifiable data for commercial purposes. New Hampshire adopted the first law, which was later found unconstitutional in violation of the 1st Amendment’s free speech clause for commercial speech. Maine and Vermont followed with a new law that was written to counteract New Hampshire’s legal ruling. Legal scholars agree both Maine and Vermont’s laws should equally be found unconstitutional on the same grounds.

iBIO concurs with the US Federal District Court in New Hampshire, which concluded such information is subject to commercial speech. State prescriber-identifiable data legislation must conform to the US Supreme Court’s commercial speech jurisprudence, it must: demonstrate that the statute “directly advances

(d) a “substantial (state) interest” and is “not more extensive than necessary to further the state’s interest.”

More fundamentally, iBIO opposes such prohibitions of prescriber-identifiable data as threats to patient safety which can occur if physicians do not receive timely information regarding treatment issues associated with medications they are prescribing to their patients. Doctors should also be allowed to know when a prospective substitute remedy may be available to provide enhanced efficacy or fewer side effects for some or all of their patients than the currently-used drug.

- G. Drug Importation. iBIO opposes programs promoting importation of pharmaceuticals from other countries when such programs 1) threaten to circumvent the rigorous public safety protections afforded by FDA review and current Department of Health and Human Services safety certification requirements; 2) create disincentives to innovation in life-saving and -enhancing research and the pace of new job creation associated with such research; and/or 3) abrogate the commercial exercise of patent-holder’s rights under U.S. patent laws. iBIO also urges exclusion of biologics for any importation program, as the risk of harm from mishandled or counterfeit biologics is particularly acute.
- H. Follow-On Biologics. iBIO supports creation during calendar 2008 of a United States federal statutory pathway for the approval of follow-on biologics in accord with the following principles.

"Biologics" are complex medicines that are manufactured using living organisms. Due to their size and complexity, biologics generally cannot be scientifically characterized to the same degree as small molecule chemical drugs. A generic drug is a product that is shown to be the same as an innovative drug, and is generally designated as therapeutically interchangeable with the innovator drug. Because of the complex science involved, the Food and Drug Administration (FDA) and foreign regulators have indicated that the generic drug approval pathway is not appropriate for complex biologics.

As Congress explores the creation of any regulatory pathway for follow-on biologics, it is essential that Congress recognize and adopt the following key principles:

- Ensure Patient Safety. Patients should not have to accept greater risks or uncertainties in using a follow-on product than an innovator's product. Thus, Congress should:
- Ensure that approval of follow-on biologics is based on the same rigorous standards of safety, purity, and potency applied by FDA for the approval of pioneer biotechnology products.
- Recognize that clinical trial evidence and data are fundamental for evaluating and demonstrating the safety and effectiveness of a follow-on biologic, and must be conducted on a product-by-product basis.
- Maintain the Physician-Patient Relationship. Small molecule generic drugs can be designated as therapeutically equivalent and may be dispensed interchangeably with innovator products without physician knowledge. In

contrast, the current state of science is not sufficient to establish interchangeability for complex follow-on biologics. Accordingly, Congress should ensure that patients are not given follow-on biologics unless expressly prescribed by a physician.

- **Preserve Incentives for Innovation.** In order to preserve incentives to research, develop and manufacture new innovative therapies and cures, as well as new indications for such products, any statutory pathway for follow-on biologics must: Include substantial non-patent data exclusivity, during which time follow-on manufacturers could not rely on FDA's prior approval of pioneer biologics to support approval of their own products.
- **Respect intellectual property and other legal rights.** Follow-on biologic products should not be approved until after all statutory protections, including data exclusivity and patent protections, are no longer available for the approved pioneer product.

Recognizing that follow-on biologics is a developing issue, iBIO will revisit these principles not less than once per year and sooner as needed and requested by its membership.

- I. **Patent Protections.** iBIO supports strong patent protection that ensures market exclusivity so that pioneering companies can make a return from their R&D investments. iBIO also supports extension of patent protection to product variants that constitute genuine innovations.

iBIO notes with grave concern efforts in Congress to reform the Patent Act which, in some formulations, would dramatically weaken the protections afforded patented inventions and reduce disincentives to infringement of valid patents. Specifically, iBIO will strongly oppose:

- Provisions creating extended or “second windows” for the administrative challenge of patents conferred under the Act. Under such provisions, a patent holder—or its investors—could never have final assurance of patent protection. This uncertainty would be particularly harmful to Illinois’ life science community, because in all application areas—medical, agricultural, industrial, and environmental—the investments required to bring products to market are enormous.
- Failure to adequately remedy the “inequitable conduct” litigation defense, where an accused infringer can allege that a valid patent should be held unenforceable because of a material misrepresentation before the PTO. This frequently encountered defense has been called a “plague” by the Federal Circuit, and “inefficient” and “expensive” by the National Academies of Sciences. It is an oft-used, subjective doctrine in patent litigation where an accused infringer can allege that a valid patent should be held unenforceable because of a material misrepresentation before the PTO. True reforms to this doctrine, among other changes, would heighten the standard for materiality such that unenforceability would be a remedy only where the patent would not have issued absent such misconduct.

- Provisions which alter methods for calculating damages on patent infringement in such a way as to in effect incentivize infringement. Particularly troublesome are measures which would direct courts to award royalties based upon a “patent’s specific contribution over the prior art,” rather than “the value of infringement to the infringer?” which is the relevant question under current law. Under the new calculation method, a wrong-doing competitor may find it more beneficial to infringe (rather than engage in legitimate licensing) because damages, if it gets caught, will be lower.
- J. Protection of Intellectual Property. iBIO opposes legislation that would threaten the intellectual property (including patents, copyrights, and trade secret protections) of Illinois technology companies through restriction of judicial discretion over litigation discovery procedures. Such proposed litigation, including recent bills nicknamed “Sunshine in Litigation”, have been rejected by nearly 40 other states, and, if enacted, would serve as a barrier to investment in Illinois technology companies. These companies, both large and small, are expected to be leading engines of future job-creation within Illinois. The so-called Sunshine in Litigation bills, therefore, threaten the elimination of many technology jobs in Illinois.
- K. Stem Cell Research. iBIO supports the continued pursuit of therapeutic stem cell research aimed at curing or alleviating otherwise-debilitating diseases and injuries.
- L. Bio Defense. iBIO supports appropriate uses of biotechnology that include products and services to inoculate citizens against infectious agents that may be used in an attack, to detect biological or chemical attacks, and to diagnose and treat those who may have been exposed to a biological or chemical attack.
- M. Freedom from Trade Barriers. iBIO supports ensuring that export markets remain clear and unobstructed by unreasonable trade barriers. This applies to products of biotechnology research, whether they are food products or biotech medical products.
- N. Product Labeling. iBIO fully supports product labeling that is accurate, informative, and not misleading, and communicates scientifically significant information relevant to health, safety, and nutrition to consumers. The current labeling policy of the USFDA thoroughly informs and protects consumers by giving them accurate information about the products content. That information identifies ingredients and tells the consumer when products have undergone substantial changes in composition, nutrition, or safety.
- O. Application of the Foreign Franchise Tax. iBIO opposes the Illinois Foreign Franchise Tax when based on the number of shares in development stage biotech companies. Taxing pre-profitable biotech companies in Illinois is a disincentive for doing business in State during their development stage.
- P. Tort Reform. iBIO supports meaningful, comprehensive business tort reform that includes 1) capping of non-economic damages, 2) limits on "venue shopping" by defining venue as the county in which the tort action occurred, and 3) changes in joint and several liability definitions to limit liability to the percentage of fault attributed to each defendant, and, 4) providing companies in product liability cases a government standards defense when their products meet or exceed government standards for product safety. iBIO would oppose any attempts to separate medical malpractice tort reform from comprehensive business tort reform, as the legal

principles involved are identical and there is no rational legal reason for separating them.

Agricultural Principles

- Q. Renewable Fuels Standard. iBIO supports the creation of a federal "Renewable Fuels Standard" (RFS) under which a growing percentage of our nation's transportation fuel supply is provided by renewable, domestic fuels such as ethanol, biodiesel, and second-generation biofuels which the tools of biotechnology will help deliver. Such a standard can reduce crude oil imports; reduce the U.S. trade deficit; create thousands of new American jobs; stimulate billions of dollars in new investment in renewable fuel production facilities; and increase demand for corn and soybeans by hundreds of millions of bushels.
- R. Agribusiness and Food Safety. iBIO supports programs dedicated toward agribusiness and food safety as well as nutritional genomics.
- S. Illegal Trade Barriers. iBIO supports lifting the European Union (EU) moratorium on new product approvals. The EU has maintained for years a WTO-illegal moratorium on the approval of biotech products.
- T. Unreasonable Zero Tolerance Standards and Liability. iBIO supports coexistence of biotechnology-based crop production with that of organic crop production, since both of these methods are recognized by the USDA to fill different U.S. production and market needs. In accordance with the USDA National Organic Program rules, iBIO recognizes that trace amounts of biotechnology related traits in an organic crop do not render that crop non-organic, assuming organic methods were used in the production of the organic crop. As such, iBIO opposes the establishment of zero-based standards for U.S. approved biotech traits in organic or non-biotech crops. In addition, iBIO would oppose legislation which attempts to shift liability for the presence of such trace amounts of biotech traits from the organic or non-biotech producer to the seed or technology provider.
- U. Insurance Policy Exclusions. iBIO opposes insurance policy exclusions for crops produced using biotechnology.
- V. Non-pre-emption of Federal patent laws; level playing field for U.S. producers. iBIO opposes state legislation that would allow farmers to save patent protected seed in conflict with federal patent and contract law. iBIO supports U.S. efforts to strengthen patent laws regarding biotechnology and enforcement against illegal use of biotechnology outside the U.S., thereby leveling the playing field for U.S. producers who will otherwise be placed at a competitive disadvantage on account of such illegal behavior.
- W. Plant-based pharmaceuticals. iBIO supports the use of plants to produce pharmaceutical and industrial proteins. iBIO also supports the establishment of reliable, science-based production standards as necessary to ensure that plant made pharmaceuticals and industrial enzymes are kept out of food products. iBIO is concerned both with human safety as well as avoidance of economic damage to Illinois brought about because of commingling of commodity and trait-engineered crops in shipment to markets shunning the latter.

- X. State testing and labeling. iBIO supports the US policy that once a trait is approved for release in a crop, it is considered equivalent to other genetic characteristics comprising the variety. Therefore iBIO opposes legislation that would differentiate these traits in varietal purity regulations or legislation requiring specific required testing schemes for such traits.
- Y. USDA field test safeguards. iBIO supports USDA, EPA, and FDA safeguards that permit continued field testing of nutritional crops with appropriate safety assessment under protective regimes that reduce to near zero the opportunity for introduction of such crops into the commodity crop distribution channels.
- Z. Updated field test Requirements. iBIO supports the policy outlined by Office of Science and Technology Policy (OSTP) and urges rapid implementation of the proposed federal actions to update field test requirements for biotechnology-derived plants intended for food or feed use and to establish early food safety assessments for new and unfamiliar proteins produced by such plants (67 FR 50578).
- AA. Preemption of local control of biotechnology. iBIO opposes any attempts by local governmental entities to ban or otherwise control or regulate the growing of biotechnology-derived crops, or the raising of genetically modified organisms for use in industry.

About iBIO

The Illinois Biotechnology Industry Organization (iBIO) is a not-for-profit industry organization whose mission is to strengthen the leadership position of Illinois and the Midwest as a globally recognized life sciences center, a great place to do business and a great place to start businesses involving advanced technologies.

iBIO's goals are to create new jobs, wealth, and excitement in Illinois and the Midwest. More importantly, success in biotechnology means that our community will be contributing to the well being of people worldwide through medical, agricultural, industrial, and environmental solutions.

iBIO's primary objectives are to

- Advocate sound public policy at the local, state, and federal levels
- Create a strong sense of community among public, private, and academic/research sectors
- Promote development and retention of new companies and corporate expansions

iBIO is an affiliate of the Washington, D.C.-based Biotechnology Industry Organization (BIO), which held its 2006 Annual International Convention in Illinois. Because Illinois and its Midwest neighbors caused the BIO event, nicknamed "the Olympics of Biotech" to break all attendance, program and revenue records in its 15-year history, the BIO organization has announced that it will return the convention to Chicago in 2010. No community has ever won a repeat BIO event in such a short time.

In 2001, the iBIO organization named its annual government service award after Illinois State Senator John W. Maitland, Jr. in honor of his effective leadership on issues such as research and education. For the last seven years, the Maitland Award event has been hosted at the State Capital and attended by many public officials, including both Republican and Democratic members of the General Assembly, the Secretary of State and State Treasurer, and senior appointed officials, as well as many representatives of industry.

iBIO recently founded the iBIO Institute, an IRS-certified not-for-profit company which provides biotechnology education, training and research to the life sciences community and general public. The iBIO Institute implements

- K-12 and community college education programs
- Training for new and experienced biotechnology workers and entrepreneurs
- Public Education
- Outreach to minority and other underserved communities
- Research special interest to Chicago, Illinois and the Midwest

iBIO proudly partners with organizations like the Chicagoland Chamber of Commerce, the City of Chicago, the Illinois Corn Growers, Farm Bureau, and Soybean Association, the Illinois State Chamber of Commerce, the State of Illinois Departments of Agriculture (DOA) and Commerce and Economic Opportunity (DCEO), the Illinois Venture Capital Association (IVCA), the St. Louis Regional Chamber and Growth Association, and World Business Chicago.

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Ceres Venture Fund

Notes

For further information, please contact:
ibioadmin@ibio.org
Illinois Biotechnology Industry Organization
65 East Wacker Place
Suite 1600
Chicago, Illinois 60601
Phone: (312) 422-1111
Website: www.ibio.org